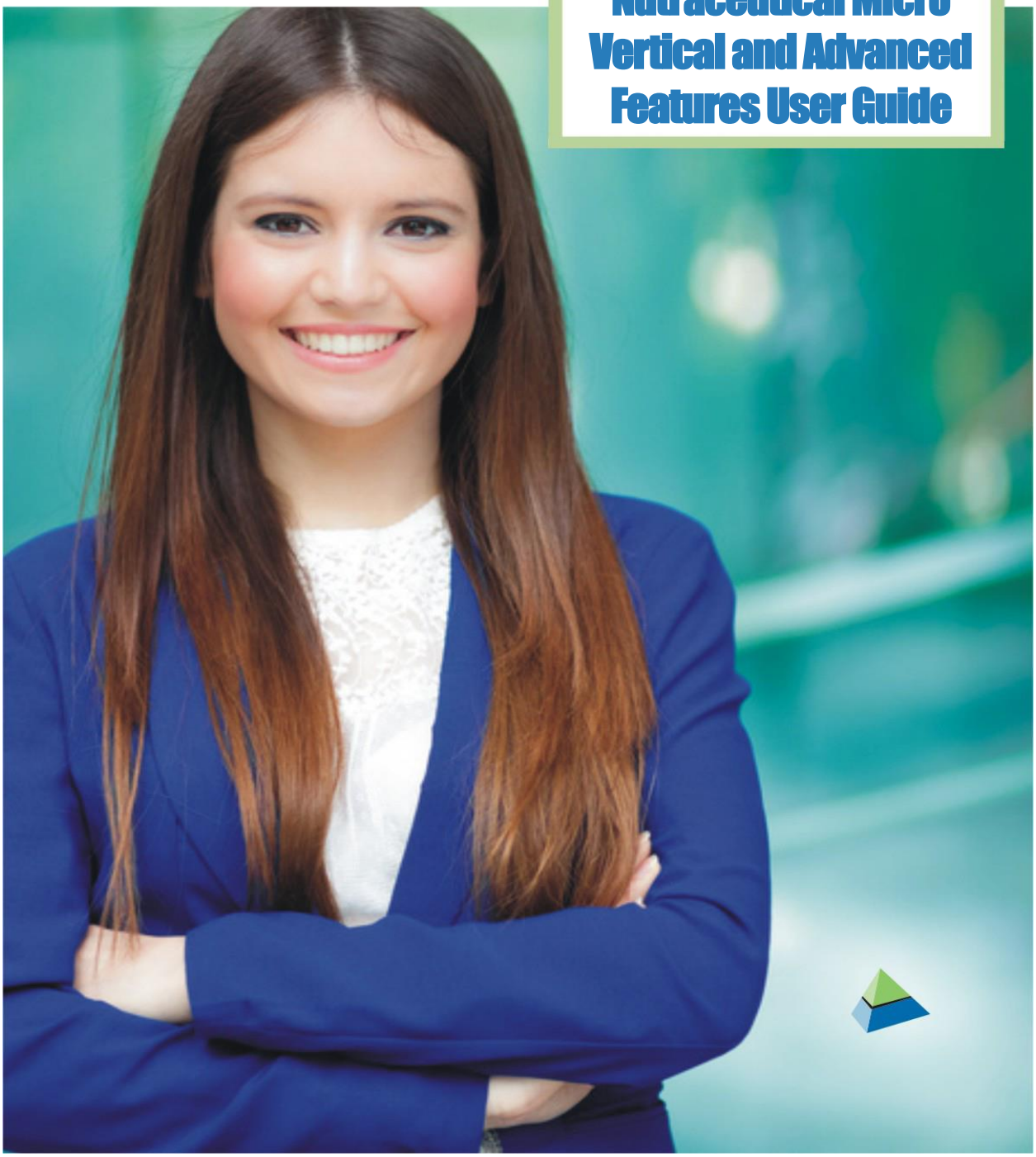
BATCHMASTER® ERP 18.2

BatchMaster ERP with SAP Business One
BatchMaster Solutions
for Process Manufacturers

Nutraceutical Micro Vertical and Advanced Features User Guide



Copyright and Legal Information

About the Manual

Symbols & Conventions

Symbol	Description
	Note
	Mandatory setting
	Tips

Convention	Description
Italicized (Sales Order Entry)	Module name, screen name & components
“ ” (“BatchMaster-ERP-with-SAP-Business-One-18.2-Nutraceutical Micro vertical-Features-Installation-Guide.docx”)	Reference document

Abbreviation	Description
QC	Quality Control
QA	Quality Assurance
GRPO	Goods receipt purchase order
FG	Finished Goods
BOM	Bill of Materials
ERP	Enterprise Resource Planning
PO	Purchase Order
UOM	Unit of Measurement
SO	Sales Order
Whse	Warehouse
NC	Non-Conformance
CAPA	Causes and preventive actions

Contents

1 Document Overview

BatchMaster ERP for SAP Business One (BatchMaster ERP) can provide special functions to cater to the needs of the nutraceutical and pharmaceutical industries. It is also applicable for other formula-based manufacturers who need to bring their production processes in line with the guidelines set by the Food & Drug Administration (FDA).

BatchMaster offers separate licensing packs for Nutraceutical Micro vertical and Advanced Features. For process manufacturers who only require the capabilities of:

- *Advanced Production*, (Sections 2, 3, 4, 10, 11, and 14)
- *Advanced Quality Control*, (Sections 2, 4, 5, 6, 7, and 11) and/or
- *Sampling*, (Section 8,9),

the Advanced Features License is sufficient.

If your business requires any of the following in addition to the above features:

- *Define Soft-Gel types*
- *Define Capsule sizes*
- *Define Tablet shapes and sizes*
- *Define Appearance colors*
- *Define Ribbon thickness*

The Nutraceutical Micro Vertical license is required. These functions are discussed in Section 12 & 13.

1.1 Who Should Read This Document?

This document is intended for anyone who is implementing the software, learning how to use it, or training another person.

1.2 What's New in this Release?

Configuring and Mapping Service Charges in Third-Party Processing.

1.3 Objectives

This document is intended to help the reader:

- Identify the industry-specific utility of each feature.
- Record data in the system to perform transactions.
- Explain the purpose of features to others using examples.
- Identify the business uses.
- Identify the purpose and functioning of the features in BatchMaster ERP Mobile.

1.4 Getting Started

Before you begin using the Nutraceutical Micro Vertical or Advanced Features you should understand how the Laboratory, Formulation, and Quality Control modules work. Please read the corresponding user manuals for information.

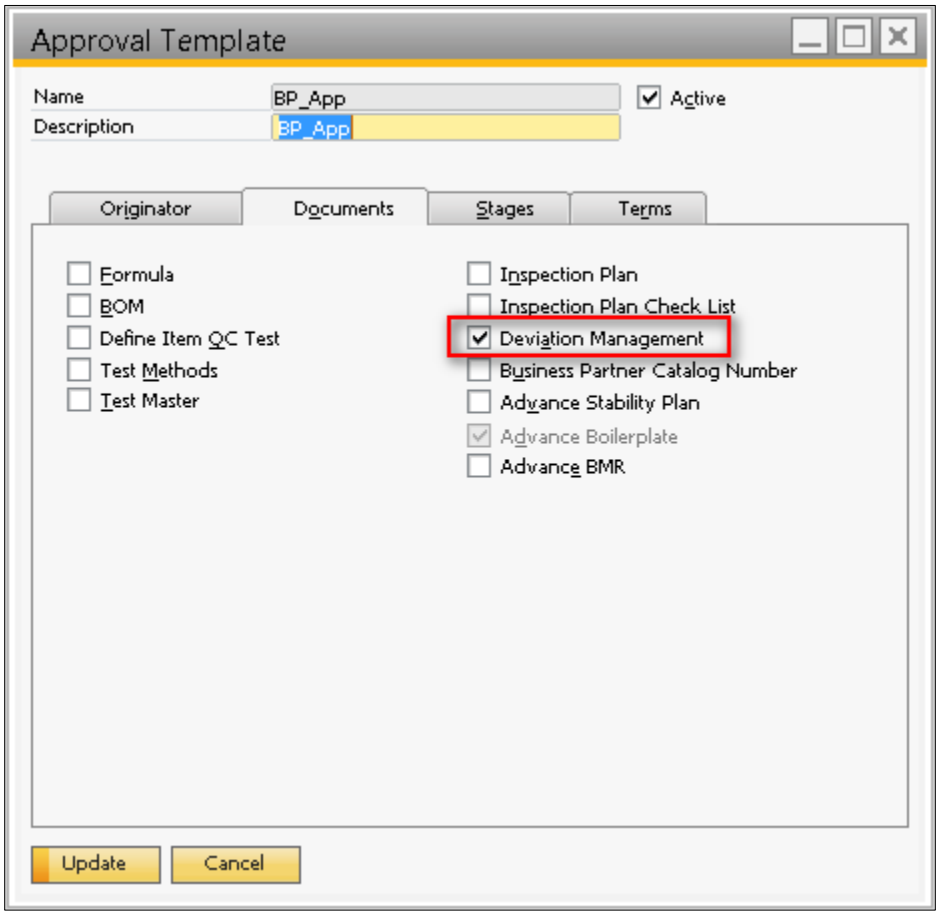
2 Deviations

You may need to make changes in a batch for many reasons. In such cases, you can put the batch on hold and apply a deviation. Example reasons are a change in the quantity of raw material or change in the proportion of the formula. Let us learn how we can manage deviations in BatchMaster ERP.

Before creating a deviation record, you need to apply the approval procedure for *Deviation Management* on the *Approval Template* screen.

Go To: Administration → Approval Procedures → Process Mfg. Approval Procedures → Approval Template

In the *Approval Template* screen, on the *Documents* tab, select the *Deviation Management* checkbox.

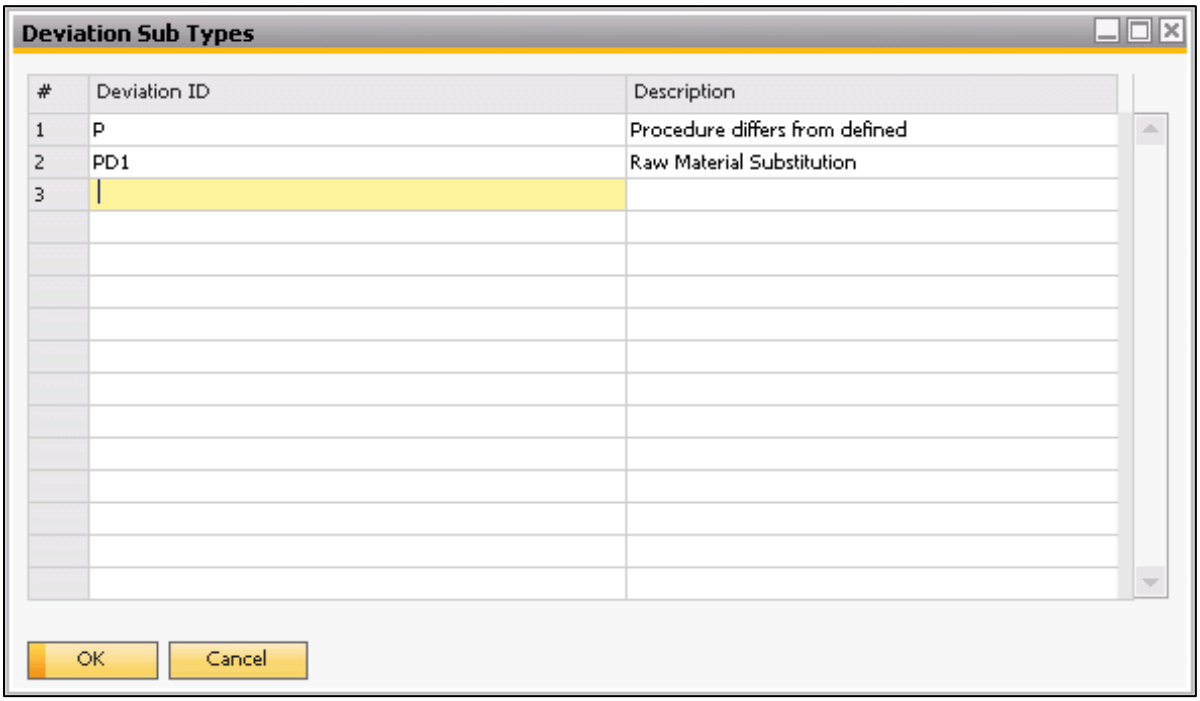


For details on Approvals set-up and the purpose of the other tabs, consult the *BME-B1 18.2 Approvals User Guide.*

2.1 Deviation Sub Types

Categorizing deviations helps manage and implement deviations easily. Use the *Deviation Sub Types* screen to categorize deviations.

Go To: Administration→ Setup→ Production→ Deviation Sub Types

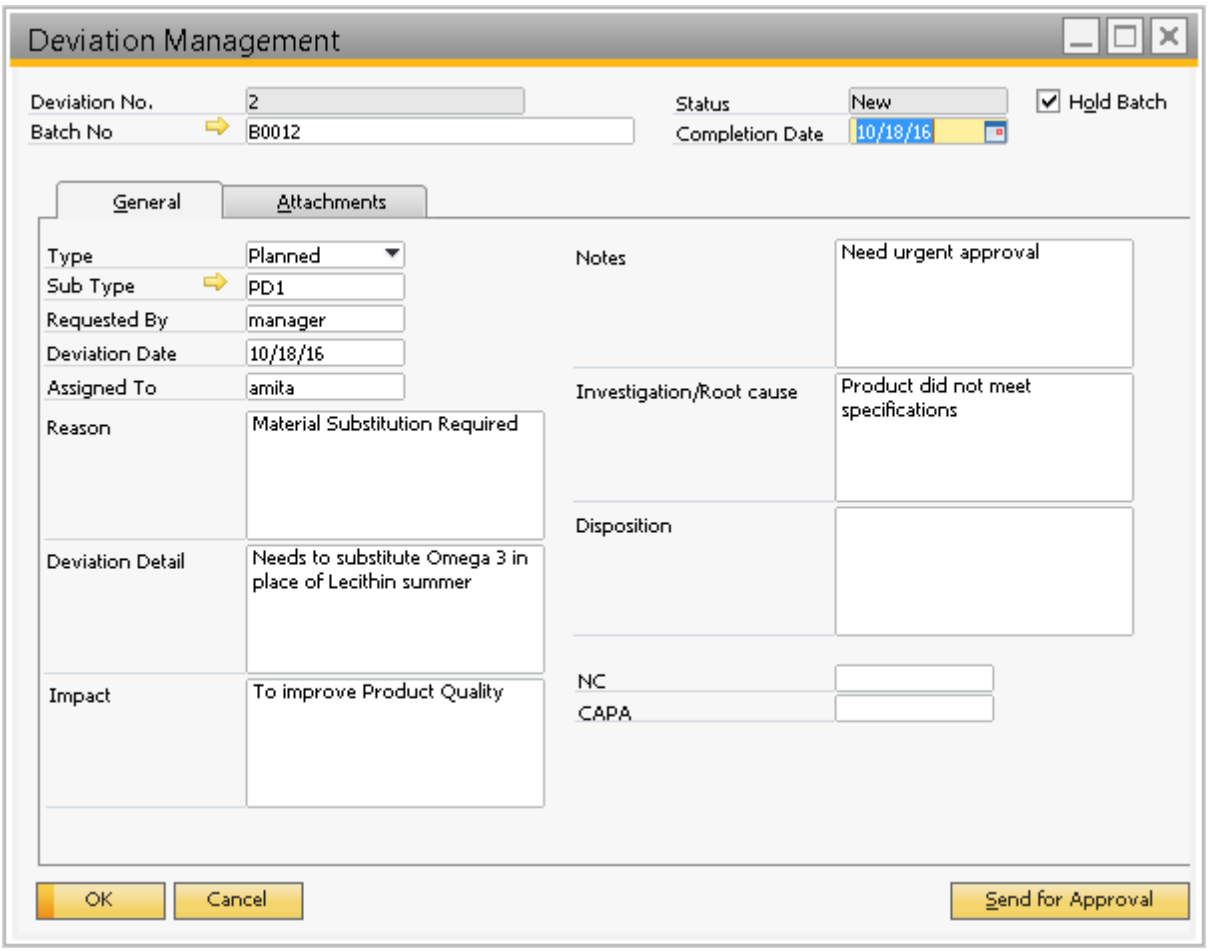


For every deviation that you are defining, enter a unique identification code in the *Deviation ID* field and enter a description of the code in the *Description* field. Click the *Update* button to save the record.

2.2 Deviation Management

You can create a deviation record using the *Deviation Management* screen.

Go To: Process Manufacturing → Deviation Management

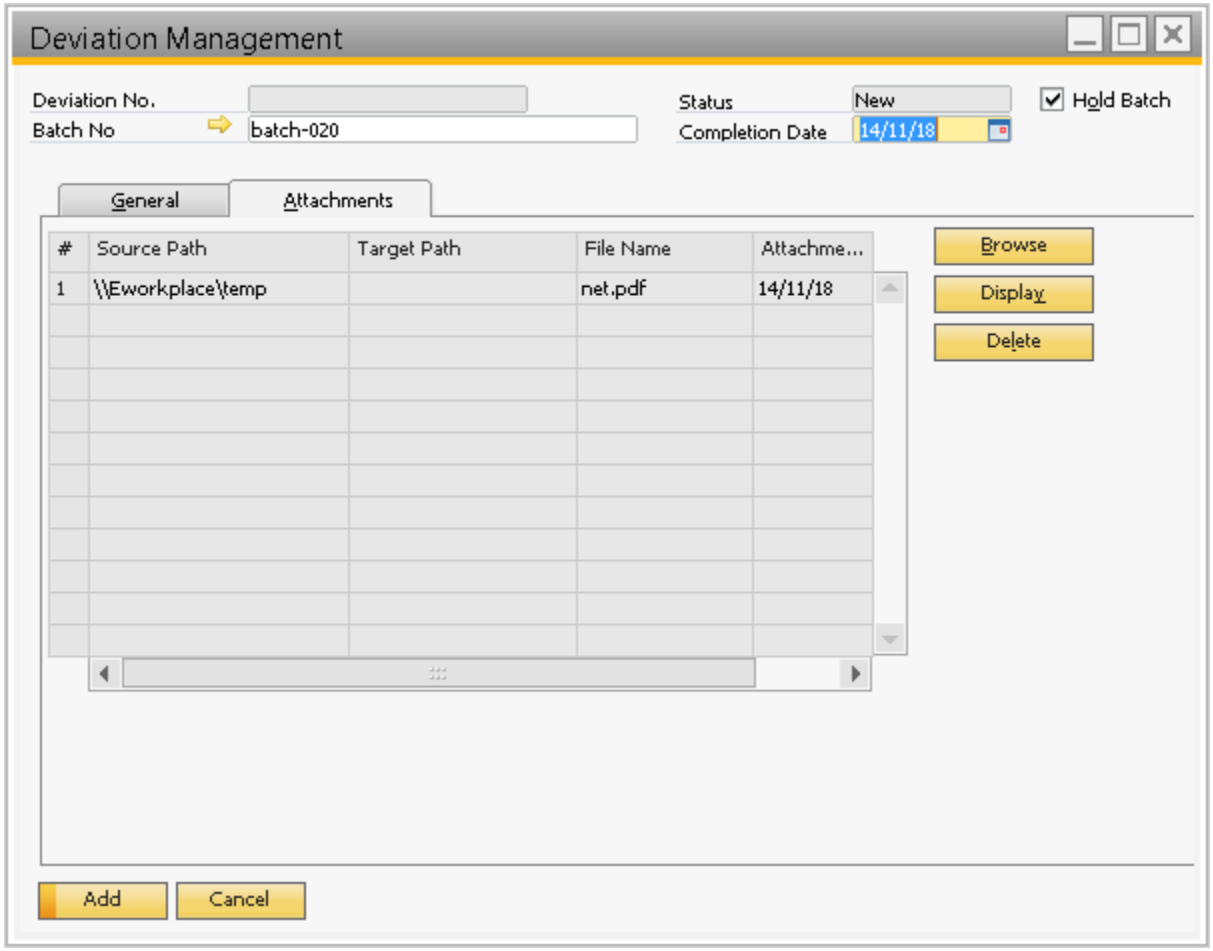


The screen opens with the status "New". Search and select the batch on which you want to apply deviations. The drop-down menu in the *Batch No* field will list all batches except those with the status *New* or *Closed*. Select the *Hold Batch* checkbox to put the batch on hold while you are making changes. In the *Completion Date* field, enter the date on which you expect to complete the deviations.

On the *General* tab, select the appropriate deviation type from the options *Planned, Unplanned, Critical* and *Employee Suggested*. Then choose the sub-type from the list defined earlier. Select the user who requested for the deviation and the date of request, in the *Requested By* and *Deviation Date* fields respectively. In the *Assigned To* field, enter the person to whom the deviation task has been assigned.

On the *General* tab, you can add all relevant details about the deviation. Especially important are the root cause of the deviation and the method of disposition. In addition, if the deviation is associated with a non-conformance, you can enter the NC record number and also the CAPA number.

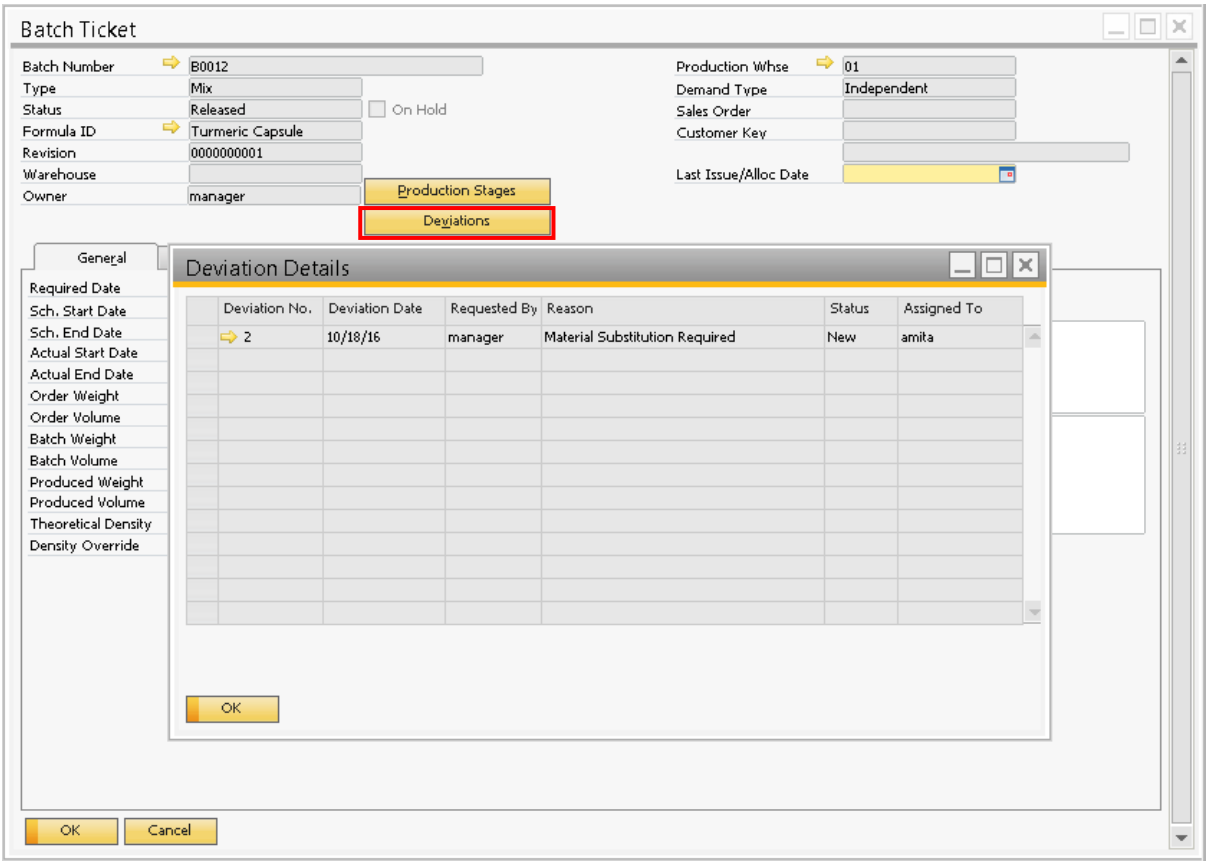
On the *Attachments* tab, you can browse and locate the file(s) that you want to attach with this deviation management record. This file could be any document that can be of use to the approver. It must be located on a shared server.



Click the *Add* button to save the record.

2.3 Batch Ticket

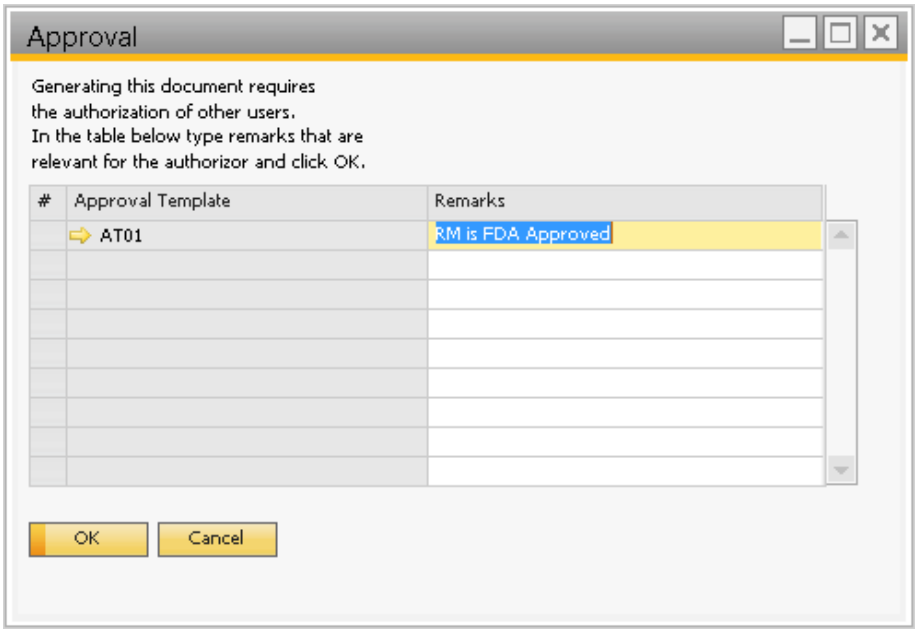
In addition, you can view the deviations applied on a batch from the *Batch Ticket* screen. When you click the *Deviations* button on the screen, the *Deviation Details* screen appears.



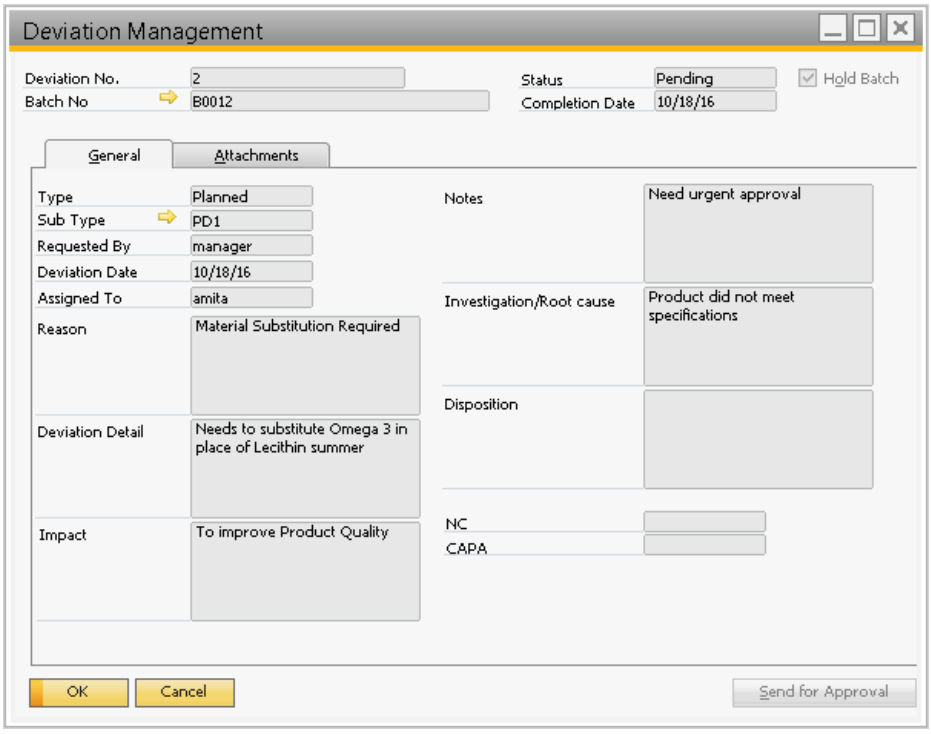
On the Batch Ticket or Batch Close screen you can also attach the deviation record with the formula item (in the formula grid) or BOM item (in the finished good packaging item grid).

2.4 Approval Procedure

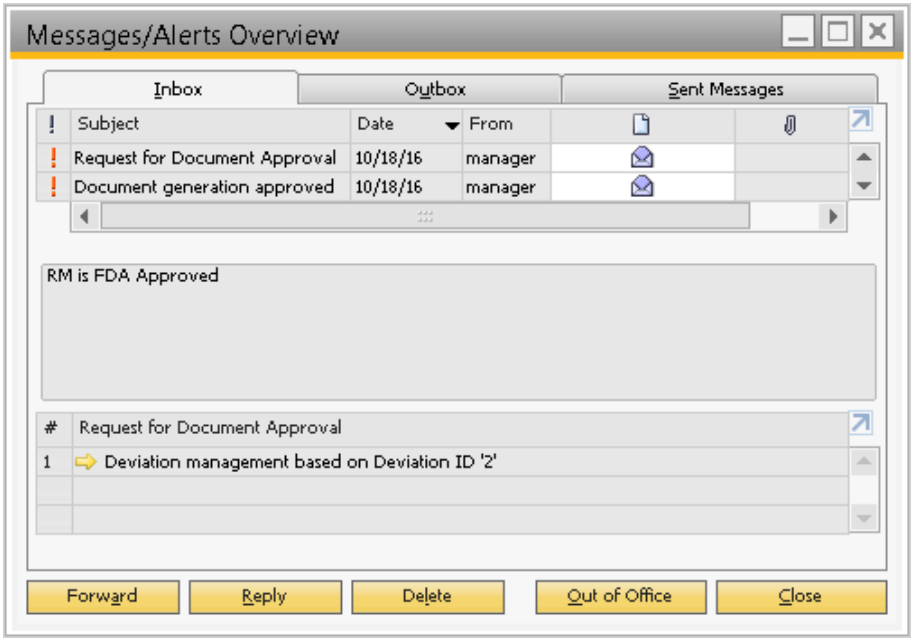
When you save a deviation management record, the *Send for Approval* button is enabled. Click this button to view the *Request for Approval* screen. On this screen, you can select the approval template that you wish to follow for the approval of the deviation.



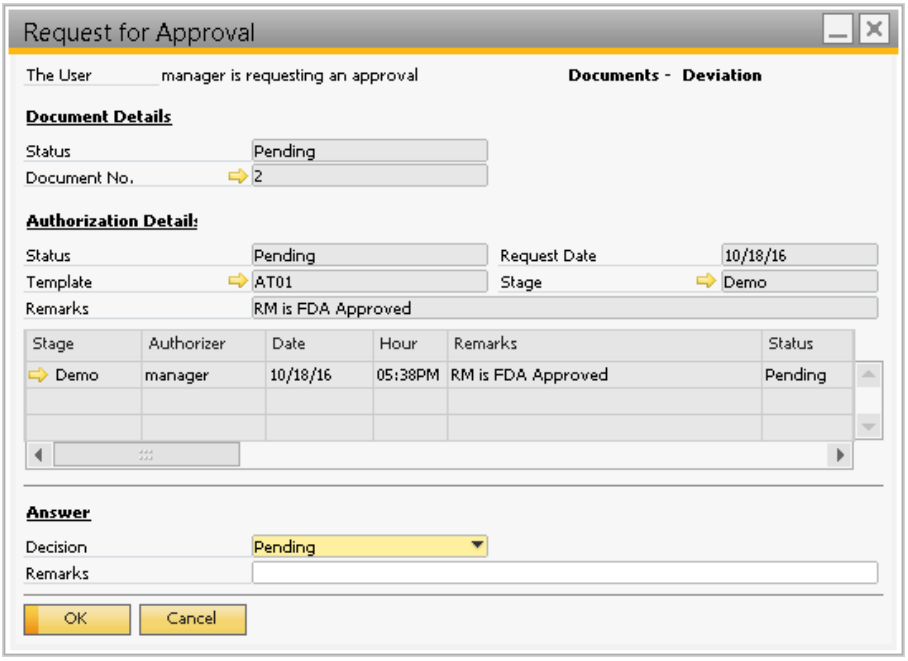
The status of the deviation record changes to *Pending* and the status of the batch changes to *Hold.*



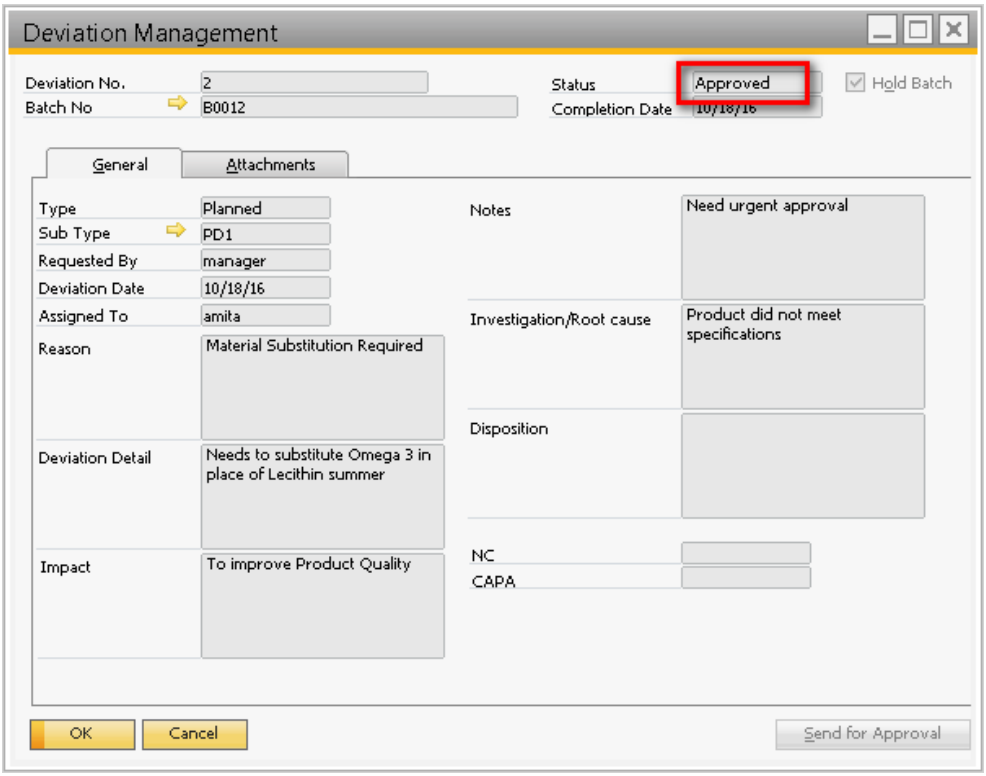
The first approver receives the message alert, requesting his approval. He/she can open the screen using the hyperlink/golden arrow, go through the deviation, and approve it.



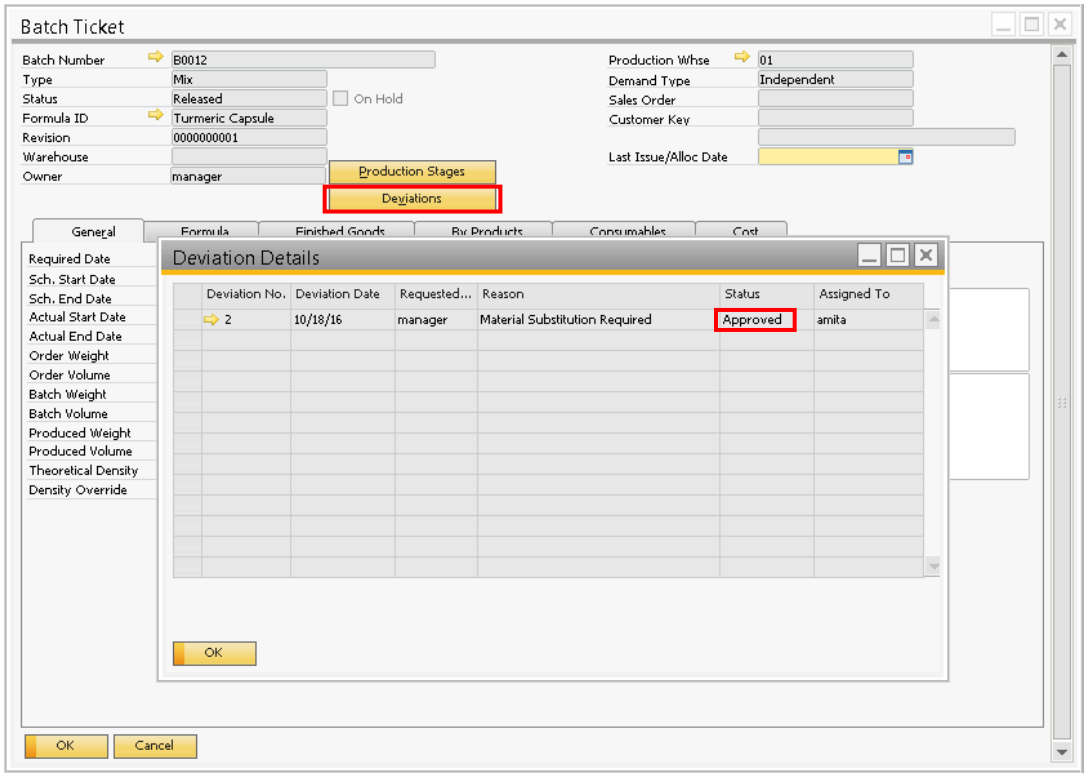
The first approver clicks on the golden arrow, and the *Request for Approval* screen appears.



The approver checks and approves or rejects the deviation. The approver can also leave it in *Pending* state. If the approver approves/rejects the deviation, then it passes on to the next approver. The status of the deviation on the *Deviation Management* screen changes to *Approved or Rejected* state, as per the decision taken by the approvers.



In addition, you can view the deviations applied on a batch from several screens such as *Batch Entry, Batch Ticket, Batch Close, Super Batch Entry,* and *Super Batch Close*. When you click the *Deviation* button on any of these screens, the *Deviation Details screen* appears.

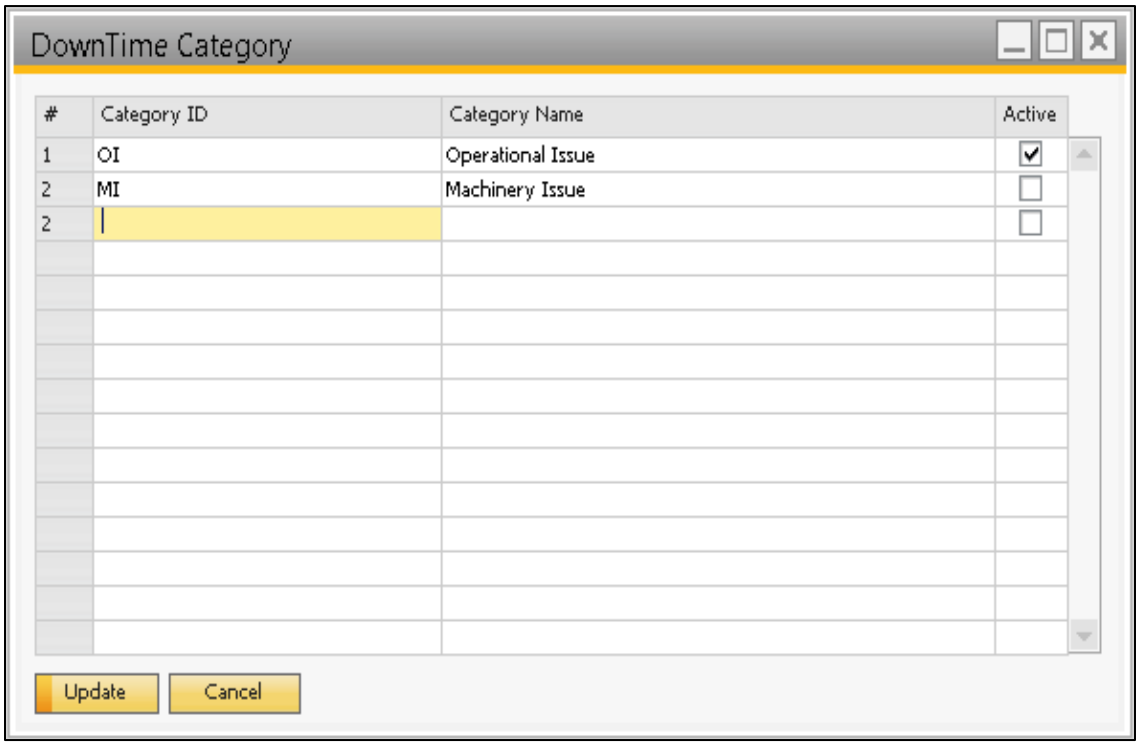


3 Downtime Management

3.1 Downtime Category

You can use this screen to categorize the downtime against your batch. You can also enter the reason for maintaining downtime on this screen.

Go To: Administration→ Setup → Production→ down Time Category



In the *Category ID* field, enter the unique identification code, say OI. In the *Category Name* field, enter a description for your Category ID for better understanding, say Operational Issues. Select the check box on the *Active* field to activate the Category ID.

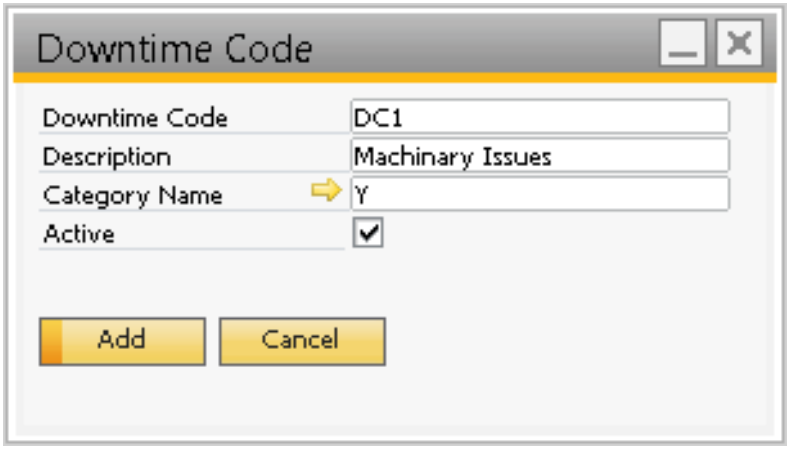
Click the *Update* button to update your record or click the *Cancel* button to leave the screen unsaved. You can create multiple categories on this screen. Only active categories can be applied to production batches.

You can apply downtime to production batches with status *Released, Allocated, Issued, Part-allocated,* and *Part-closed*.

3.2 Downtime Code

You can create downtime codes using the *Downtime Code* screen. These codes can then be associated with production batches.

Go To: Administration→ Setup→ Production→ Downtime Code



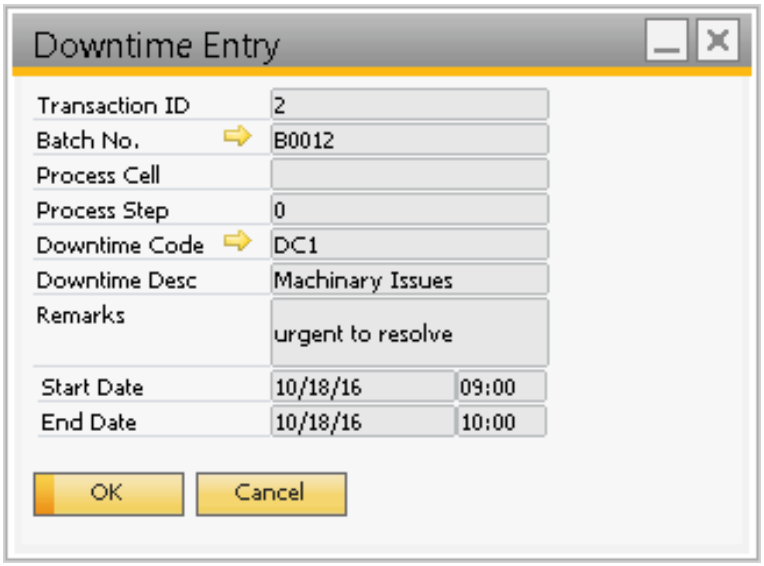
On the *Down Time Code* field, enter the unique identification code, say DC1. Then enter a description of the *Downtime Code* in the *Description* field, say Machinery Issues. Next, select the *Category Name* using the lookup available next to Category Name field. Activate the code by checking the *Active* option. Lastly, click the *Add* button to save the record.

3.3 Down Time Entry

You can use the *Down Time Entry* screen to enter downtime reasons for a production batch.

Go To: Process Manufacturing → Down Time Entry

The downtimes created here can be viewed on the *Downtime By Batch* screen. This screen also appears by clicking the *Add DownTime* button on the *Downtime By Batch* screen.



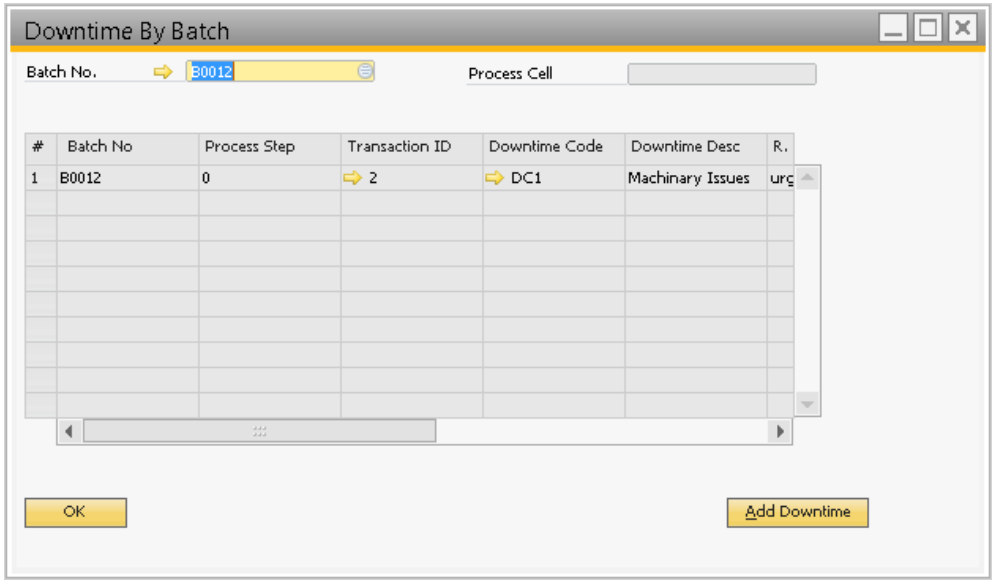
Search and select the batch number. The system will list all the batches except New and Closed batches. The process cell will be auto-filled by the system. The Process ID associated with the batch will be displayed in the Process Step field. Next, search and select the *DownTime Code* that you want to apply for the batch.

You can also enter remarks about the downtime, which could be of some importance to the reader. Enter the start and end data for the down time. Click the *Add* button to save the record. Note: You can create multiple downtime records for a batch.

3.4 Downtime By Batch

After creating master records for downtime, you can associate the downtime codes with production batches. Once you apply a downtime for a batch, you will be able to analyze the progress of the batch. You can apply multiple downtimes for a batch, if need be.

Go To: Process Manufacturing → Downtime By Batch

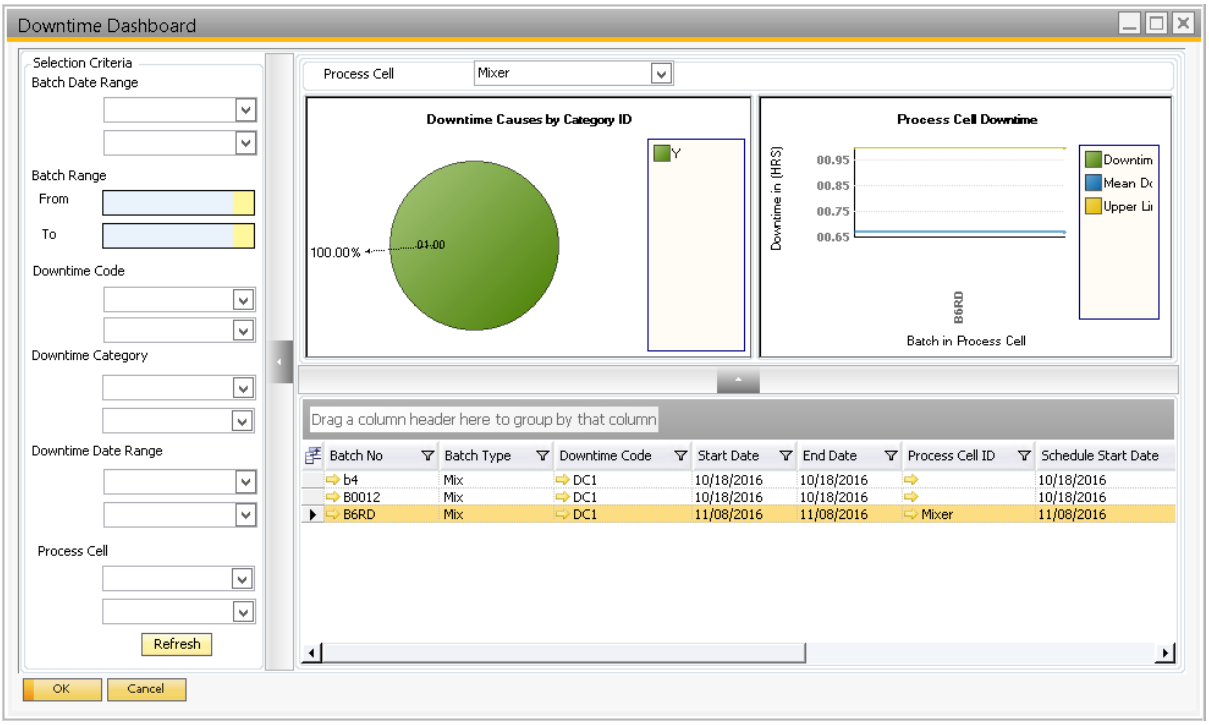


Enter the batch number in the *Batch No.* field. The *Process Cell* field gets auto-populated based on the batch. The read-only grid displays all the downtimes already applied for the batch. If you wish to add more downtimes, click the *Add DownTime* button. Once you click this button, the *Down Time Entry* screen opens.

3.5 Down Time Dashboard

Using the Downtime Dashboard, you can analyze the efficiency of production batches for which you have applied downtimes. This dashboard makes your analysis easier by providing information in a graphical screen using pie-charts and line graphs. Both the graphics use identical color codes, which help you easily analyze the reasons for production line delays.

Go To: Process Manufacturing → Production Utilities → Down Time Dashboard



The Downtime Dashboard provides you several filter criteria, namely: batch date, batch number, down time code, down time category, down time date, and process cell. For each of these criteria, you need to enter the lower and upper limit of a range of values. Those data that fall within the specified range of filter criteria will be displayed on the dashboard.

Click the *Refresh* button to view the desired data on the dashboard and thereby analyze the efficiency and progress of the batch.

4 QC (Inspection Plan) Masters

Every inspection that you undertake is recorded as a transaction. To perform an inspection transaction, you need to create records in the QC masters discussed below.

To comply with FDA specifications, the sampling plans should provide criteria and decision rules for determining whether to accept or reject a batch based on the sample quality. In BatchMaster ERP, you can choose the samples based on your requirements, both by quantity and container.

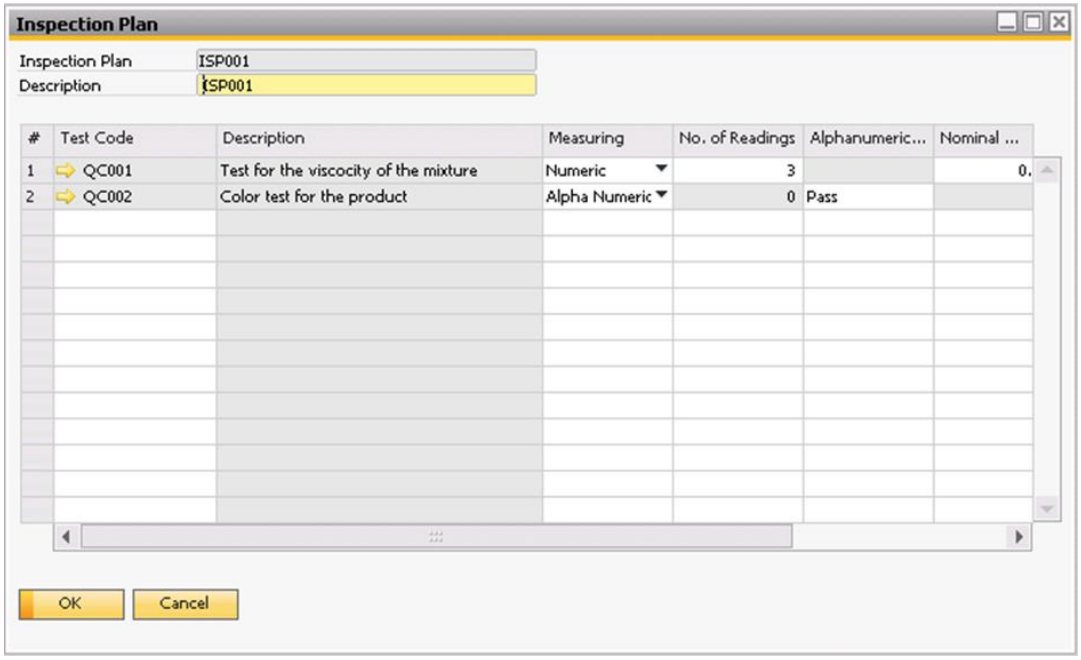
4.1 Inspection Plan

FDA cGMP requires that every nutraceutical manufacturer records various activities involved during production such as Temperature, Moisture, and pH value. Thus, a well-defined inspection plan should include all aspects required to judge whether a product is in compliance with applicable standards. You can define quality inspection plans for raw materials and finished goods using the Inspection Plan screen.

Go To: Quality Control → Inspection Plan

Every row of the grid displays detailed information about each QC test. Such information includes test evaluation criteria, number of times the test is being conducted, and the upper and lower limit of acceptable test values if the test is of numeric type.

Based on your business needs you can add multiple QC tests to the inspection plan.



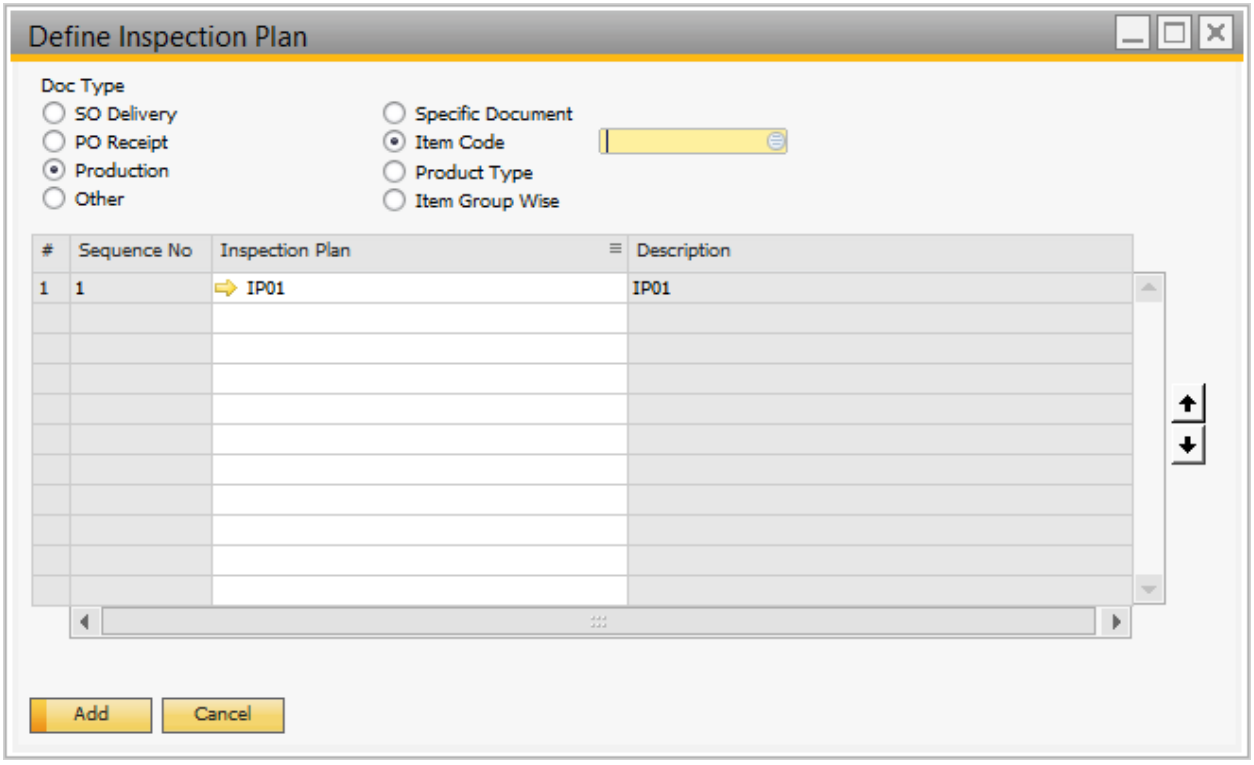
4.2 Define Inspection Plan

Once your inspection plan is ready, you can use it to monitor production, purchase receipt or shipment processes using the *Define Inspection Plan* screen.

Go To: Quality Control → Define Inspection Plan

On this screen, for all types of documents (SO Delivery, PO Receipt, Production, Other) you can now add inspections plans for Specific Document, Item Code, Product type and Item Group.

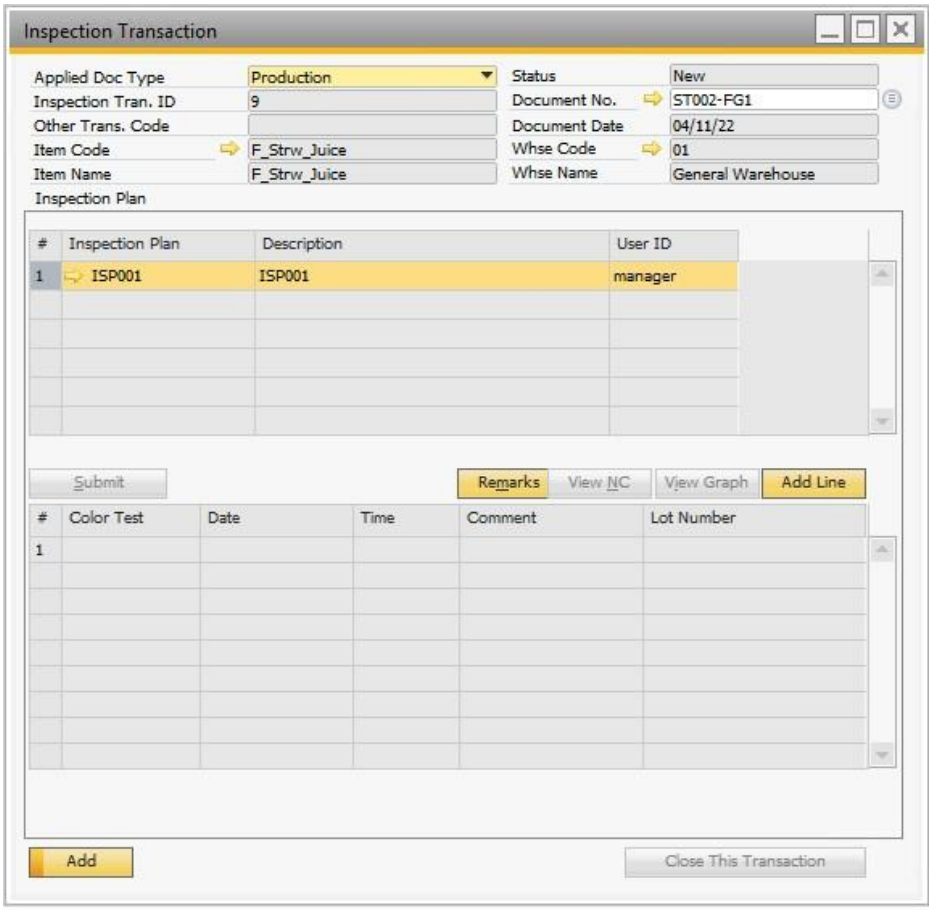
In the grid, you can include as many inspection plans as needed for the selected activity/document.



4.3 Inspection Transaction

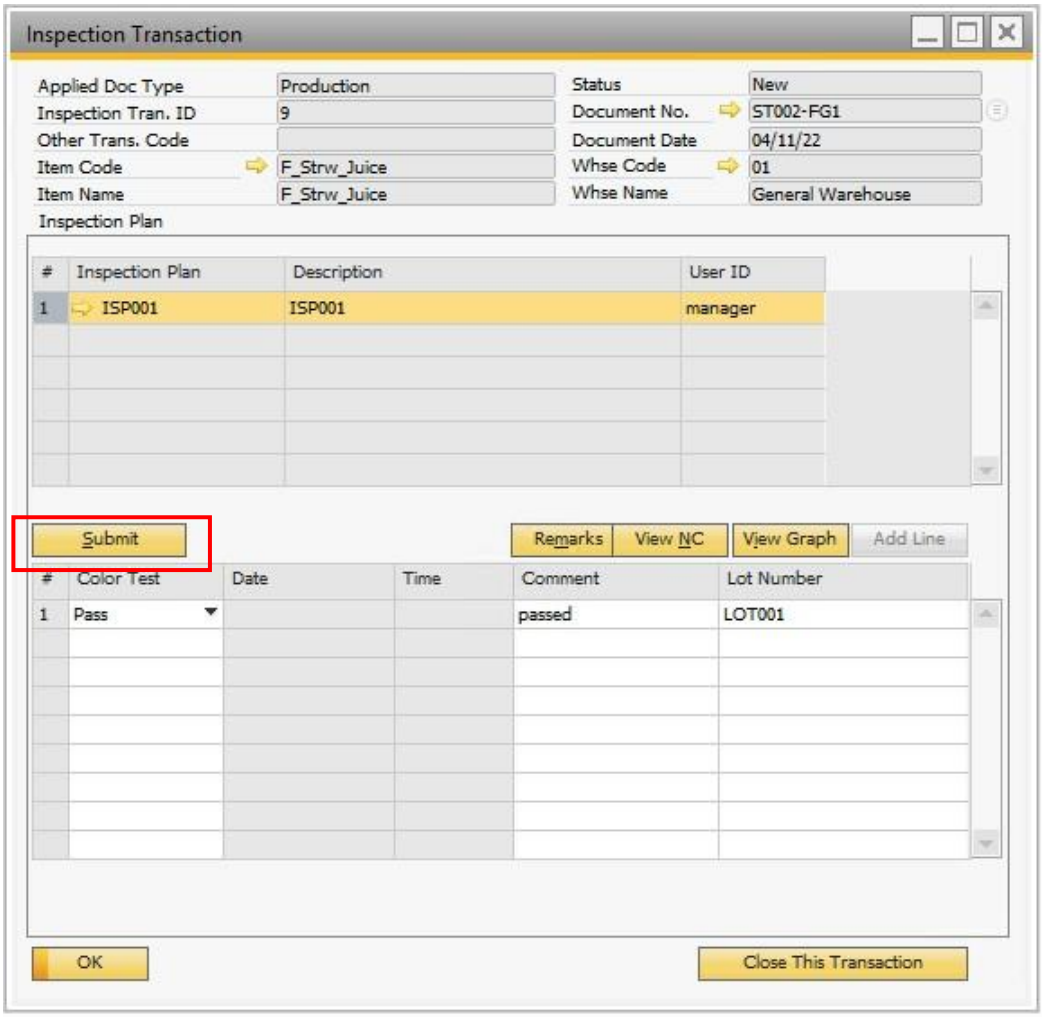
Carrying out inspections on your released batches, sales delivery, purchase receipt or any other process is a concern to meet compliance. Using the *Inspection Transaction* screen, you can perform inspections on your purchase receipt, sales orders and production orders.

Go To: Quality Control → Inspection Transaction



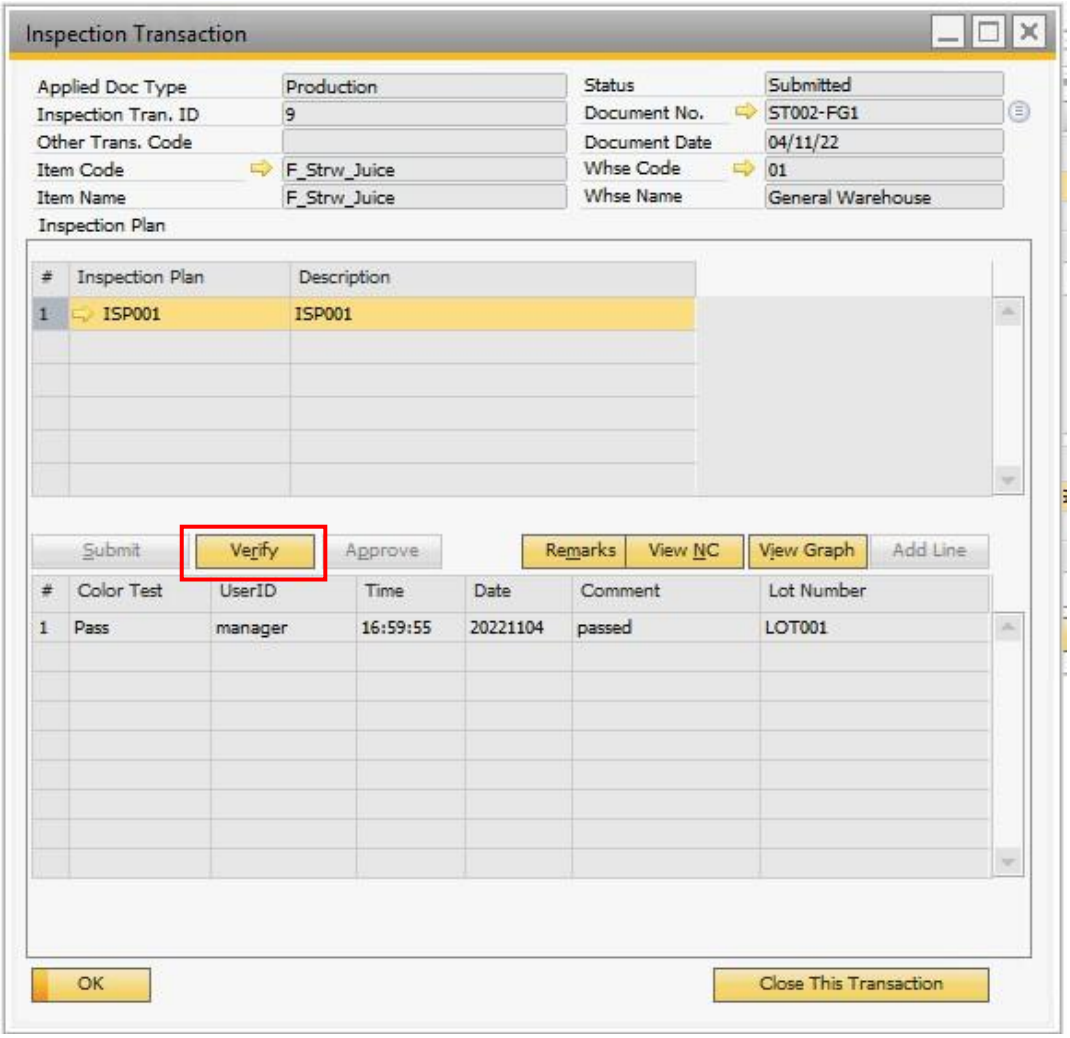
You can also add an *Inspection Transaction* record from Batch Entry, Batch Ticket, Batch Close, Super Batch Entry and Super Batch Close Screen. The *Add Inspection Transaction* option is provided on the right click of the screen.

On the Inspection Transaction screen, first you need to enter the document type on which the inspection plan will be employed, and then you need to enter the desired document number. Based on the document number you've chosen, you can view the applicable inspection plans in the upper grid and the quality control tests corresponding to each plan in the lower grid. You can click the *Add Line* button and enter test results for all the quality control tests.

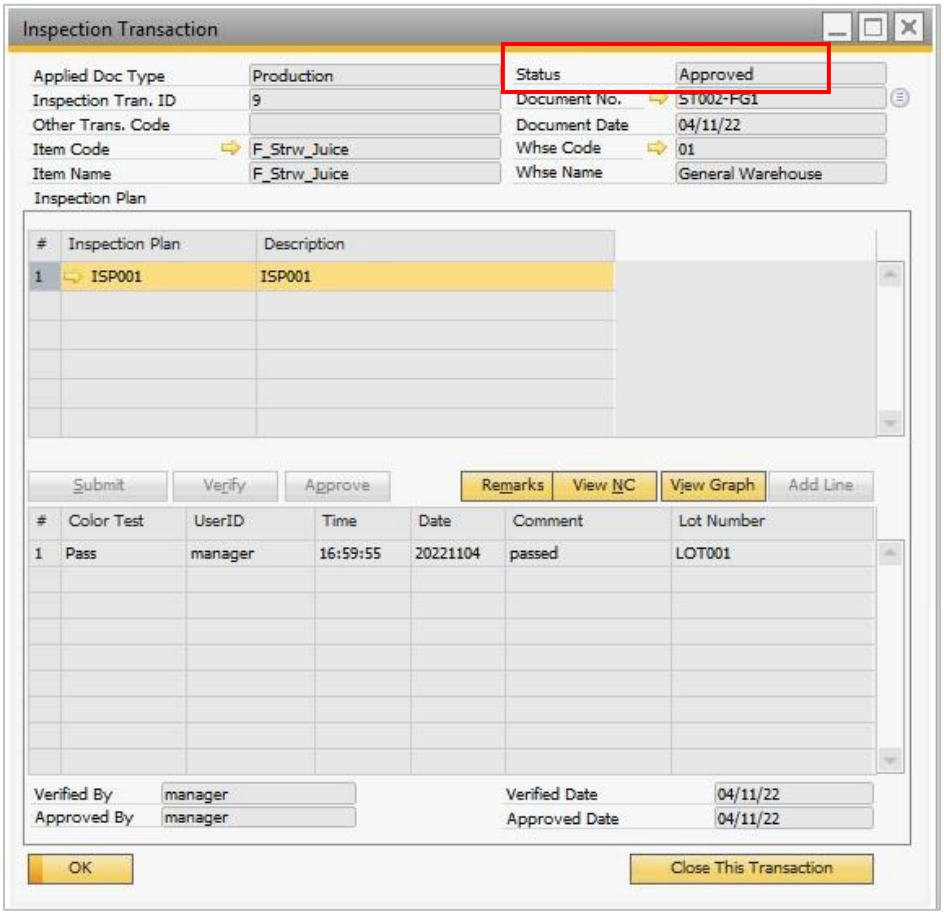


Once you are ready with the test results of all the quality control tests, you can click the *Submit* button to submit tests results for approval. At this stage, if you have implemented approvals for inspection transactions, the status changes to *Submitted* and an alert would be sent to authorize verifier for its verification. Also, you can enter Test – wise remarks with the Inspection plan. Clicking the *Remarks* button displays a remark window where you can enter the required remarks.

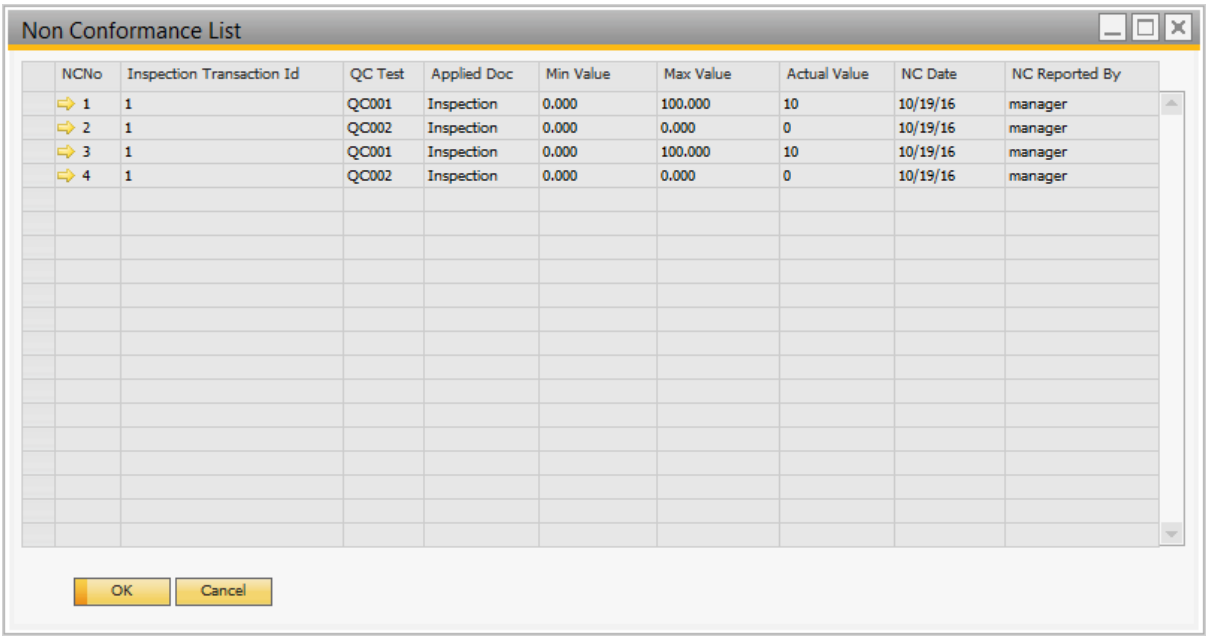
When an authorized verifier logs in, the *Verify* button is activated.



When verified, the record status changed to *Verified* and an alert would be sent to the approver for its final approval. Upon clicking the APPROVE button, transaction status changes to *Approved*.

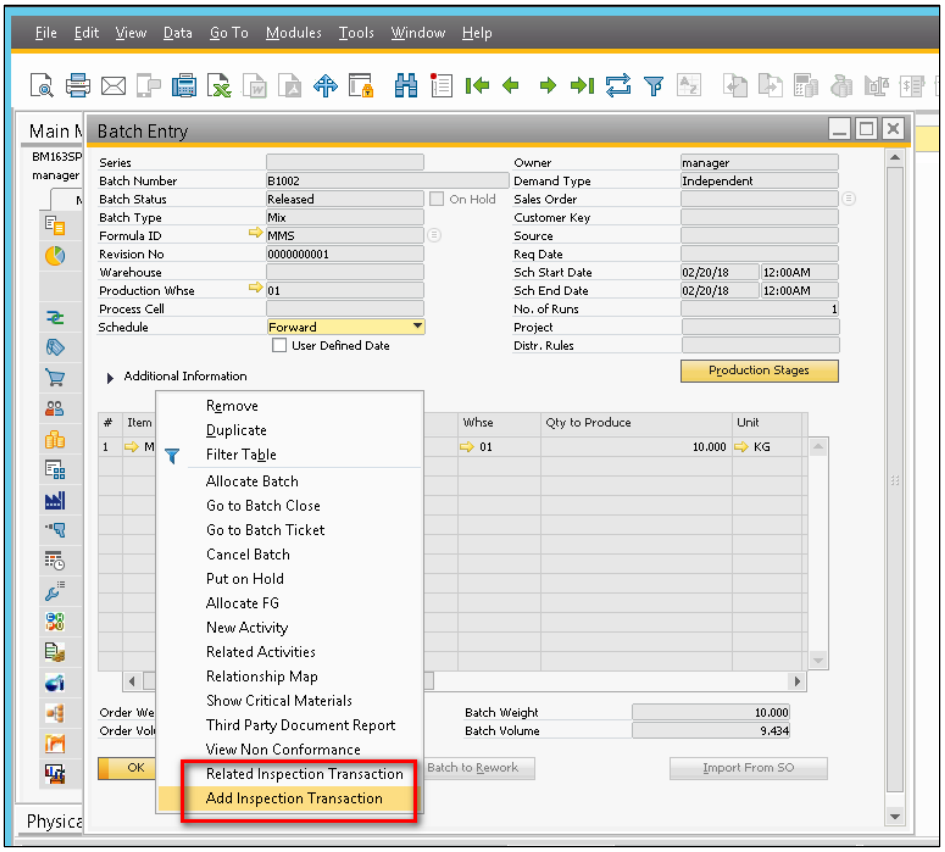


The **View NC** button is available to view Nonconformance data, if it exists.

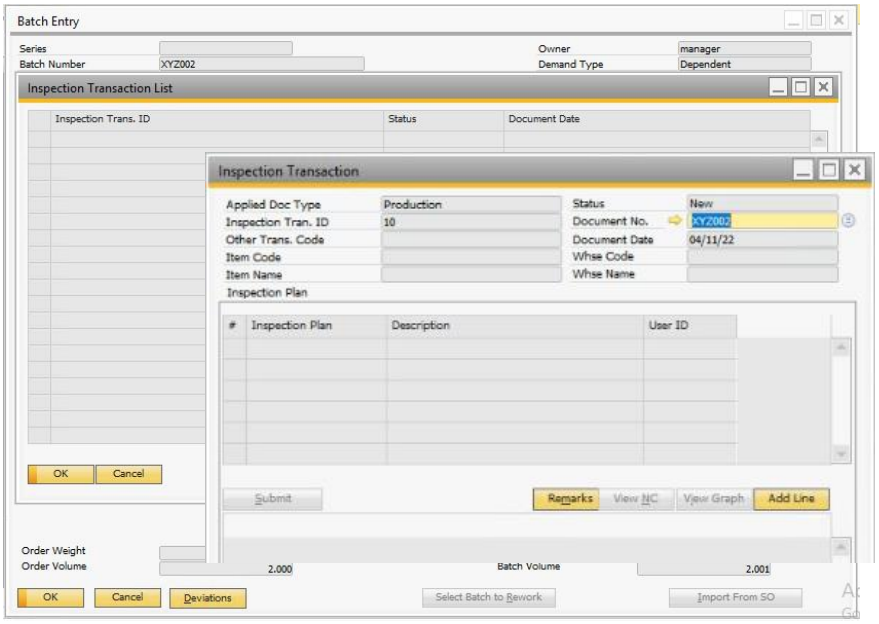


You can also view the test results in graphical format by clicking the *View Graph* button.

The *Inspection Transaction* record added during the production process can be viewed using the *Related Inspection Transaction* option, provided on the right click of Batch Entry, Batch Ticket, Batch Close, Super Batch Entry and Super Batch Close screens.



Clicking it displays the *Inspection Transaction* List.



4.4 QC (Checklist) Masters

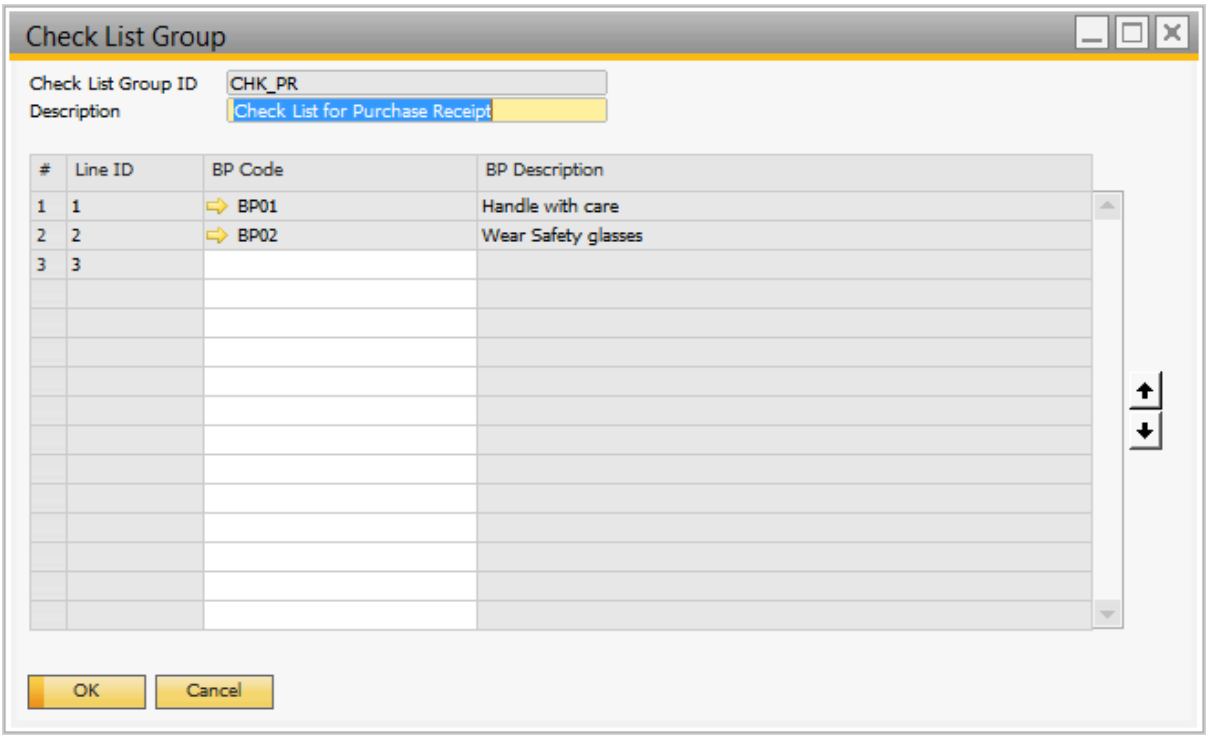
Every inspection that you undertake is recorded as a transaction. To be able to perform an inspection transaction, you need to create records of all the essential details in the corresponding QC masters.

4.5 Check List Group

Go To: Quality Control → Check List Group

FDA requires that whenever a product, process or procedure doesn't comply with the specifications or requirements in some way the issue needs to be documented. Thus a well detailed SOP is followed to ensure product consistency and safety in almost all aspects of batch processing.

Using the *Checklist Group* screen, you can group a set of manufacturing instructions (boilerplates) in a specific sequence, so that they define an SOP (Standard Operating Procedure). This helps you meet cGMP compliance for good manufacturing practices by recording the activities that affect product quality such as equipment cleaning and floor cleaning.

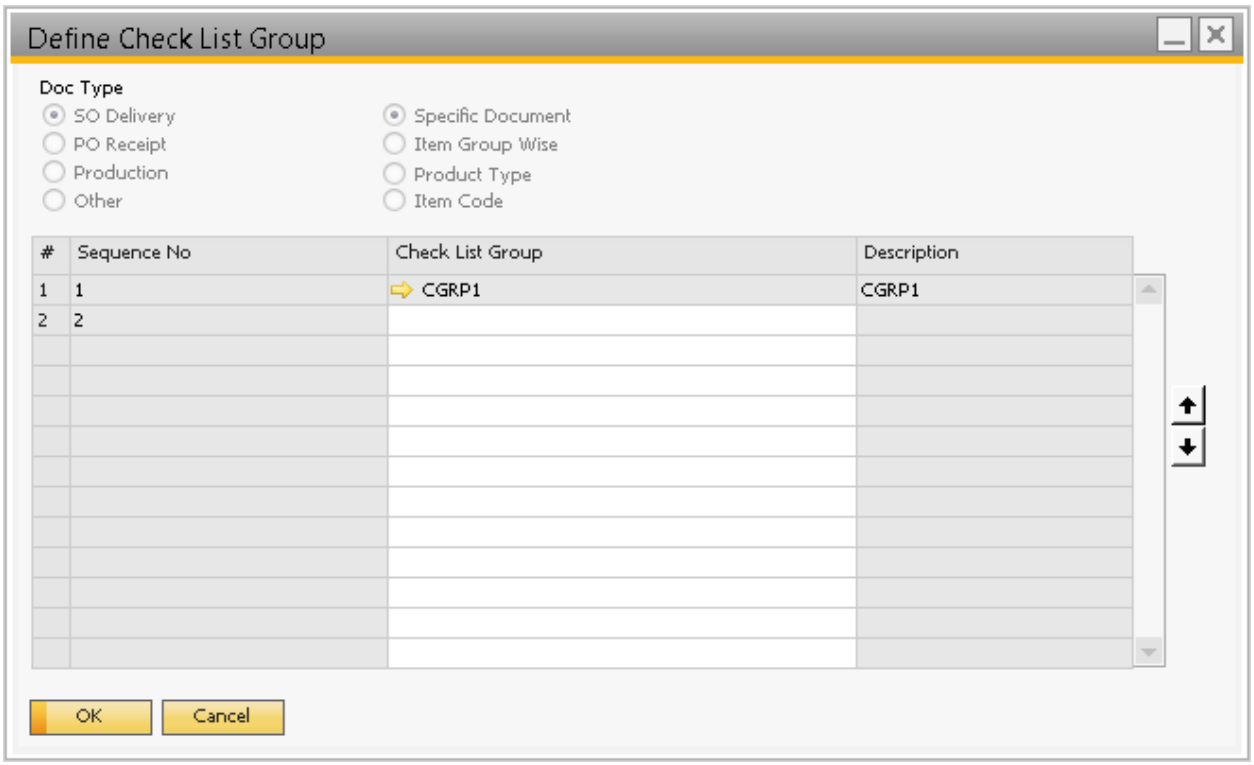


On the screen, enter a unique code for the check list group and associate boilerplates, one in each row in the grid. Click ADD or UPDATE to save your work.

4.6 Define Checklist Group

Go To: Quality Control → Define Checklist Group

When your checklist groups have been defined, you can associate them with activities/documents such as Production, Receipt, Shipment or Others. You can define a Checklist group for a specific document, item group, product type or Item code. This ensures that the attached manufacturing instructions will be followed for each activity. To define a Checklist Group, open the *Define Checklist Group* screen from the Quality Control module.



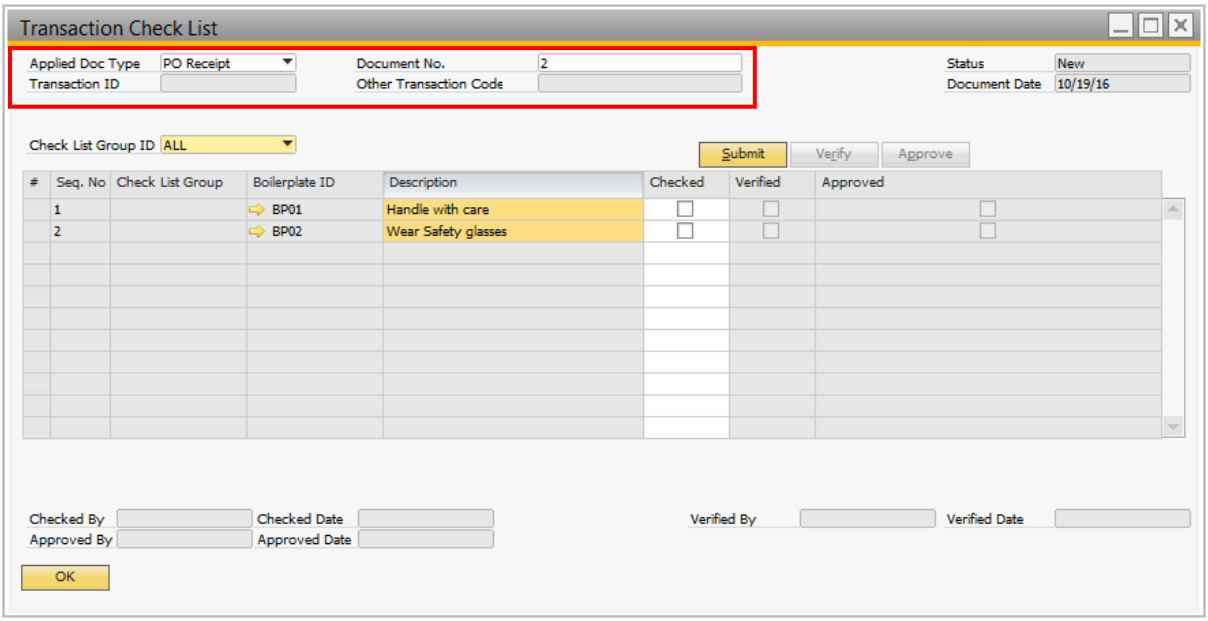
On the screen, select the desired document type from SO Delivery, PO Receipt, Production, Other and specify whether the checklist will be applied on a Specific Document, Item Group Wise, Product Type or Item Code.

In the grid, you can select as many check list groups as needed to attach to the selected document type.

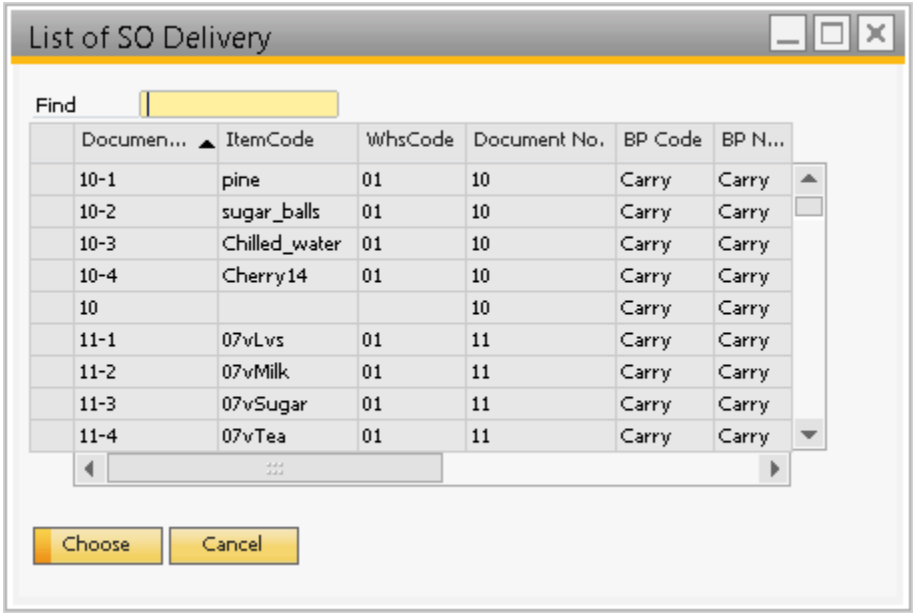
4.7 QC Transaction Check List

GoTo: Quality Control → Transaction Check List

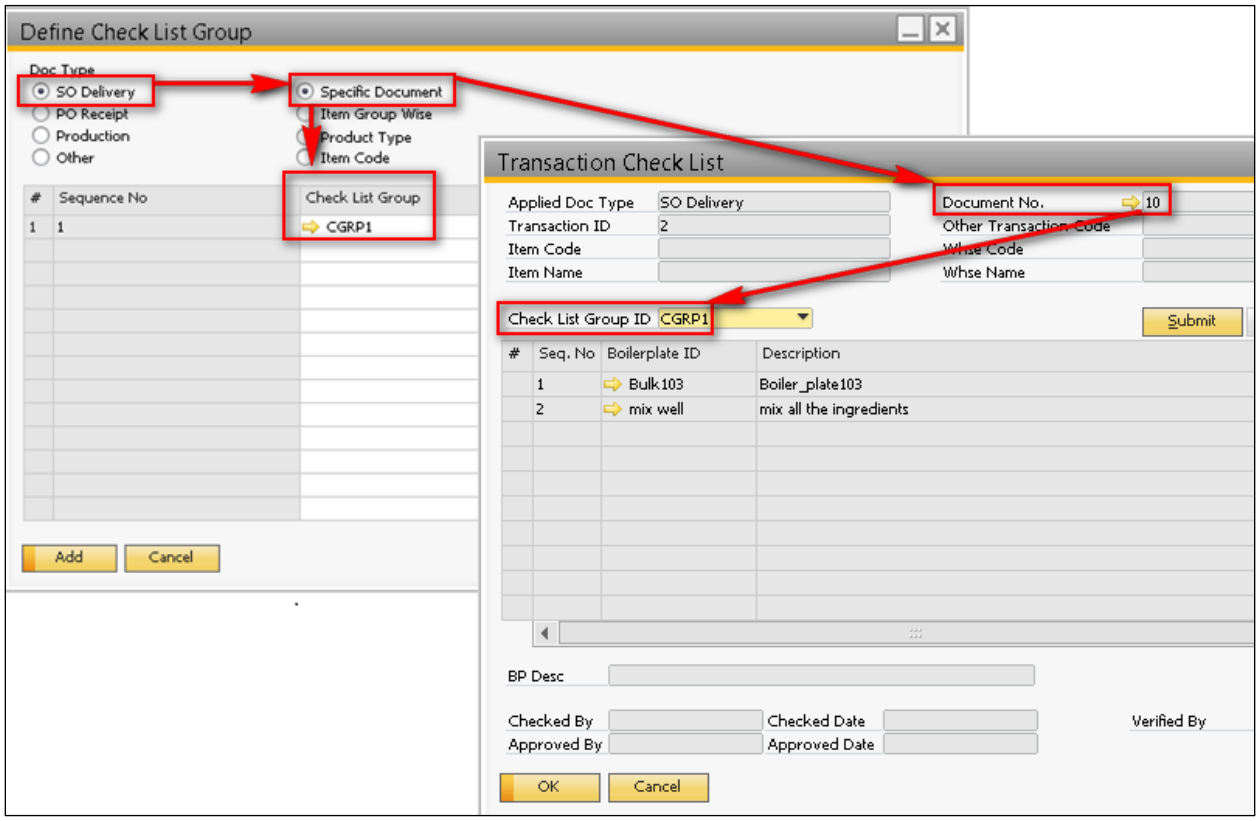
To ensure that a check list is followed during the desired activity, you need to associate it with your business process. You can do so using the *Transaction Check list* screen. On this screen, you can attach a checklist to a business transaction such as purchase receipt, sales delivery, or production receipt (using the dropdown) and to a specific document (using the Document No. field).



The *Document No* field lookup displays a list of document, as displayed below.

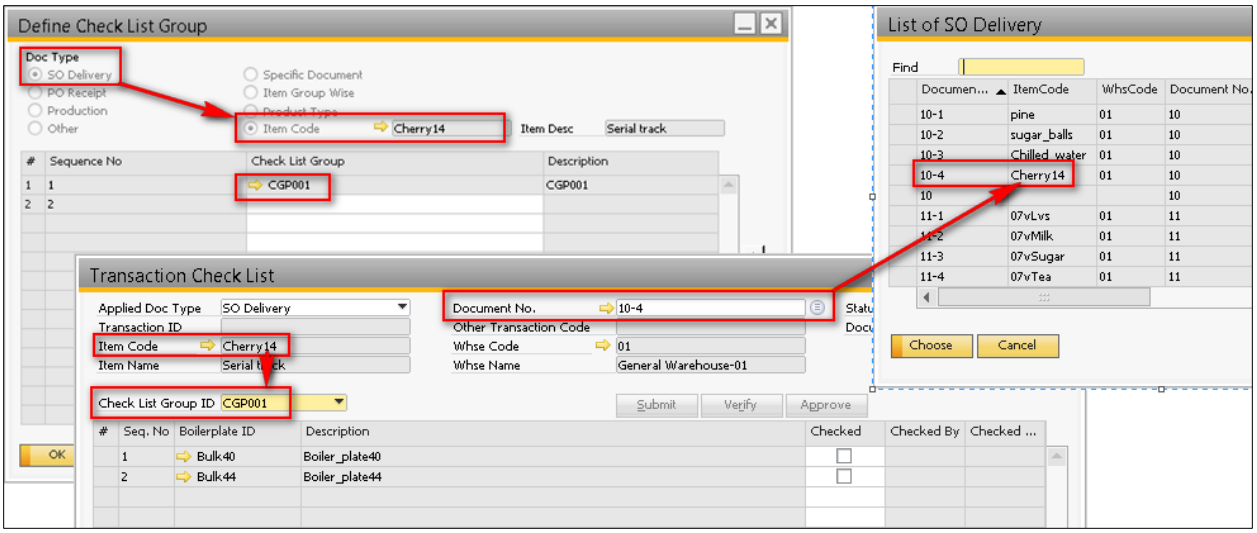


Here you can observe that the Document numbers are displayed in a format of 10, 10-1, 10-2, 10-3, 10-4. From the list, if you choose Document #10, the applicable checklist group will be the group you defined at document level.



If you select the document number as say 10-1 the system will pick the checklist group on the basis of the below order:

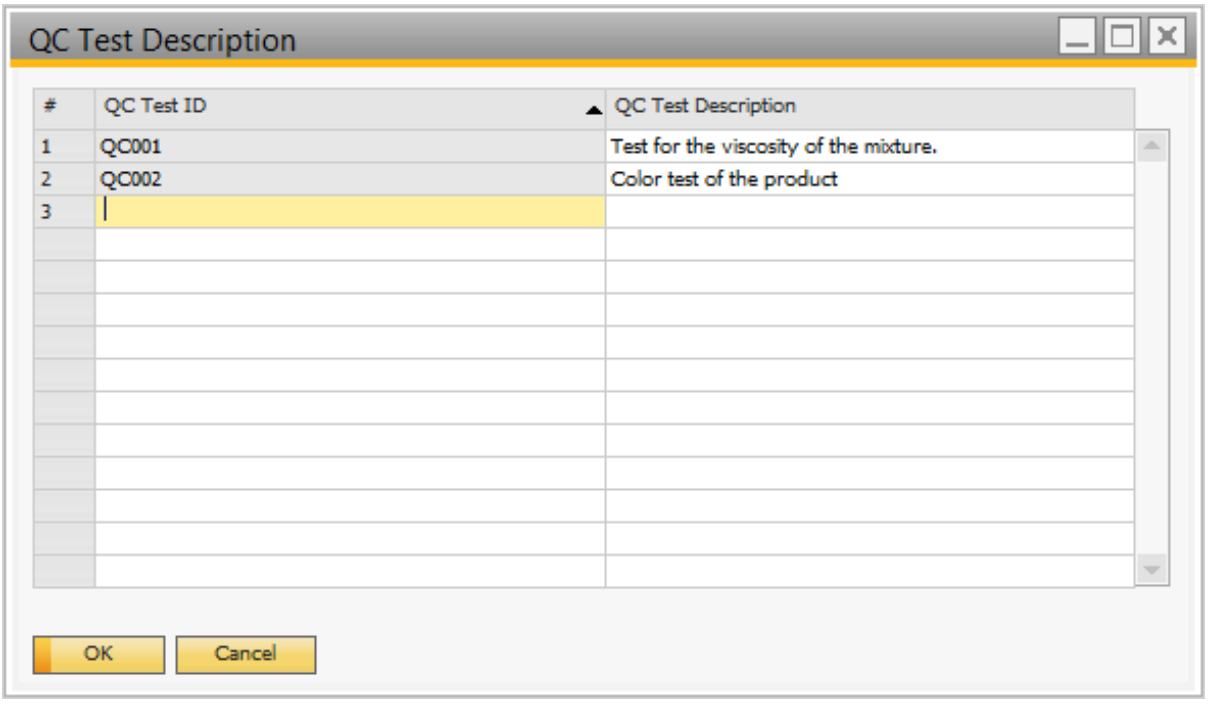
- Item Level
- Product Type Level (if Nutra is installed). This option is not visible for Advance Features
- Item Group Level
- Document Level



Once you have selected the desired document, all the checklists associated with it are displayed in the *Checklist Group Id* dropdown for selection. Applicable users will check/verify/approve the sequence of boilerplates.

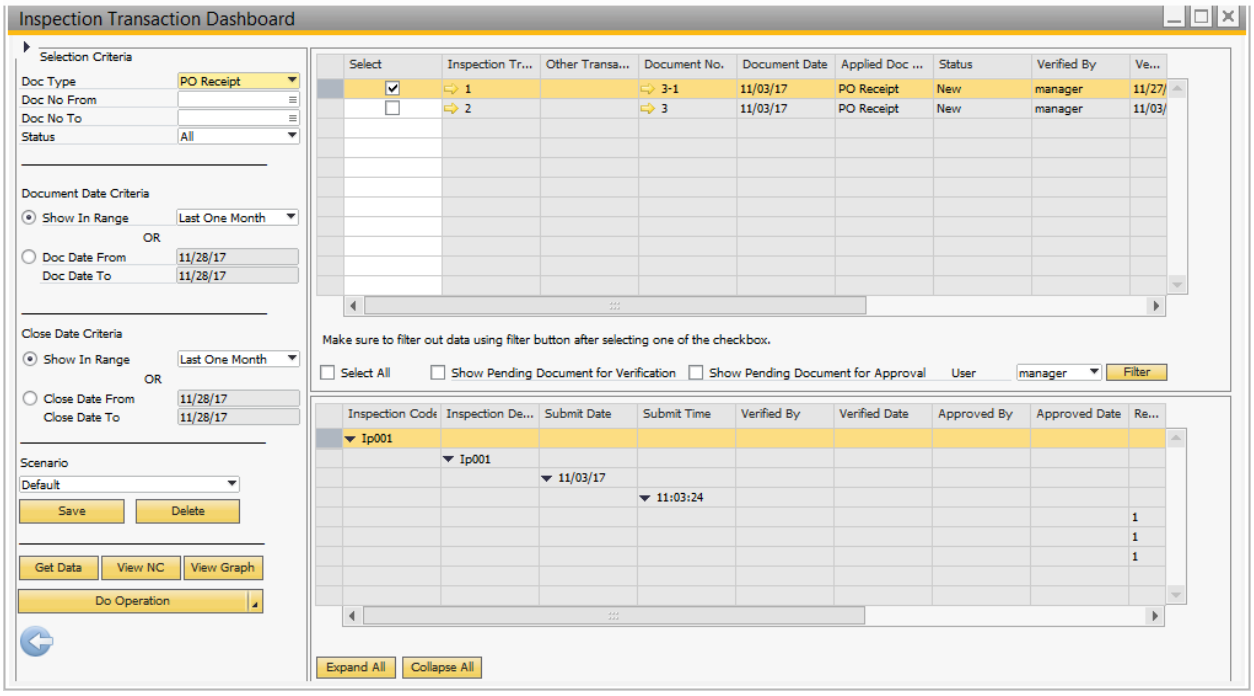
4.8 QC Test Description

On this screen we need to define the QC tests and associated descriptions for quality control. Enter the unique identification code for the QC test and give its description.



4.9 Inspection Transaction Dashboard

Use the *Inspection Transaction Dashboard* to view the inspection details of SO Delivery, PO Receipt, Production and Other types of document. Dashboard offers distinct filter criteria to render quick and crisp information. Right from the dashboard you can perform various operations such as verify/approve/close the inspection document, View NC, and View Graph.



Selection Criteria

Doc Type: Specify the type of document based on which documents will be filtered and displayed on the dashboard. The options available are *SO Delivery, PO Receipt, Production, Other and All*

Doc No From: The lower limit of document numbers to be displayed, subject to the document type chosen above.

Doc No To: The upper limit of document numbers to be displayed, subject to the document type chosen above.

Status: Use this dropdown to select the status to filter the range of documents of particular status only. Available options are *New, Submitted, Verified, Approved, Closed* and *All*.

Document Date Criteria

Show in Range: Choose this option to view the inspection transactions closed in a specific timespan, last 3 days, last 7 days, last 1 month, last 6 months etc.

Doc Date From: Choose this option to specify a custom range of dates for which documents will be display.

Close Date Criteria

Show in Range: See above description.

Close Date From/To: Choose this option to specify a custom range of dates for which documents will be displayed.

Default/Add New: Use this dropdown to save the dashboard layout for future use. It can be the default layout or you can give it a unique name. Unique naming is useful when more than one user views the dashboard.

Save: Click on this button to save the layout.

Delete: Click on this button to delete the layout.

Get Data: Click on this button to display data on the dashboard based on your criteria.

View NC: Use this button to view the non-conformance list of the selected transaction.

View Graph: Use this button to get the graphical view of the selected transaction.

Do Operation: Use this dropdown to Verify/Approve/Close the selected inspection document.

Grid Details

Select: Use this checkbox to select corresponding line in the grid.

Inspection Transaction ID: Identification number of the inspection transaction.

Document No: Unique identifier of the document. You can use the available hyperlink to navigate directly to the document.

Document Date: Displays the date on which document is created.

Applied Doc Type: The type of document on which inspection transaction was accomplished.

Status: Shows the current status of the document.

Verified By, Verified Date, Approved By, Approved Date: Self-explanatory

Closed Date: Shows the date on which the document was/is finalized.

Closed By: Displays an id of the user who has closed the respective document.

Select All: Check this option to select all document lines displaying in the grid.

Show Pending Document for Approval: Select this checkbox to view all those documents whose approval is pending.

Show Pending Document for Verification: Check this option to view all documents whose verification is yet to be done.

User: Use this dropdown to select and filter data based on who is responsible for the inspection transaction.

Lower Grid

Displays the details of inspection plan applied on the document.

Inspection Code: The inspection plan applied on the document.

Inspection Description: Shows the name or description of the inspection plan.

Submit Date: Displays the date on which the document was submitted.

Submit Time: Shows the submission time of the document.

Verified By, Verified Date, Approved By, Approved Date: Self-explanatory.

RefLineID: System-maintained field.

Test Code: Shows the unique identifier of the QC test being applied on the document.

Value: Displays the QC test value.

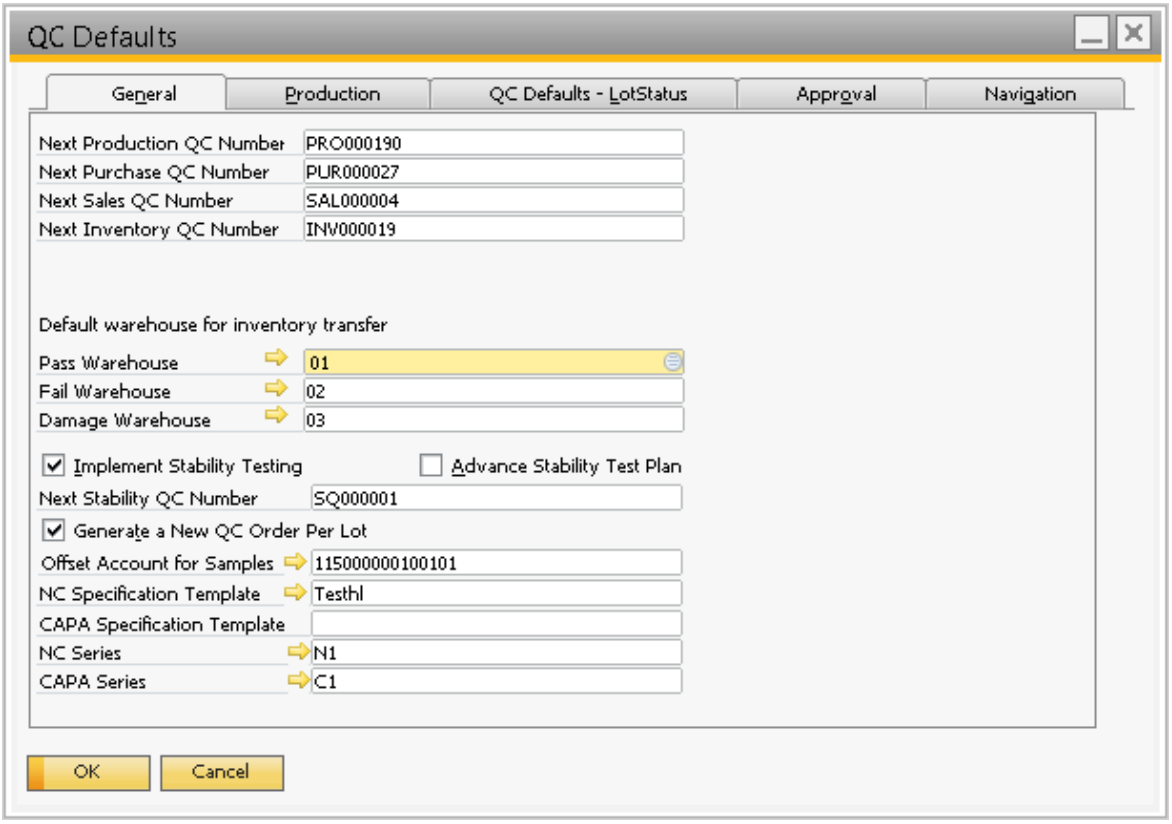
Comment: Field displays note or remark added on the document.

Lot No: The lot on which inspection was performed.

5 NC/CAPA

5.1 QC Defaults

Specify the NC and CAPA Series to be used to generate the NC/CAPA document number.

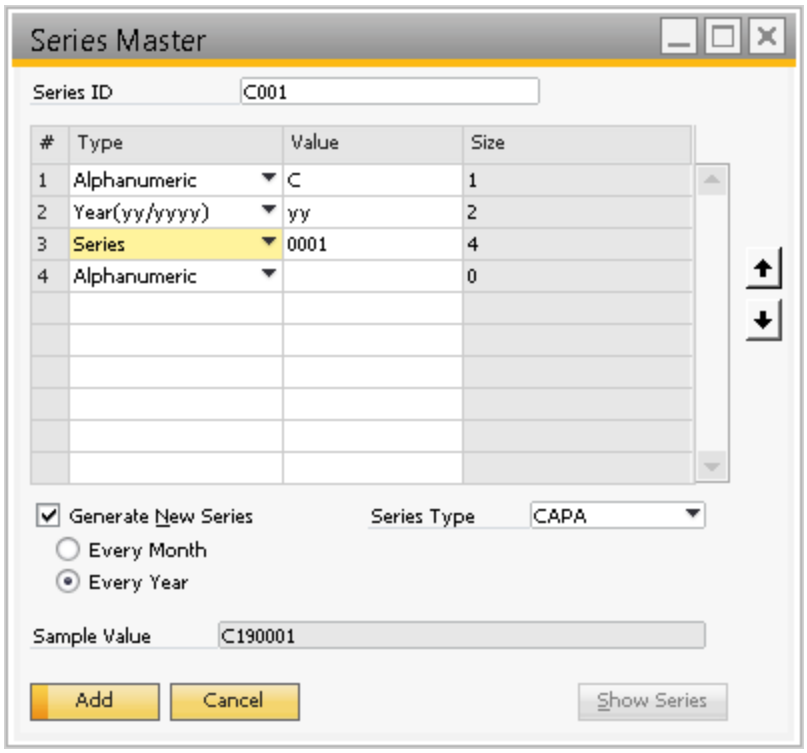


5.2 Series Master

Using the *Series Master* screen, you can define a prefix that can be added to the NC/CAPA document number. This prefix can be alphanumeric, a customer number, a date (a combination of month/day/year), or a numeric serial value. The series you set here will be used to generate the NC/CAPA document number sequentially after the prefix.

Go To: Administration → Setup → Quality Control Setup → Series Master.

On this screen, specify the unique series identifier in the *Series ID* field. Next, specify the series mask using the *Type* field in the grid. Available options are *Alphanumeric*, *Customer*, *Month (MM/MMM)*, *Series*, *Year (yy/yyy)*, or *Day (dd/ddd/JD)*. Specify whether the *Series Type* of the series you are creating is CAPA or NC.



Type: Choose one of the following options for each line of the grid. Based on the segment *Type* chosen on each line of the grid, enter the *Value* for the series mask. If you have selected:

- ***Alphanumeric***, you must enter alphanumeric characters in the grid cell (maximum 19 characters).
- ***Customer***, you will be prompted to enter the customer name at the time of batch close (maximum 15 characters).
- ***Month (MM/MMM)***, select the month format from the drop-down box in the grid cell.
- ***Year (yy/yyyy)***, choose the year format from the drop-down box in the grid cell.
- ***Day (dd/ddd/JD)***, select the year format from the drop-down box in the grid cell. (Note: JD = Julian date.)
- ***Series****, you must enter a starting numeric serial value in the grid cell. (Note: This entry must be the last row.)*

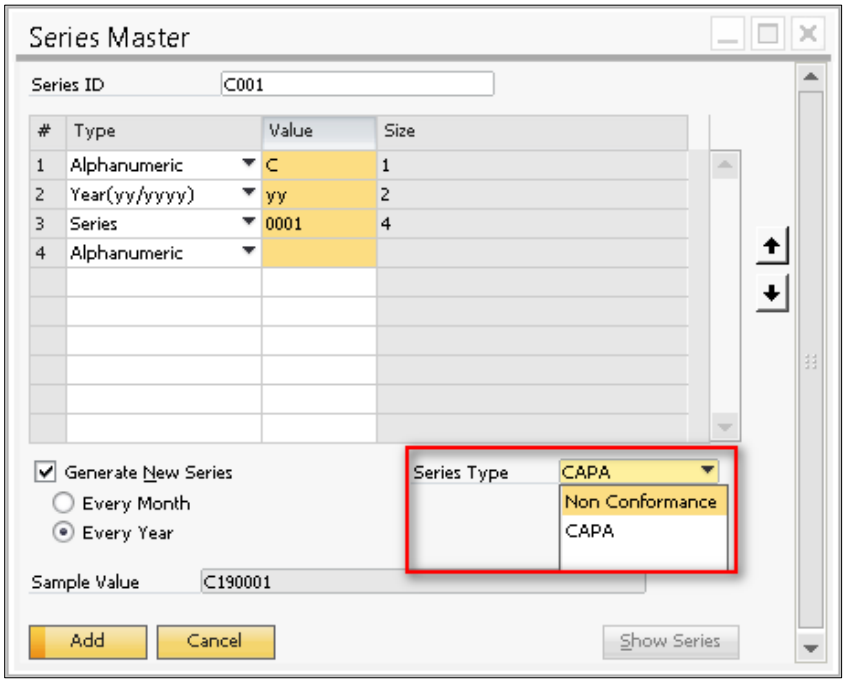
Value: Enter the characters that make up the alphanumeric or the series. Month, day, and year formats are listed in parenthesis and are case-sensitive (i.e., the use of capital letters versus lowercase letters must be followed).

Size: Displays based on the entries made in the *Value* column. The cumulative size of all the grid rows cannot be more than 35 characters.

Generate New Series: Check this box to have the system change the month or the year automatically. Then pick *Month* or *Year* by clicking the appropriate radio button.

If you select *Generate New Series Every Month*, you must have *Month* as one of the numbering segments. *Generate New Series Every Year* requires *Year* as one of the numbering segments.

Series Type: Choose a relevant series type as one from the options, Non Conformance/CAPA. Further, you can use the respective series in the selected document type only.



Sample Value: Displays the series sample value based upon the Type and Value you set.

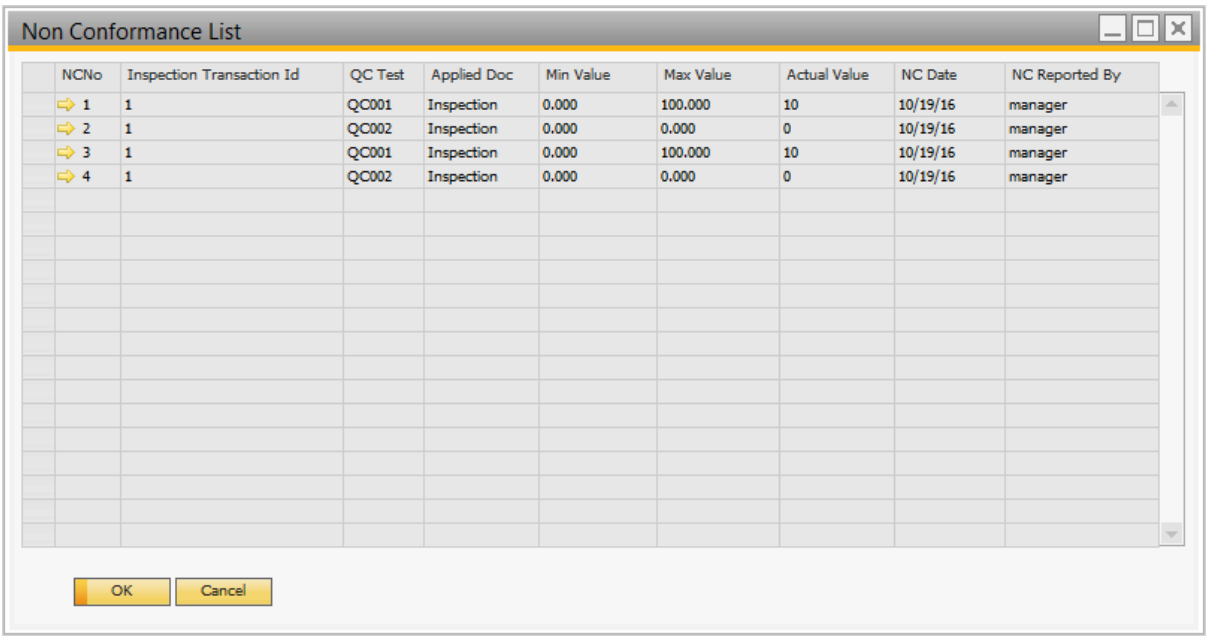
Add: Click the *Add* button to save your work.

Show Series: Use this button to view series already defined.

5.3 Non Conformance

The FDA requires that whenever a product, process, or procedure doesn't comply with specifications or requirements in some way, the discrepancy needs to be documented. To help manufacturers meet this requirement, the Nutraceutical Micro-vertical offers a non-conformance report. Using this report, you can easily record a new or existing problem in a clear, logical, and concise way so that management takes steps to implement corrective actions.

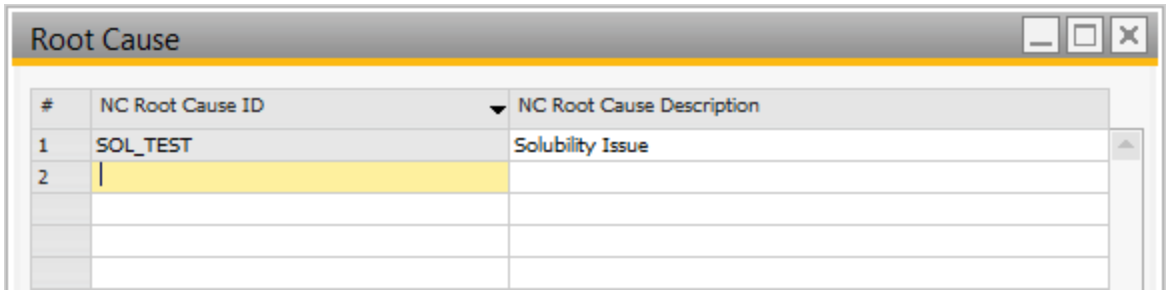
This report is generated automatically as a result of product failure in QC tests defined in the inspection plan, inventory, purchase or production QC. You can also enter customer complaints manually using the *Non Conformance* screen. This is useful if you want to file a non-conformance report despite the fact the item passed a QC Test.



5.3.1 Root Cause

Every non-conformance occurs for some reason and needs to be identified and recorded. Using the Root Cause screen, you can store all possible causes of non-conformance. You can access this screen from the QC module.

Go To: Administration → Setup → Quality Control → Root Cause

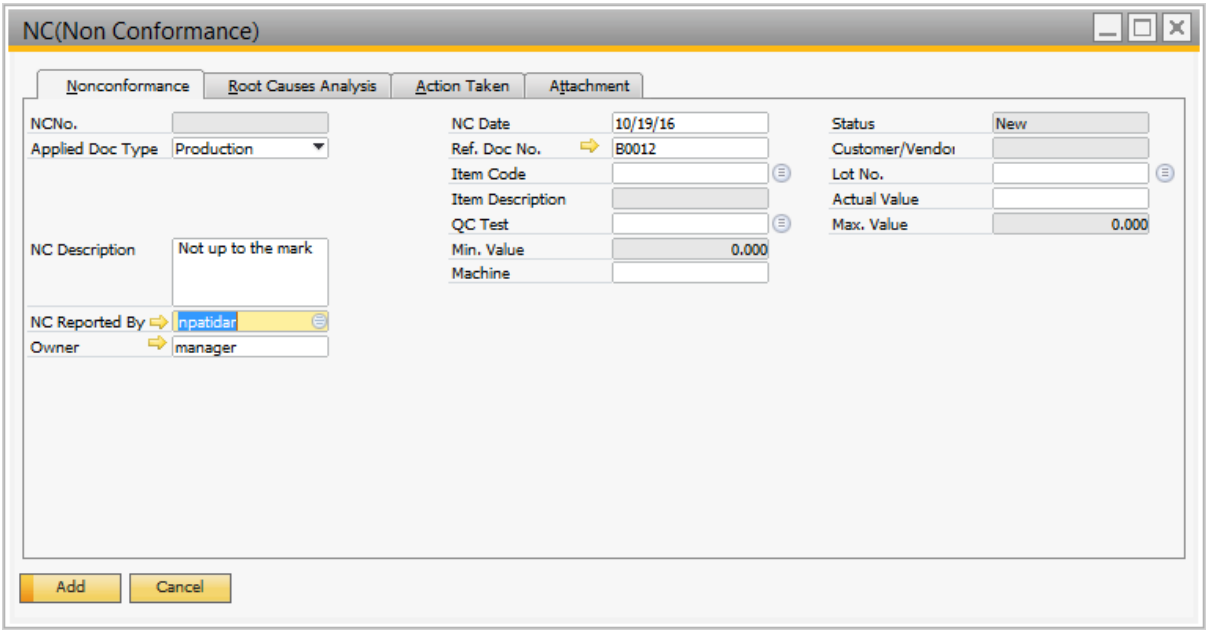


In the *NC Root Cause ID* field, enter the unique identifier code for the root cause. Enter a brief description of the root cause, in the *Description* field. Click the *OK* button to save the record. You can create as many records as needed.

5.3.2 NC (Non Conformance)

Let's access the *NC (Non Conformance)* screen to record nonconformity manually.

Go To: Quality Control → NC (Non Conformance)



Begin with the *Nonconformance* tab. This tab holds general information about the non-conformance record.

In the *Applied Doc Type* field, enter the type of the document for which you are recording a non-conformance. The type can be SO Delivery, PO Receipt, Production, QC, Inspection or Other.

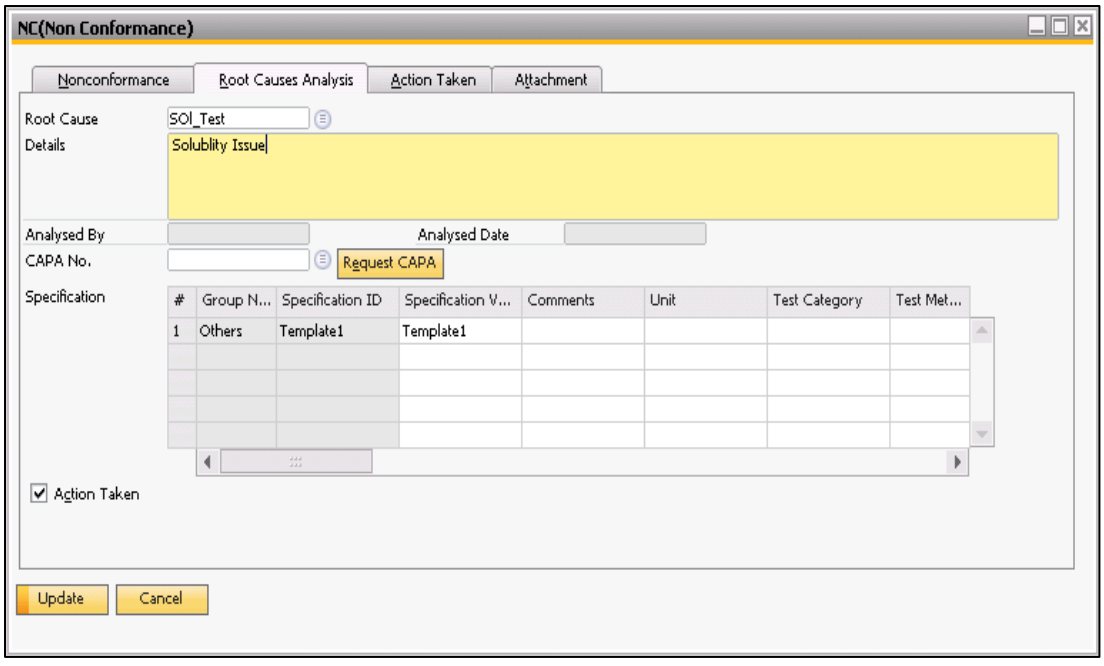
Next in the *NC Description* field, you can enter some details about the non-conformance. In the *NC Reported By* field, enter the user who reported non-conformance. In the *NC Date* field, enter the date on which the non-conformance was reported.

If you have any supporting document, then enter that document number in the *Ref Doc No* field. For example, if the non-conformance is associated with a particular production batch, then the batch number can be entered in this field.

In the *Item Code* field, enter the name of the product or item against which you are recording the non-conformance. In the *QC test* field, enter the quality control test as defined under the Inspection Plan applied to the item. In the *Lot No* field, enter the suspected lot's identification code.

Once you have identified and recorded the problem, you should record the underlying causes. You can do so on the *Root Cause Analysis* tab.

Switch to *the Root Cause Analysis* tab. Select the basic reason or "define as new" the root cause of the problem being raised. In the *Details* field, give a detailed description of the root cause.



Since you have recorded an issue, you may now want to plan for its resolution.

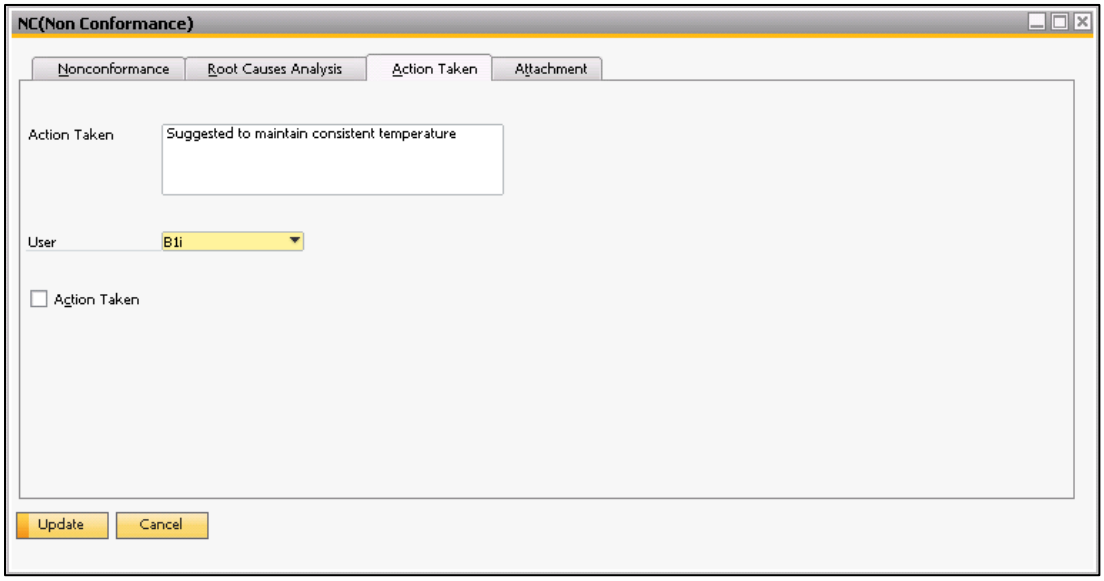
In the *CAPA No.* field, enter the CAPA number if you have already requested a record for the nonconformity. If you want to request a new CAPA now, then click on the *Request CAPA* button. This will generate a CAPA request for the respective NC. Every CAPA request is identified by a unique code.

Check the *Action Taken* option once you have completed the root cause analysis process. On updating the record, its status changes to *Root Cause Analysis*.

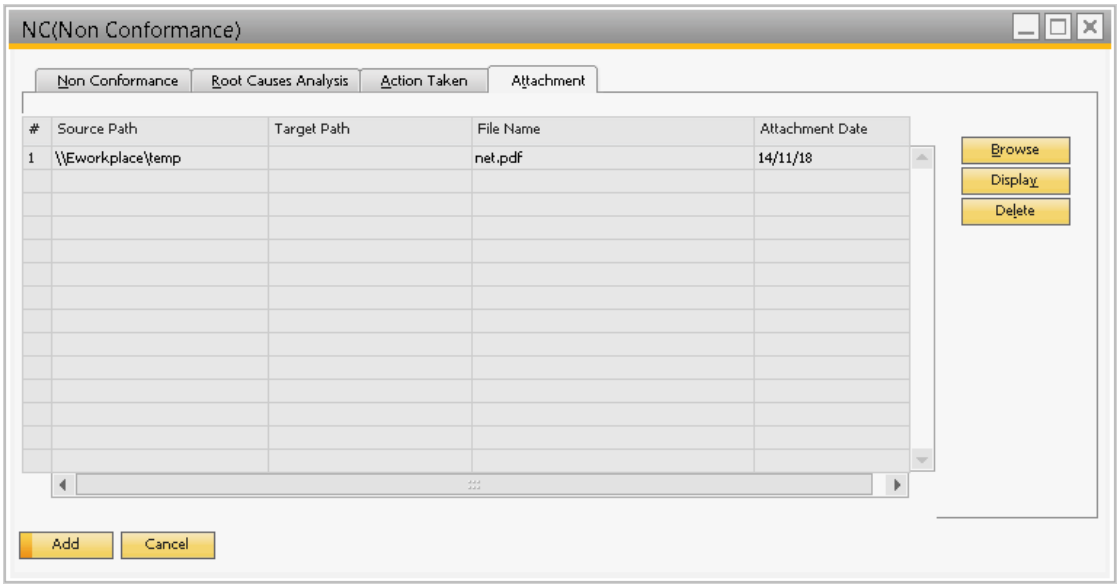
Now move on to the *Action Taken* tab. Here, enter the activities that you have undertaken to prevent recurrence of the nonconformity. In the *User* field, enter the user who defined or applied these activities.

Select the *Action Taken* checkbox. If you have authorization to close the NC document then after finishing all the required activities, check the Action Taken checkbox and click on the Update button. On updating the record, the status changes to *Action Taken*.

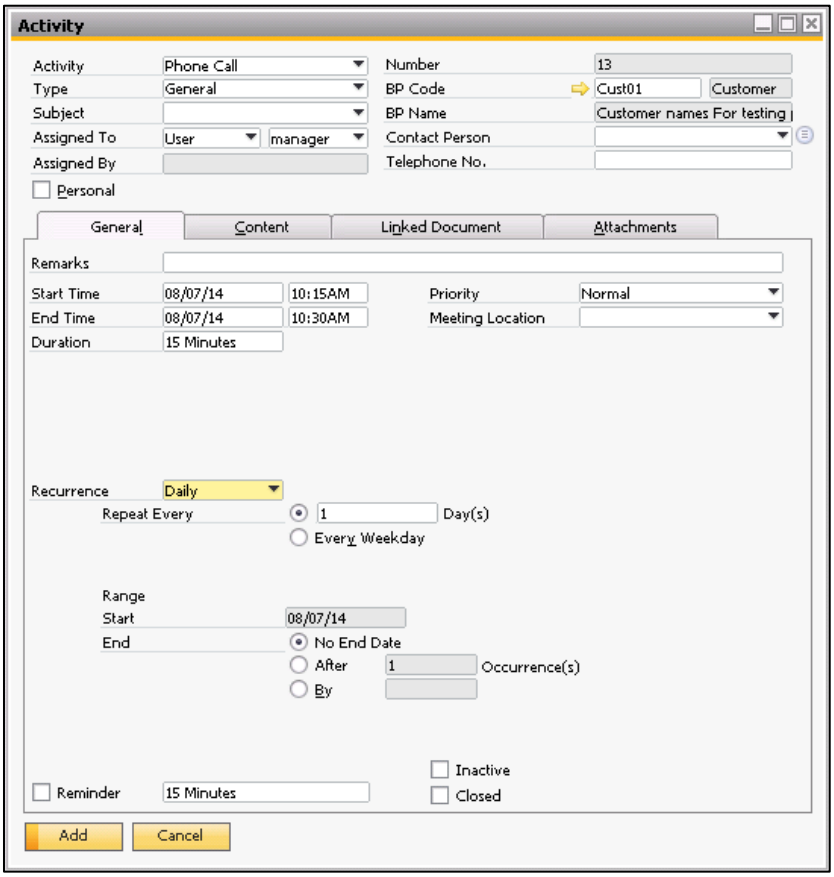
On the General Authorization screen, if user has not assigned authorization to Close the Non Conformance document then the "Action Taken" tab will be disabled with a message saying "Only authorized users can perform this operation"



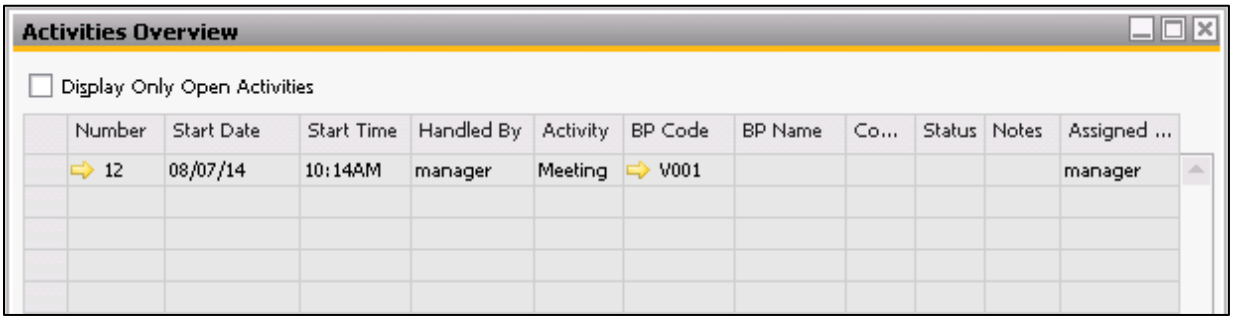
Next, switch to the *Attachment* tab. On this tab, you can associate all files related to nonconformity. To do so, click on the *Browse* button and select the path of the file you need to attach. Note that the path you enter here should lead to a **network location.** Finally, click the *Update* button.



Your nonconformance is logged in with its root causes and action accomplished details. Now if you wish to add any activity related to nonconformance, then right click on the screen and choose the option *Add Activity*.

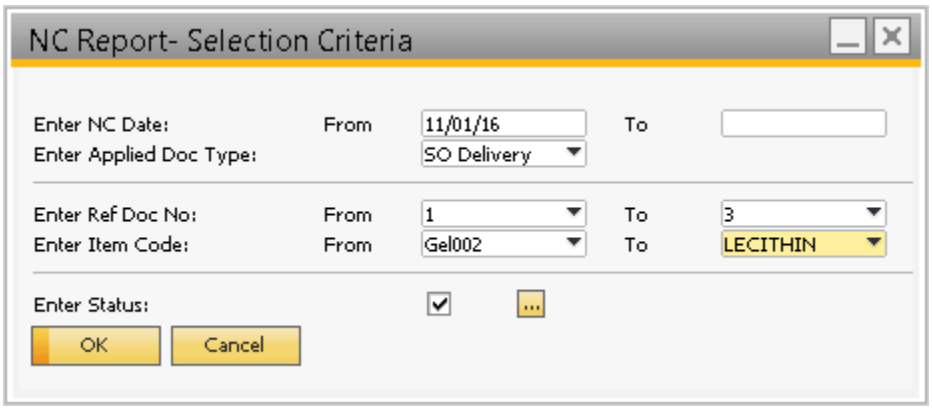


To view previously added nonconformance activities, right-click on the screen and select the option *Related Activities*.



5.3.3 Nonconformance Report

Use the *Nonconformance Report* to view a list of recorded nonconformities that fall within the specified filter criteria.



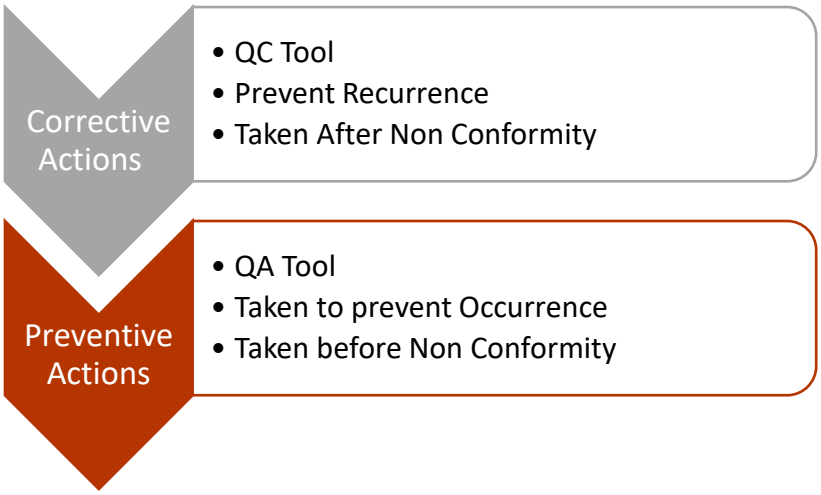
Next, you may want to look for methods that will help you ensure that the issues don't repeat. CAPA can help you do that. BatchMaster ERP provides you a well-centralized and consolidated CAPA system to manage all incidents that have occurred.

Before proceeding to CAPA main screen, let's have a look at the master screens of CAPA which help you create records associated with CAPA.

5.4 CAPA Overview

CAPA refers to Corrective and Preventive Actions, which is a critical part of quality management. It involves four basic steps. First step is to identify the problems in the product. Secondly, you need to prioritize the problems. At the third step, you need to assign the responsibility to rectify the problems to appropriate personnel. Finally, you need to track whether the problem has been resolved.

Let us now compare corrective actions and preventive actions, for better understanding.

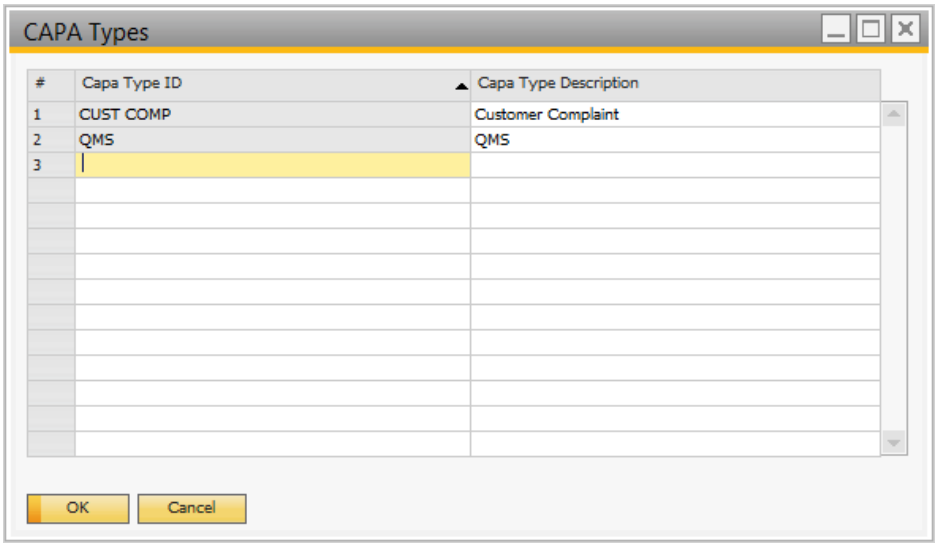


Corrective action is a QC tool because it focuses on identifying defects in the product, whereas preventive action is a QA tool because it focuses on monitoring the process so as to prevent defects in products.

5.4.1 CAPA Types

CAPA processes can be grouped on the basis of their characteristics. You can define such groups using the *CAPA Types* screen.

Go To: Administration → Setup → Quality Control Setup → CAPA Types



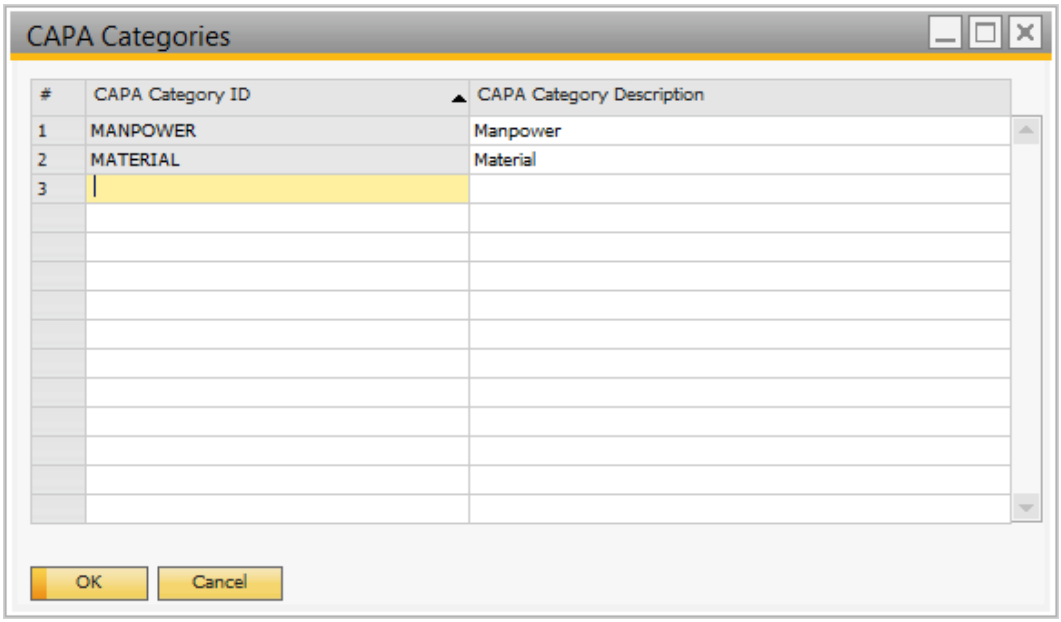
For every CAPA type that you are defining, enter a unique code in the *CAPA Type ID* field and a brief description in the *CAPA Type Description* field.

Click the *ADD or UPDATE* button to save the record.

5.4.2 CAPA Categories

BatchMaster ERP helps you classify CAPA records using the *CAPA Categories* screen. “Category” can refer to any parameter that you choose. For instance, you may need to classify records based on the resource involved in the action such as manpower or material.

Go To: Administration → Setup → Quality Control Setup → CAPA Categories



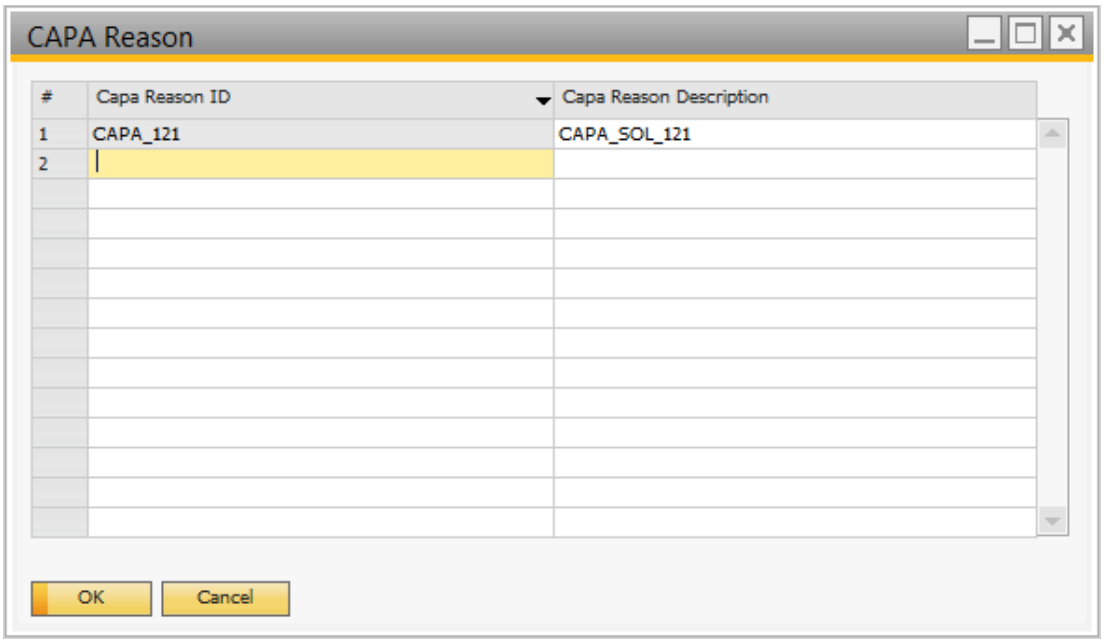
On this screen, enter a unique identification key for CAPA category, in the *CAPA Category ID* field. Then, give a brief description of the category in the *CAPA Category Description* field.

Click the *Update* button (not shown) to save the record.

5.4.3 CAPA Reason

Examining the reason for quality failure is the first and foremost activity in the investigation process. Using the *CAPA Reason* screen, you can create records for all expected or encountered reasons.

Go To: Administration → Setup → Quality Control Setup → CAPA Reason



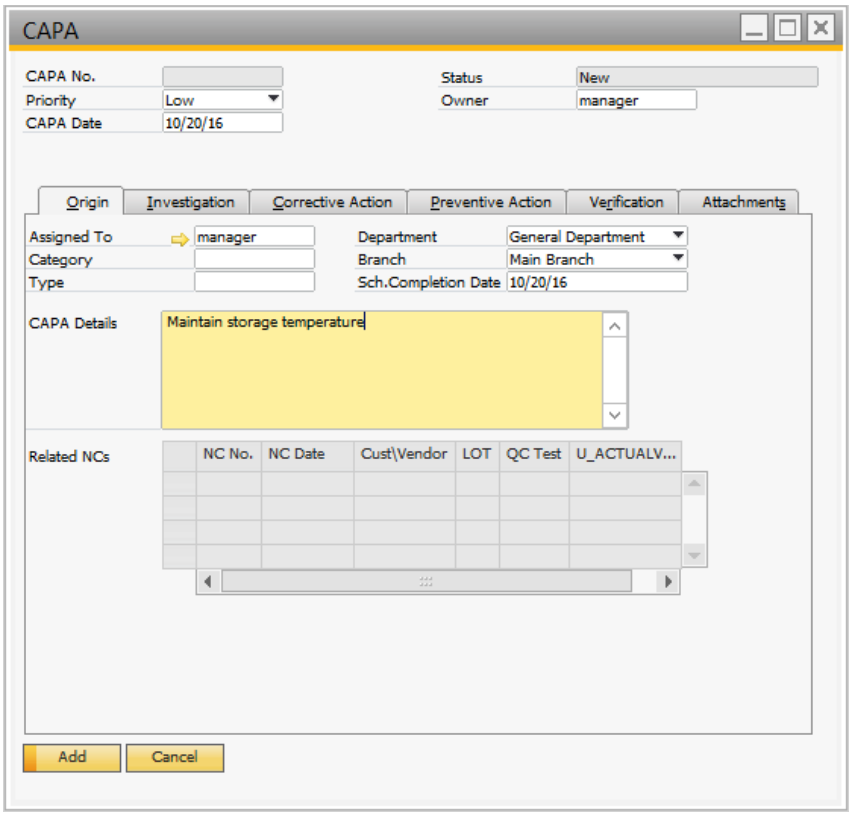
For every record, give a unique identification key in the *Reason Code* field and enter a brief description in the *Description* field.

Click the ADD or UPDATE button to update the record.

5.4.4 CAPA

The CAPA screen lets you record all details about business situations that warrant a permanent record for future reference.

Go To: Quality Control → CAPA



Let's start with the fields on the header section of the screen. In the *Priority* field, enter the urgency level of the CAPA.

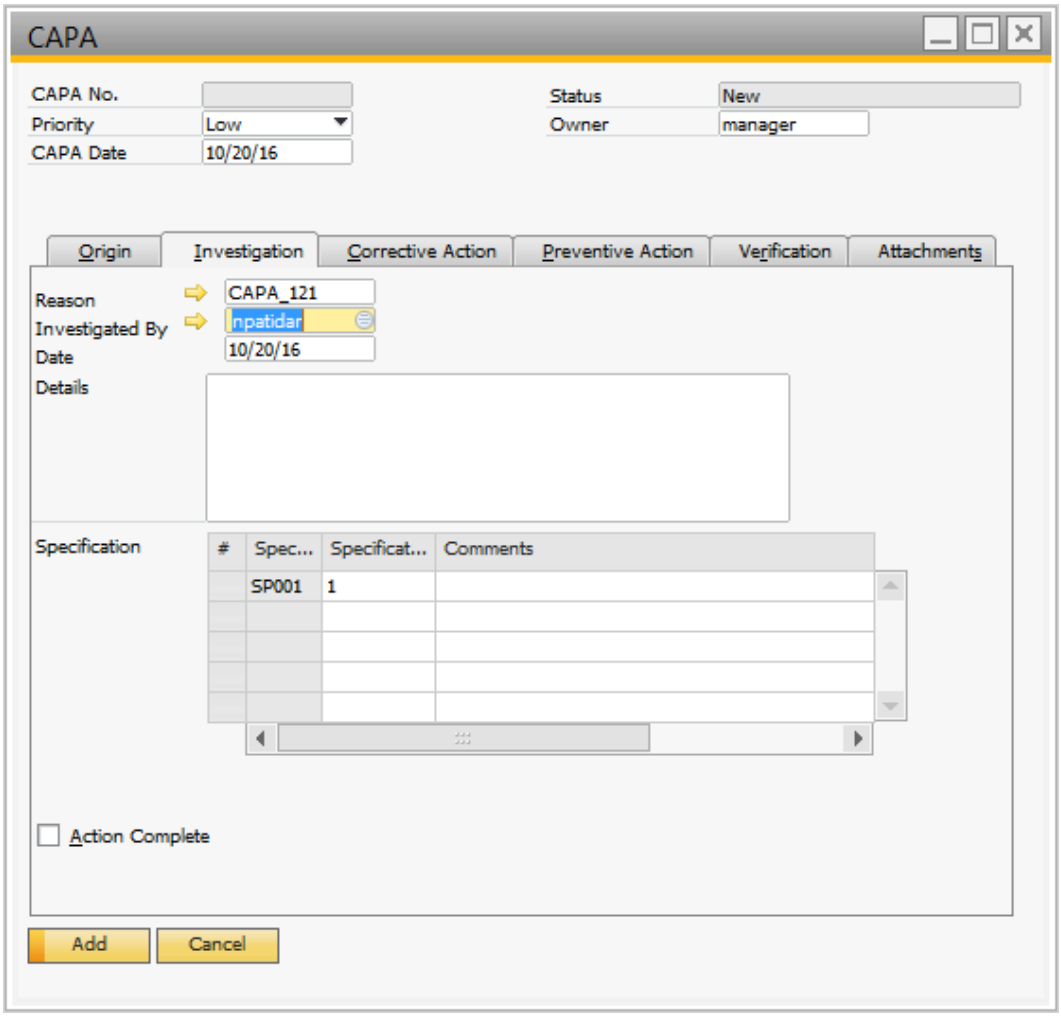
Next, in the *Owner* field, enter the user who is responsible for this CAPA process. In the *CAPA Date* field, enter the date on which the CAPA was undertaken.

Now switch to the *Origin* tab. In the *Assigned To* field, enter the user who is assigned the CAPA task. Next, select an appropriate *CAPA Category* and *CAPA Type*. In the *CAPA Details* field, enter data explaining why the record has been opened.

Next, select the department for which you are defining CAPA and also enter the branch code. In the *Scheduled Completion Date* field, enter the date on which CAPA process is expected to be completed.

Click ADD at this point to save the CAPA record.

Now switch to the *Investigation* tab.

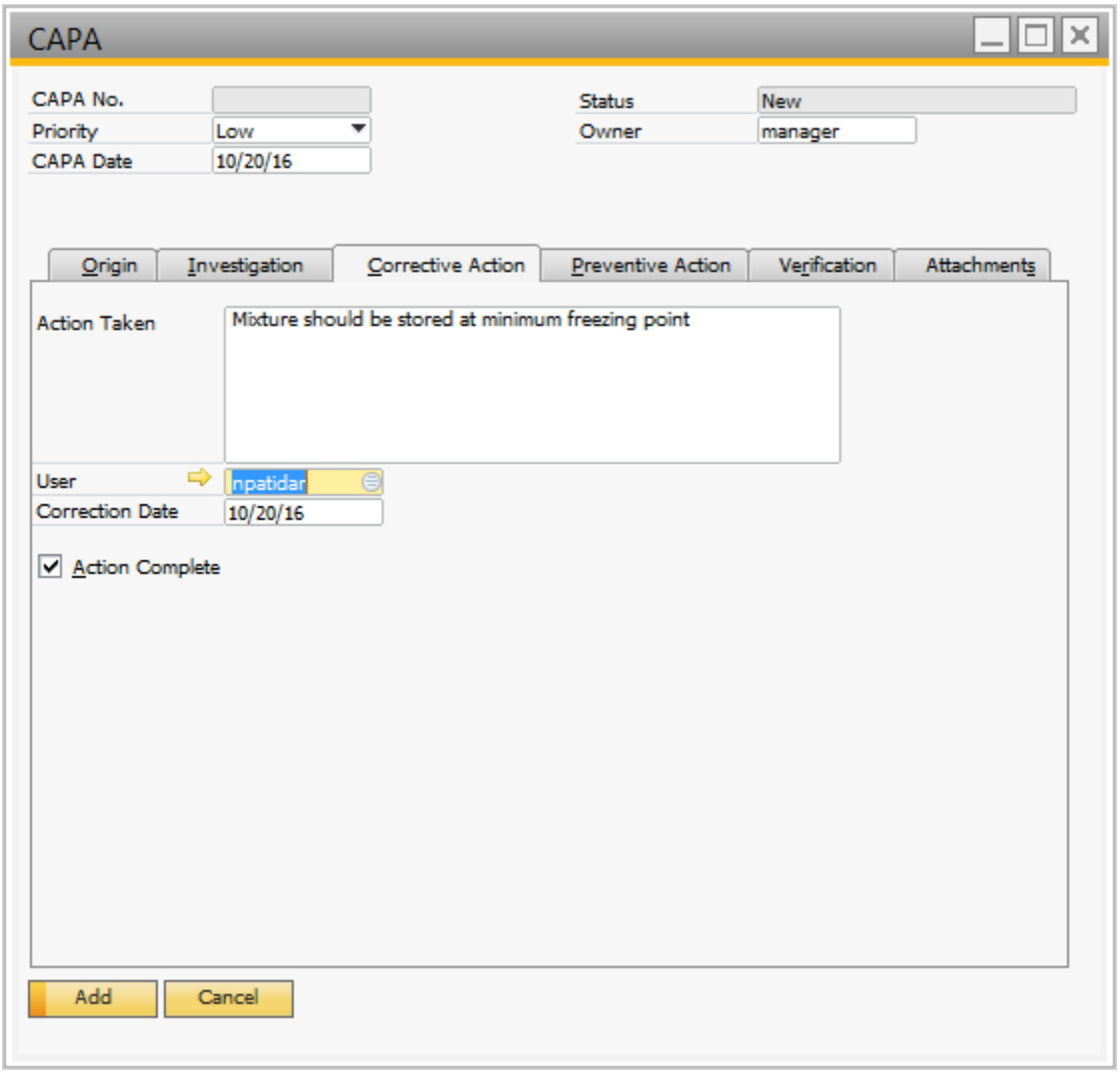


Select an appropriate reason for CAPA, in the *Reason* field. In the *Investigated By* field, select the user who has assigned the investigation job. Next in the *Date* field, enter the date on which the investigation process has been started. In the *Details* field, enter details about the investigation process.

Refer to the *BME-B1 18.2 QC User Guide* for information about Specifications and Specification Groups.

Once the investigation process is complete, check the *Action Complete* option. Click the UPDATE button to save the record. At this stage, the CAPA status changes from *New* to *Investigation Completed*.

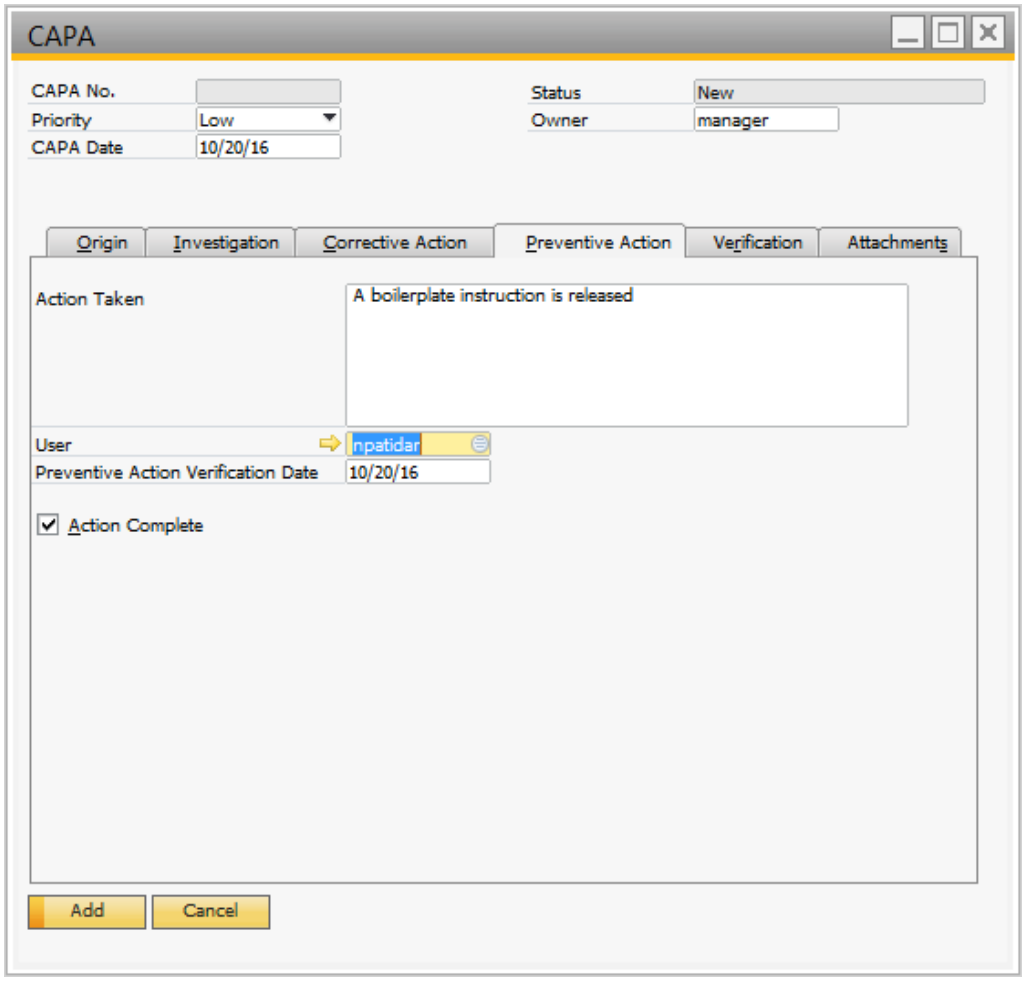
Now move on to the *Corrective Action* tab to enter the measures taken to correct the non-conformance.



In the *User* field, enter the user who is responsible to carry out the corrective action. In the *Correction Date* field, enter the date on which the corrective actions were accomplished.

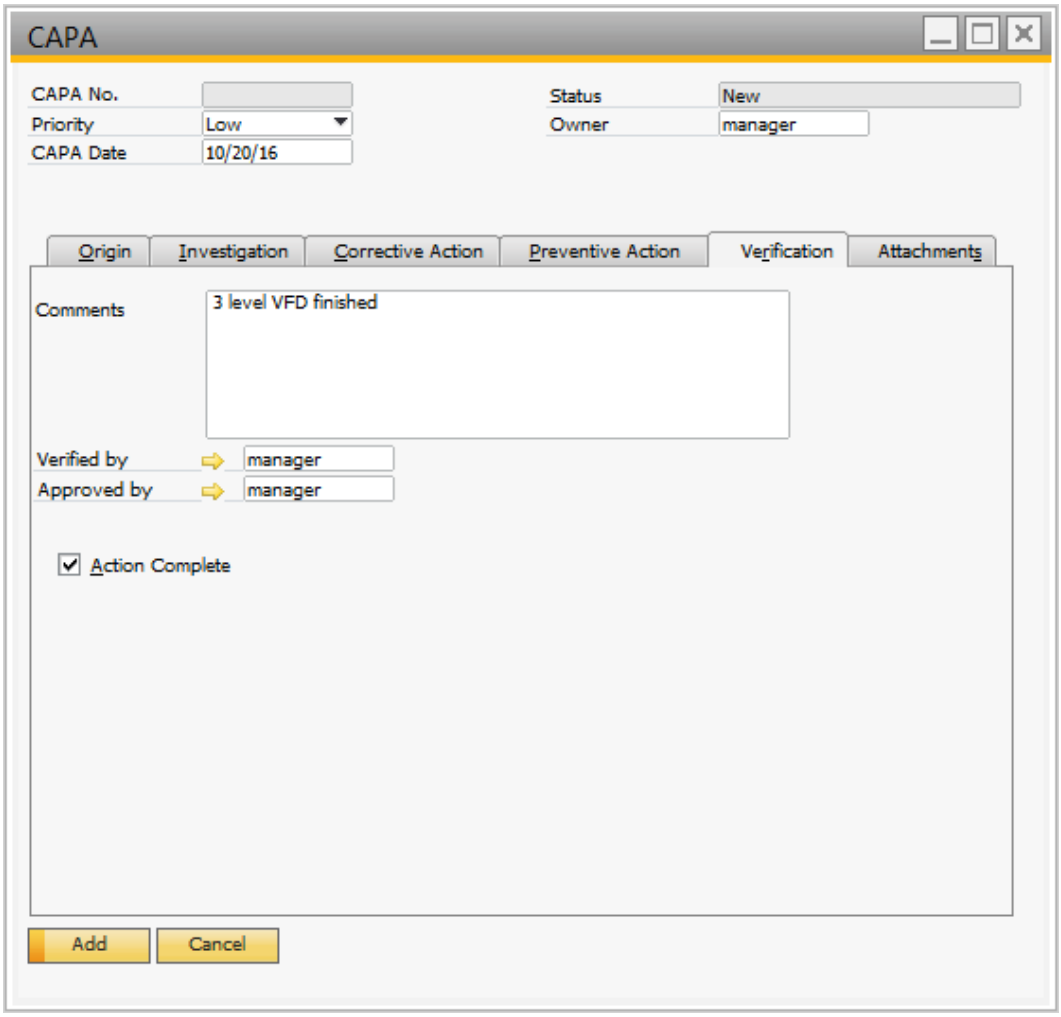
Once you have implemented the corrective actions, select the *Action Complete* checkbox and click the *Update* button. The record status changes to *Corrective Action Taken*.

Now switch to the *Preventive Action* tab.



In the *Action Taken* field, enter the action that you have undertaken to prevent the recurrence of the non-conformance. Next, enter the user who is responsible for the preventive actions. Also, enter the date on which the preventive action was verified. Finally, check the *Action Complete* option and click on *Update* button. The record status changes to *Preventive Action Taken*.

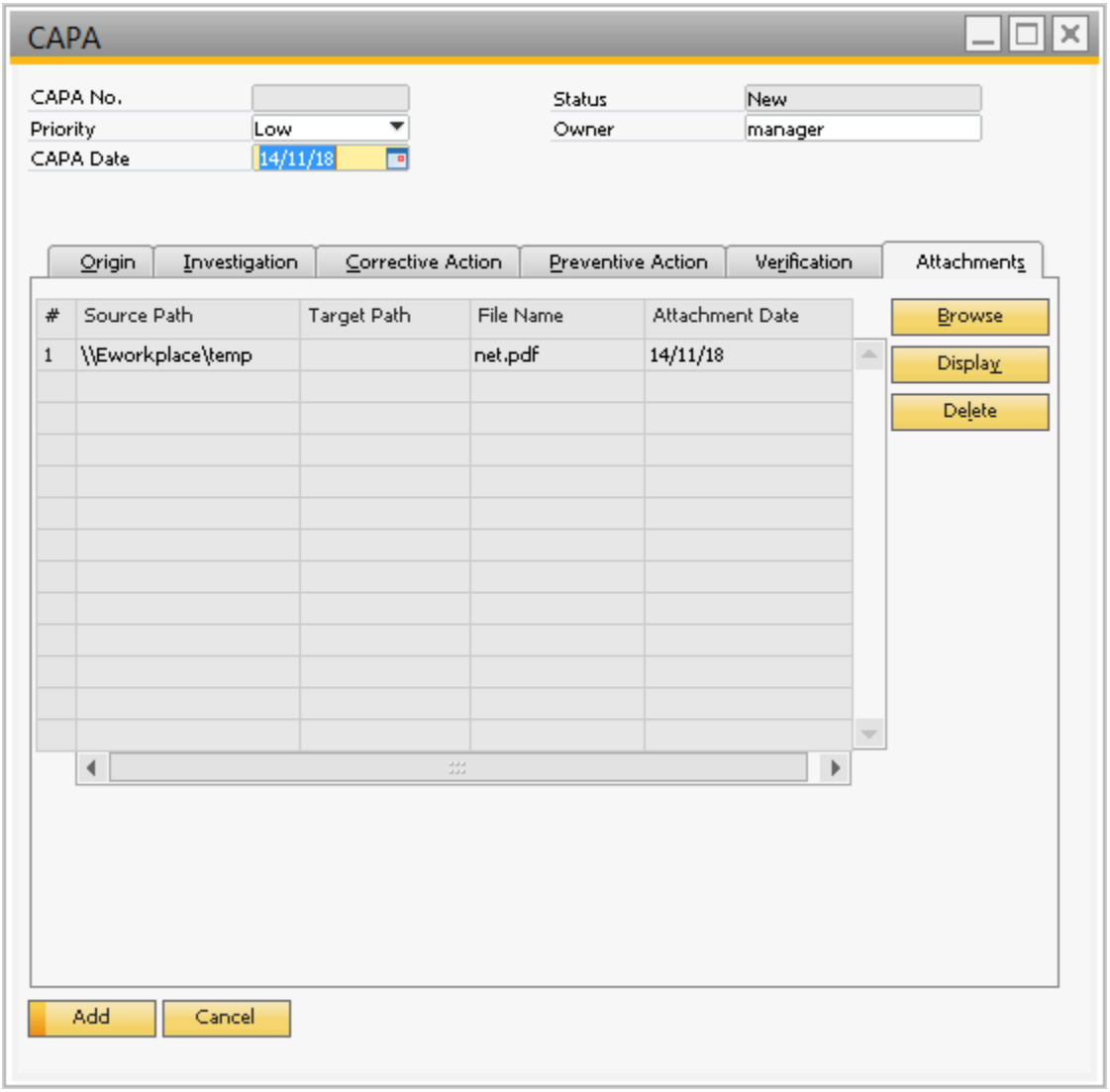
Switch to the *Verification* tab.



In the *Comments* field, enter the evaluation of the CAPA or any other information related to the CAPA verification process. It is mandatory to specify the comment. Next, in the *Verified By* field, select the user who has performed the verification process. In the *Approved By* field, select the user who has approved the CAPA process. Once the verification process is complete, check the *Action Complete* option and click the *Update* button. As a result, the record status will change to *Verification Completed*.

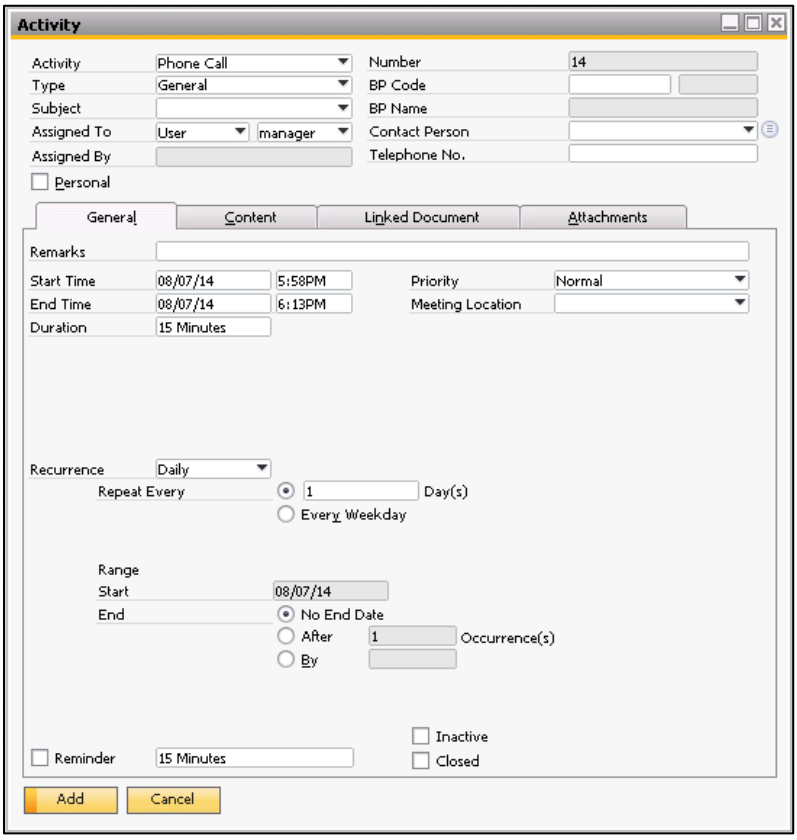
If the user does not have the authorization to close the CAPA document, then the "Verification" tab will be disabled with a message saying "Only authorized users can perform this operation"

Attach any supporting documents related to the CAPA on the *Attachment* tab. The path you browse here should lead to a network (shared) location.

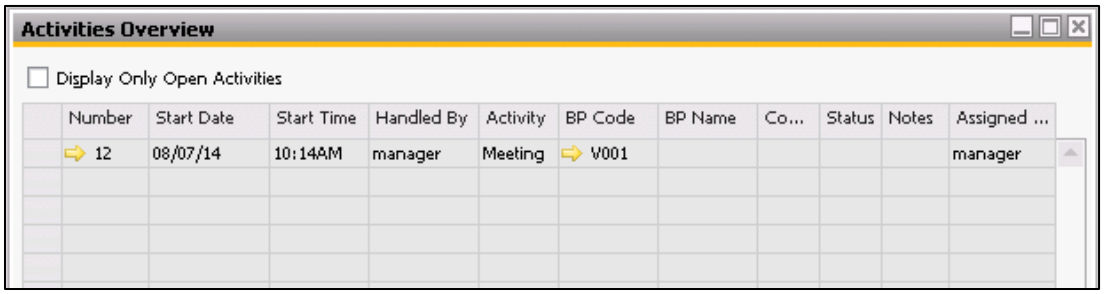


Click the UPDATE button at this point to save your edits.

You can add an activity with the CAPA process by right clicking on the screen and selecting the *New Activity* option.

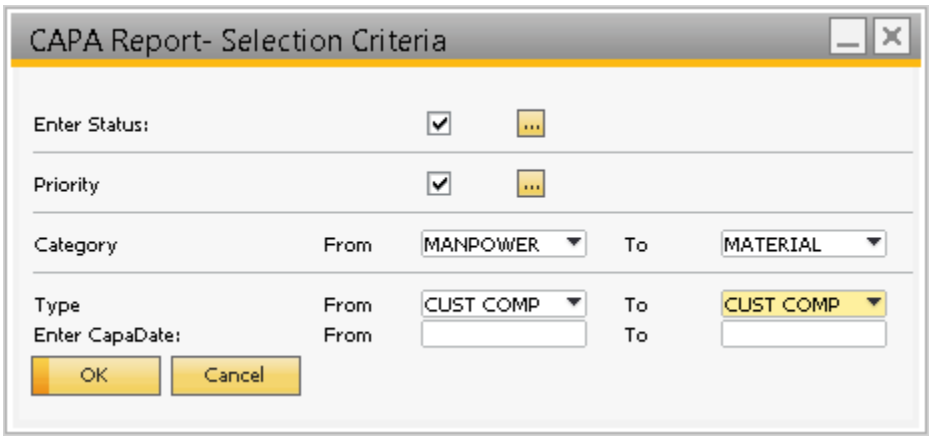


To view the activities already added with CAPA processes, select the *Related Activities* option by right clicking on the CAPA screen.



5.4.5 CAPA Report

Use the *CAPA Report* screen to generate a CAPA report that lets you monitor the root causes and suggested action plans investigated by CAPA.

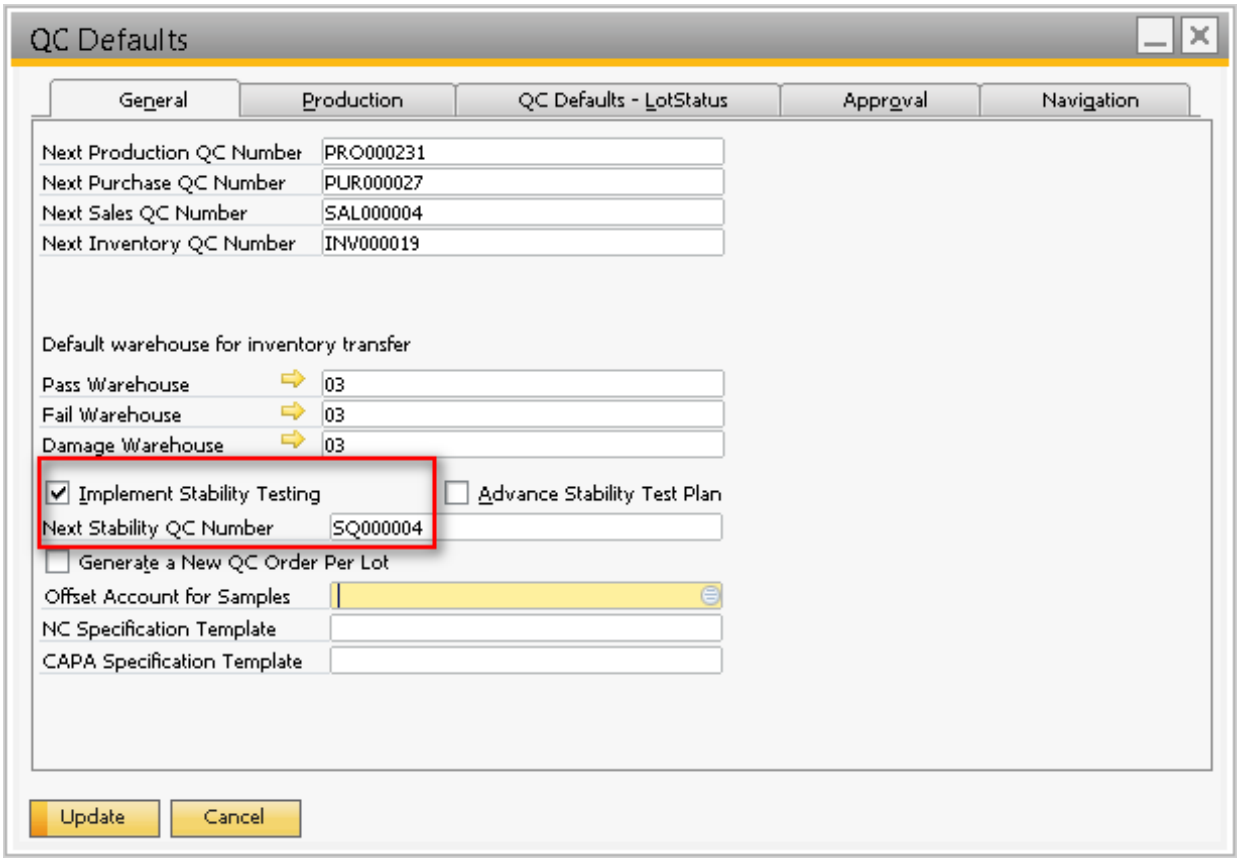


6 Stability Testing

Since you may not sell a product immediately after making it, it is important to define and enforce stability tests. By doing so you can verify the quality of a finished good over a specific time under the conditions of temperature and relative humidity. You can use this module to create stability test plans, norms, standards, and records and then implement stability testing.

6.1 QC Defaults

Using the *QC Defaults* screen, enable the stability testing feature within the system.



Select the *Implement Stability Testing* checkbox on the *General* tab. Next, you need to provide the *Next Stability QC Number* that will be used while creating next QC order.

Check the *Generate a New QC Order Per Lot* option, if you want to apply QC on individual lots of raw materials.

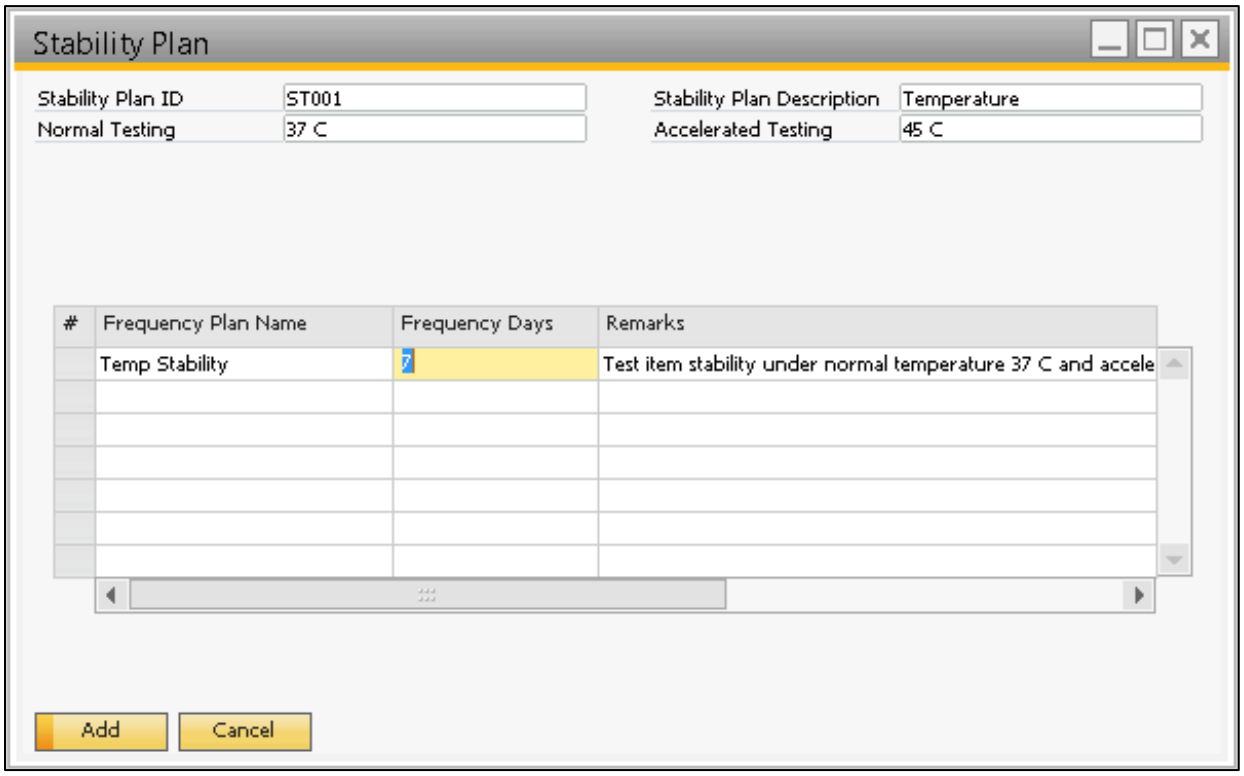
Enter the *Offset Account for Sample*, when a sample is taken from a lot. This will be considered as a Goods Issue Transaction.

Refer to the *BME-B1 18.2 QC User Guide* for information on defining Specifications.

6.2 Stability Test Plan

Testing product stability is a major concern for all Nutraceutical and Pharmaceutical industries. The stability testing feature in BatchMaster ERP records how the quality of a product varies with time under the impact of environmental conditions such as temperature, humidity, and light. This helps you determine effective storage conditions.

Go To: Administration → Setup → Quality Control Set-up → Stability Plan



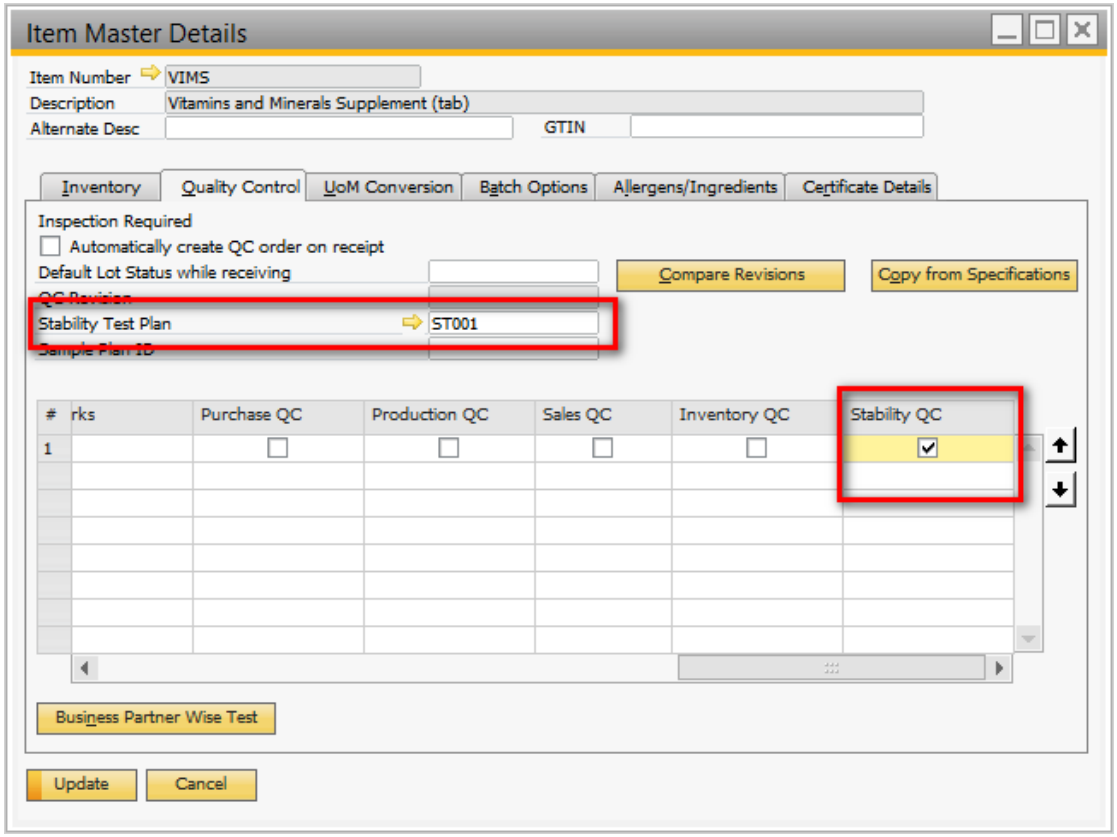
First, you need to enter a unique stability plan identifier at the *Stability Plan ID* field. Next, enter the related description. Your company's products may evaluated under specific storage conditions. You can use the *Normal testing* and *Accelerated testing* fields. The values in these fields decide the subsequent testing actions.

Next, you need to define the frequency for stability testing. Consider an example: For long term conditions, generally the testing frequency considered is every 3 months over the first year, every 6 month over the second year and annually thereafter. For accelerated storage conditions generally it is a minimum of 3 points including initial and final points of time. For examples 0, 3, and 6 months.

6.3 Item Master Detail Modifications

You can associate the stability test plan with an inventory item on the *Item Master Details* screen. On the *Quality Control* tab of the *Item Master Details screen,* select the *Stability Test Plan*.

On the grid, add tests for those parameters, based on how you want to test the stability of the item. Select the *Stability QC* checkbox for the desired tests on the grid to implement QC stability tests on the item while processing QC orders.

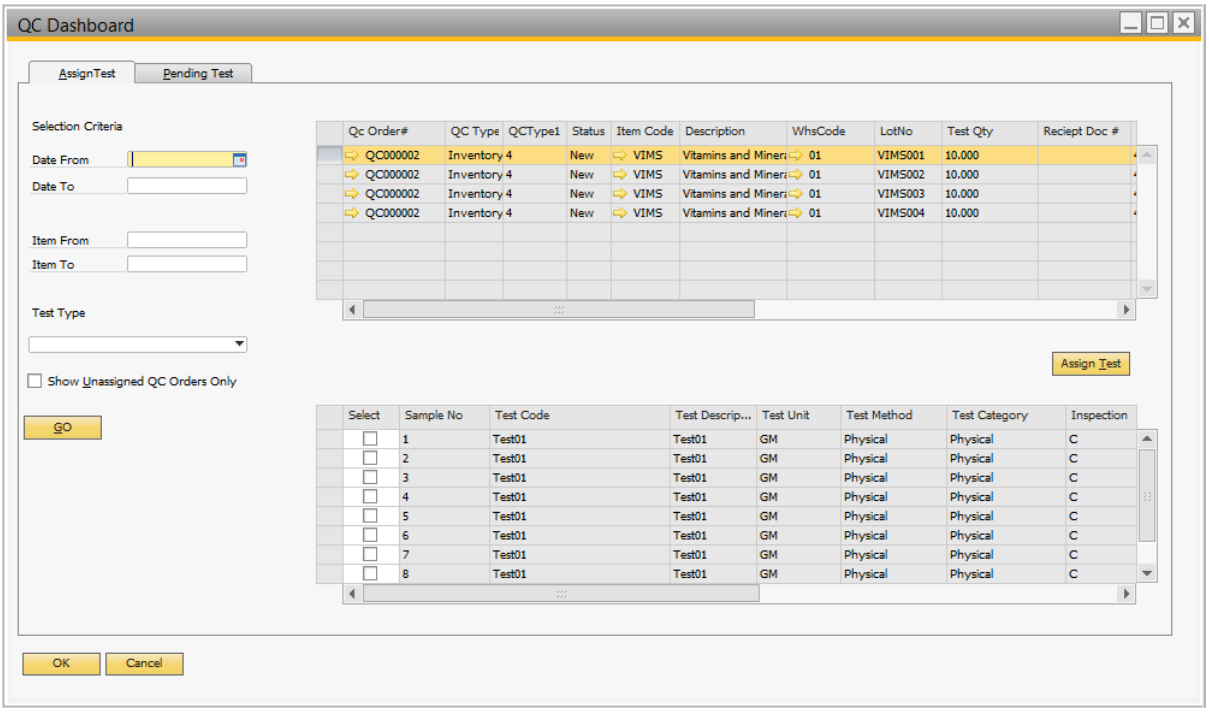


The stability test automatically gets created for the item in the frequency specified on the stability test screen. You can approve the test created from the QC dashboard screen.

6.4 QC Dashboard

You can view the QC orders as per the filter you have applied on the selection criteria in the dashboard. Also, you can assign the tests as well, using the *Assign Test* button.

Go To: Quality Control → QC Utilities → QC Dashboard

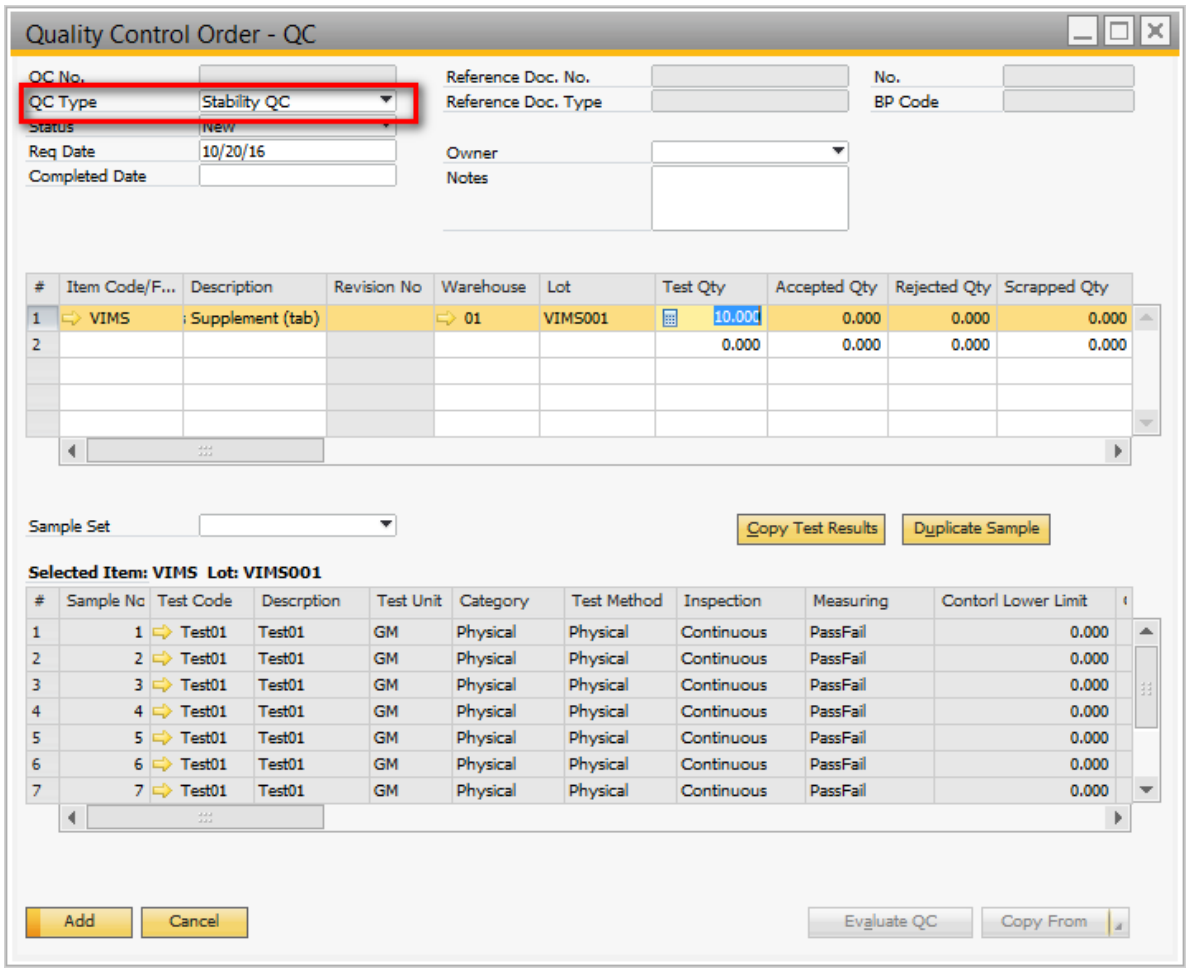


You can draw the stability test orders that are due, say 7 days, from the *Pending test* tab of the *QC Dashboard*. Refer to section 6.2.

Select the order from the grid and click the *Generate Orders* button.

6.5 Quality Control Order – QC

You can view and perform Stability QC testing of the item from the *Quality Control Order QC* screen.



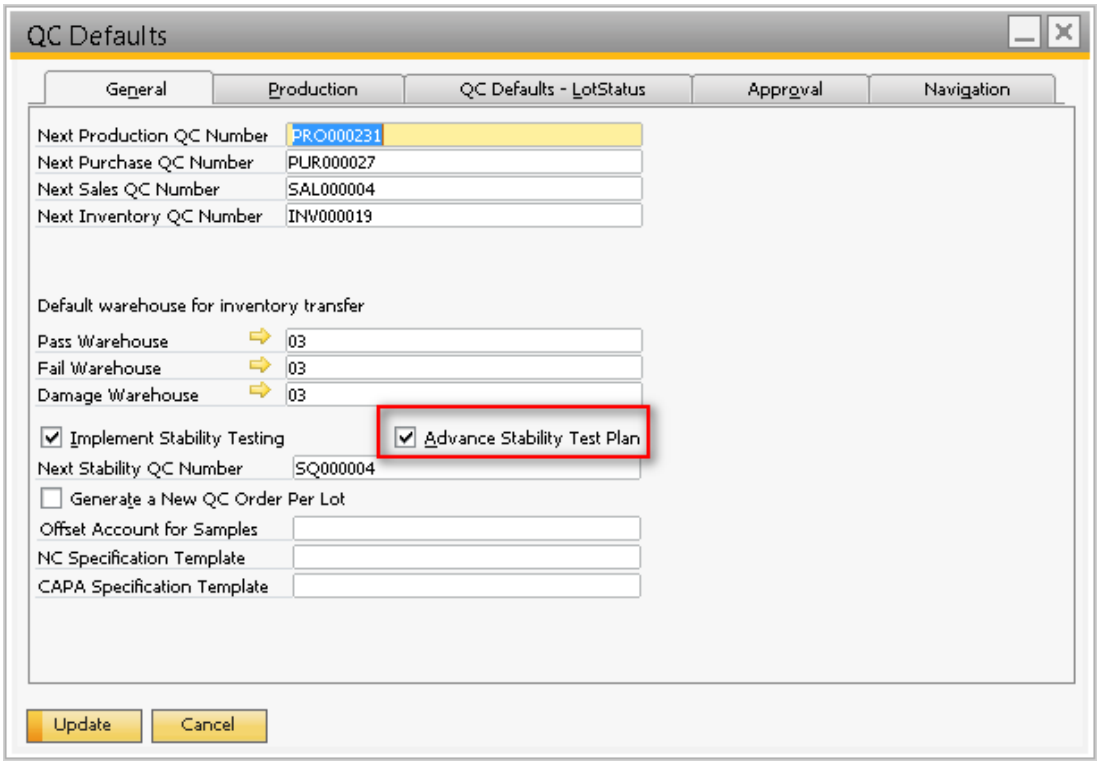
Refer to the *BME-B1 18.2 QC User Guide* for details on using this function.

7 Advanced Stability Testing

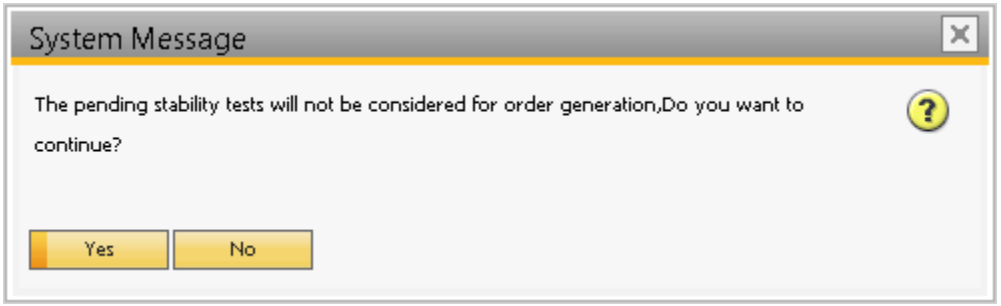
BatchMaster ERP provides you an option to implement advance stability testing using which you can define a test plan for 'n' number of days (irrespective of any frequency). You can also maintain different tests for each test plan.

7.1 QC Defaults

Using the *QC Defaults* screen, enable the Advance Stability Test Plan feature within the system.



Select the *Implement Stability Testing* checkbox on the *General* tab. Next, check the Advance Stability Test Plan to implement the advance stability. Here note that implementing the *Advance Stability Test Plan* is irreversible. Thus system confirms you to continue as pending stability test will not be considered further to generate orders.



Clicking on *Yes* will implement the Advance Stability Testing.

Next, you need to provide the *Next Stability QC Number* that will be used while creating next QC order.

Check the *Generate a New QC Order Per Lot* option, if you want to apply QC on individual lots of raw materials.

Enter the *Offset Account for Sample*, when a sample is taken from a lot. This will be considered as a Goods Issue Transaction.

Refer to the *BME-B1 18.2 QC User Guide* for information on defining Specifications.

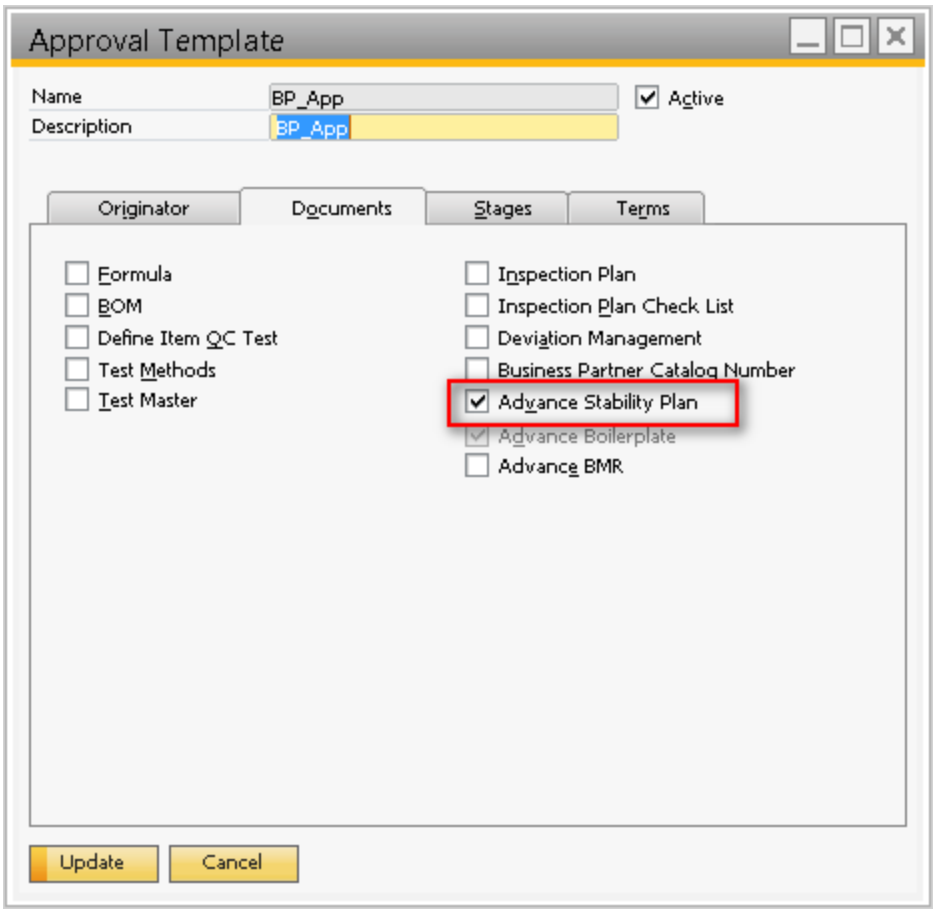
Before creating an Advance Stability Testing Plan, you can apply the approval procedure for *the Advance Stability Test on* the *Approval Template* screen.

Go To: Administration → Approval Procedures → Process Mfg. Approval Procedures → Approval Template

In the *Approval Template* screen, on the *Documents* tab, select the *Advance Stability Plan* checkbox.

Associate an appropriate approval template with the *Advance Stability Plan*.

Go To: Main Menu → Administration → Setup → Process Mfg Appr. Proce. → Approval Template

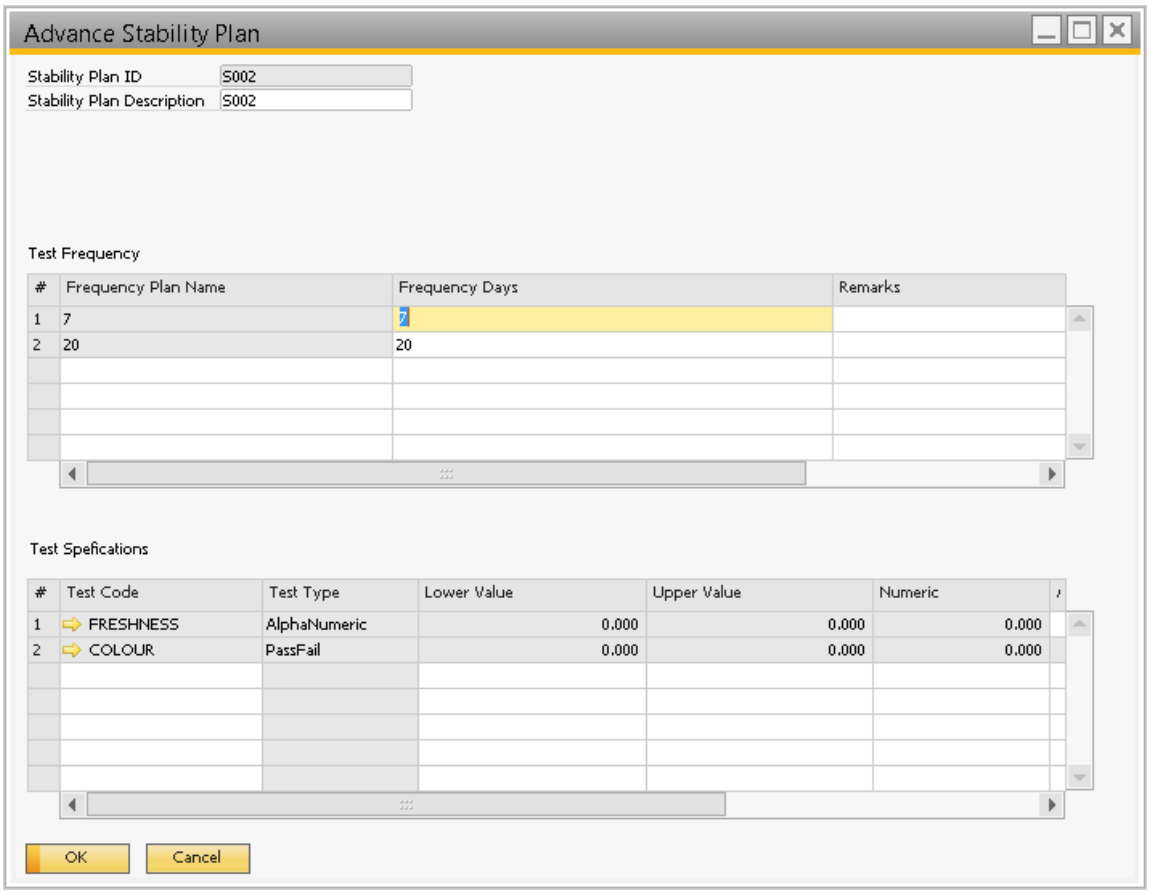


7.2 Advance Stability Plan

Testing product stability is a major concern for all Nutraceutical and Pharmaceutical industries. The stability testing feature in BatchMaster ERP records how the quality of a product varies over time under the impact of environmental conditions such as temperature, humidity, and light. This helps you determine effective storage conditions and shelf life.

On the *Advance Stability Plan* screen you can define different Frequency Plans and set the Frequency days, determining in how many days you want the system to create a Stability QC order to test the item's stability. In the Test Specifications grid, with respect to an individual Frequency plan, you can define a set of tests needed to be applied to the item. You are no longer bound to implement the same set of tests for all frequency plans as every frequency plan can have the same or different tests.

Go To: Administration → Setup → Quality Control Set-up → Stability Plan

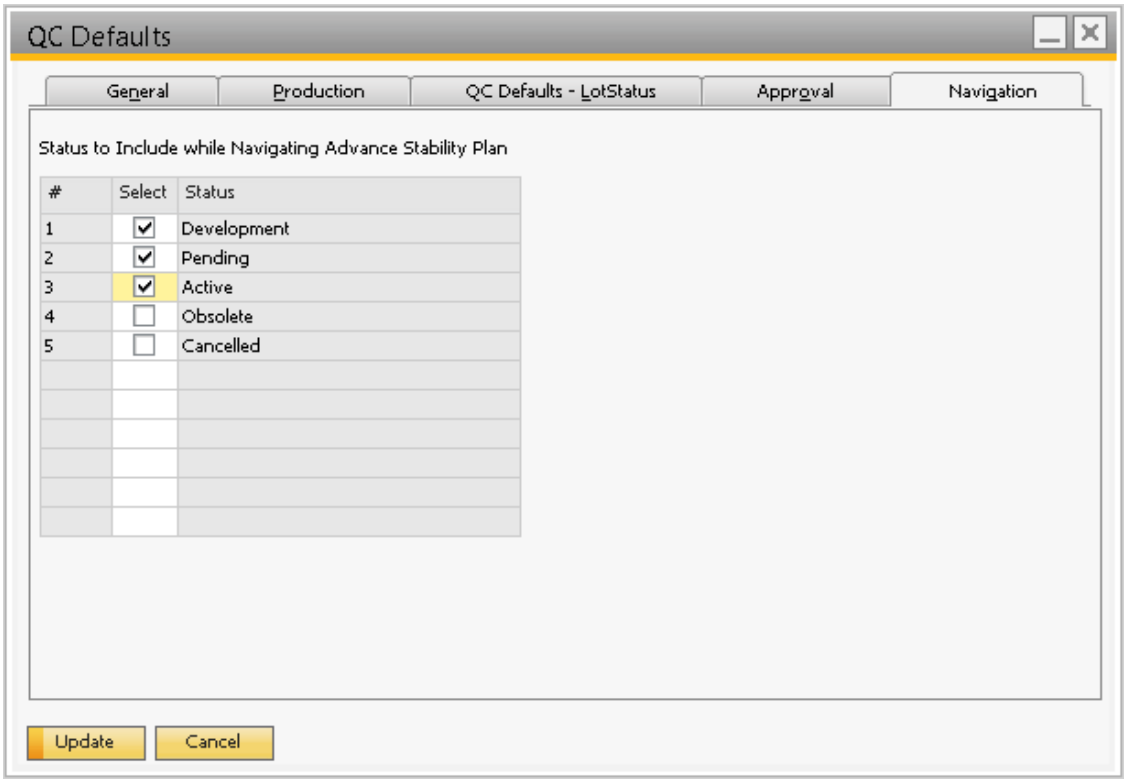


First, you need to enter a unique stability plan identifier at the *Stability Plan ID* field and enter the related description. Your company's products may be evaluated under specific storage conditions.

Next, you need to define the frequency for stability testing. Consider an example: For long term conditions, generally the testing frequency considered is every 3 months over the first year, every 6 months over the second year and annually thereafter. For accelerated storage conditions generally it is a minimum of 3 points including initial and final points of time. For examples 0, 3, and 6 months.

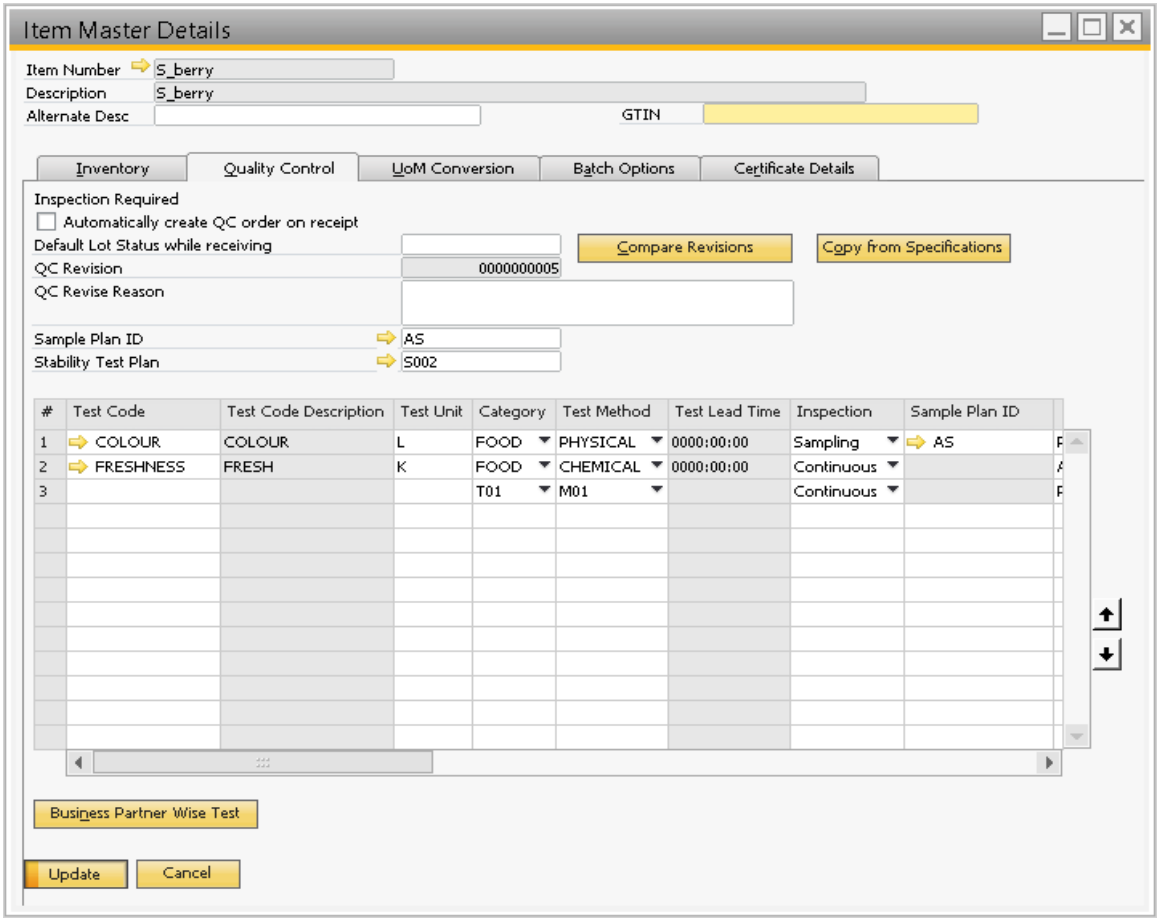
7.3 Navigation Control of Advance Stability Plan

On the *QC Defaults* screen, on the Navigation tab you can select the status need to be included when navigating on the Advance Stability Plan screen.



7.4 Item Master Detail Modifications

You can associate the stability test plan with an inventory item on the *Item Master Details* screen. On the *Quality Control* tab of the *Item Master Details screen,* select the *Stability Test Plan*.

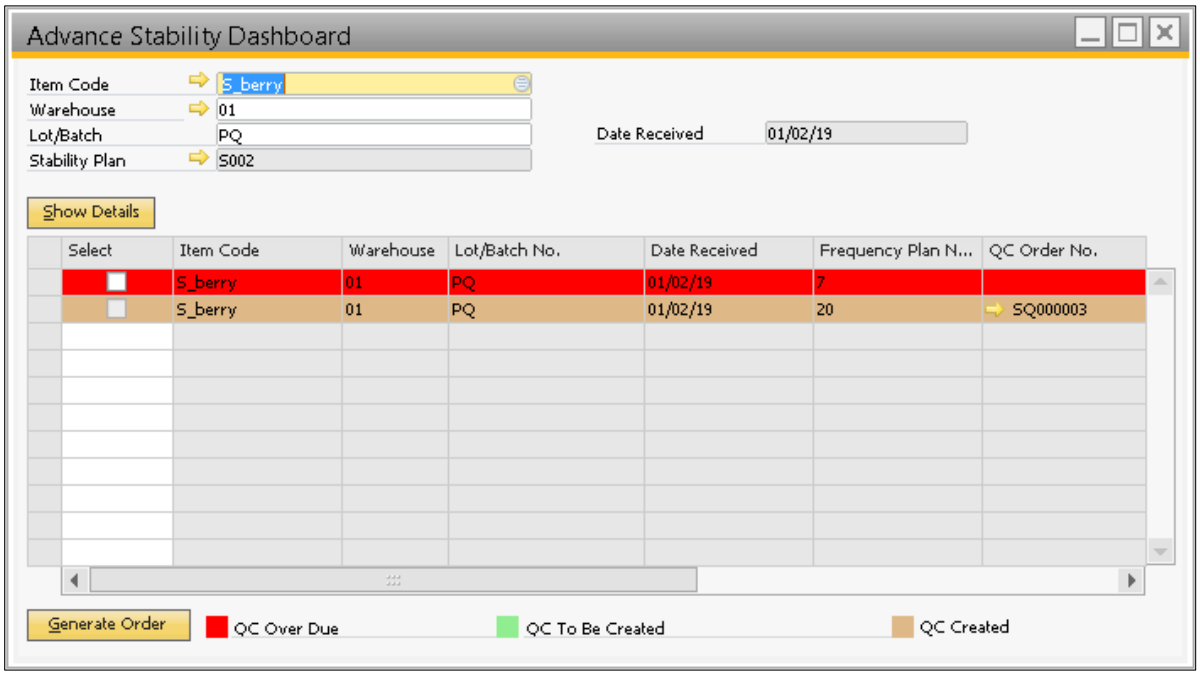


The stability test is automatically created for the item in the frequency specified on the Advanced stability plan screen. You can approve the test created from the Advance Stability Plan dashboard screen.

7.5 Advance Stability Dashboard

On the *Advance Stability Dashboard* screen you can draw the item for which a Stability Test is defined and generate the Stability QC order for the required *Stability Test Date*.

Go To: Quality Control → QC Utilities → QC Dashboard



Select the order from the grid and click the *Generate Order* button.

On the screen you can select and generate the Stability QC Orders for the required item.

Item Code: Search and select the item for which you want to generate a Stability QC order.

Warehouse: Specify the warehouse of the selected item.

Lot/Batch: Search and select the required lot.

Stability Plan: Displays the Stability Plan attached to the item.

Date Received: Shows the date on which the selected lot was received.

Show Details: Click this button to display the details on the basis of the selection made.

Select: Check this checkbox to select the respective line in the grid.

Item Code: Shows the unique code of the item.

Warehouse: Displays the item warehouse.

Lot/Batch No: Shows the item lot.

Date Received: Shows the date on which the lot was received.

Frequency Plan Name: Displays the applicable frequency plan.

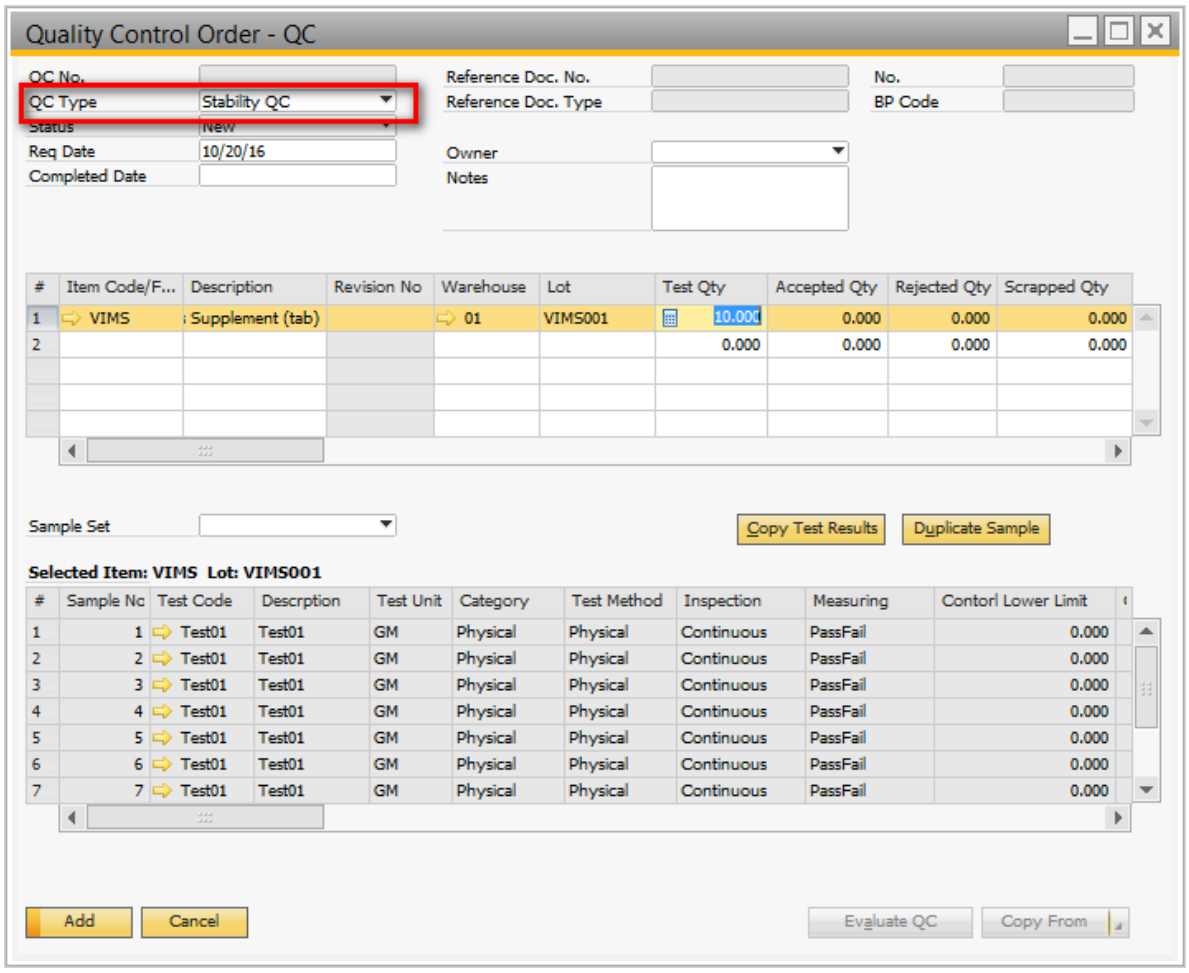
QC Order No: Displays the Stability QC order number if already generated.

Stability Test Date: Calculates and displays the date of the Stability test on the basis of frequency days of the respective Frequency Plan.

Generate Order: Use this button to generate the Stability QC order for the selected line.

7.6 Quality Control Order – QC

You can view and perform Stability QC testing of the item from the *Quality Control Order QC* screen.



Refer to the *BME-B1 18.2 Quality Control Guide* for details on using this function.

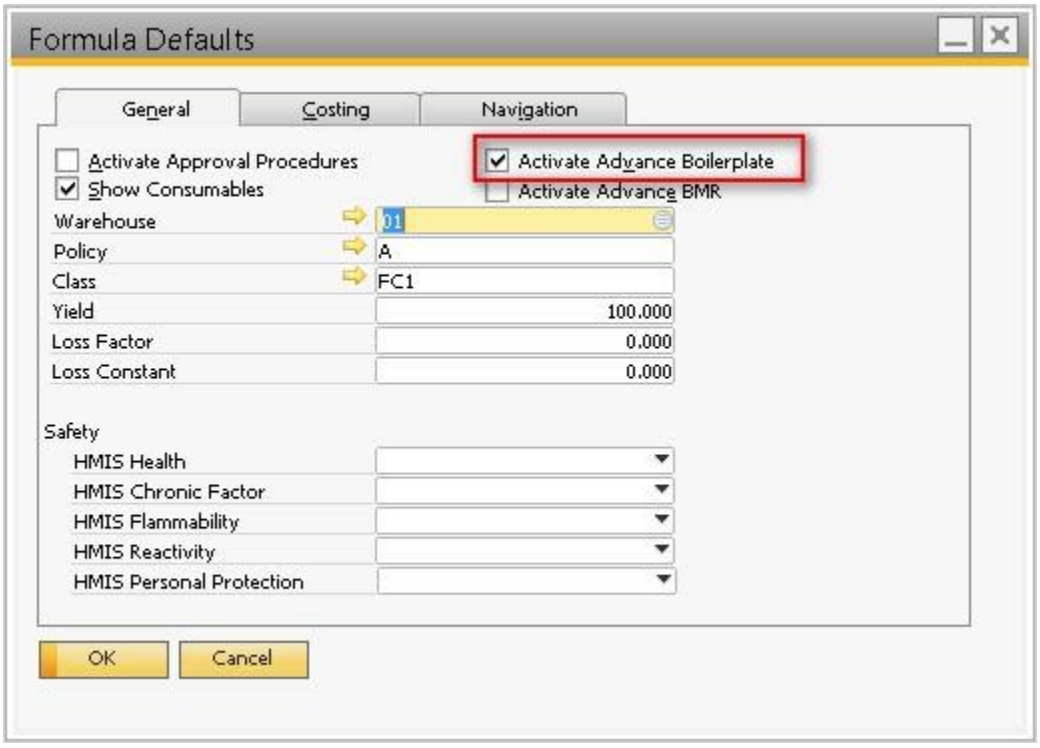
8 Advanced Boilerplate

BatchMaster ERP supports the performing of in process inspection and checklist while weighing or issuing material.

8.1 Formula Defaults

Using the *Formula Defaults* screen, select the *Activate Advance Boilerplate* checkbox to enable the Advanced Boilerplate feature.

Go To: Main Menu → Administration → Setup → Formula → Formula Defaults



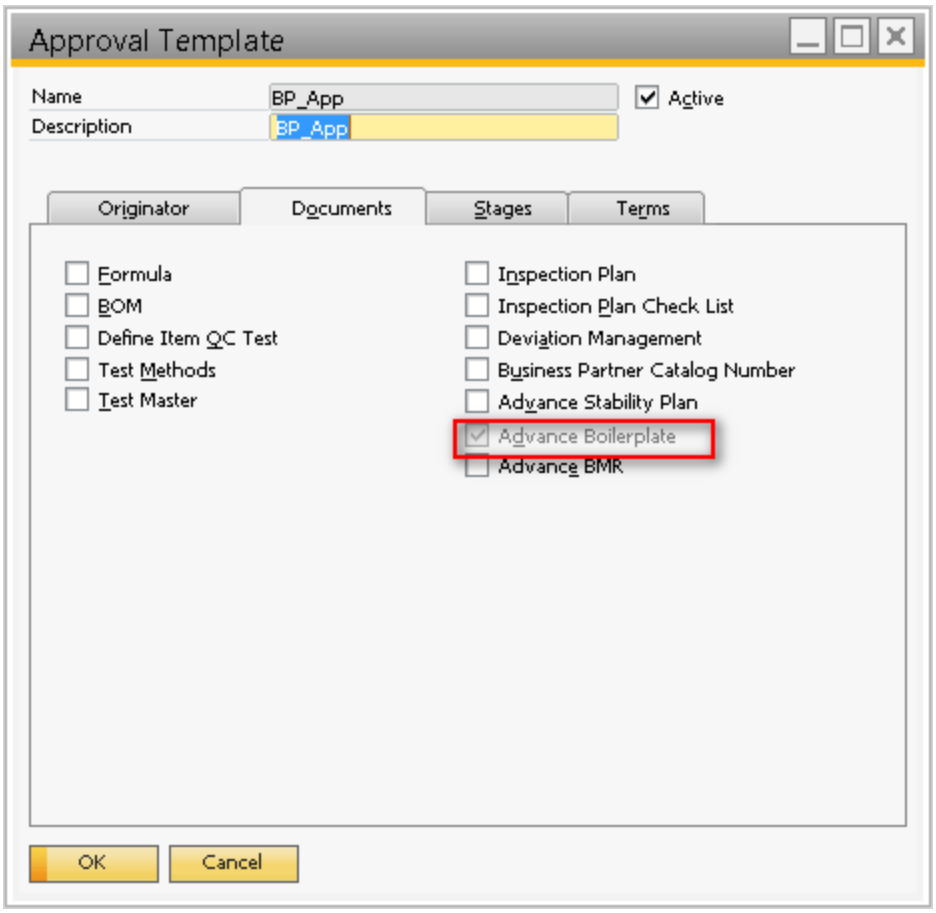
Now you can use the Manufacturing Instructions screen to create the Advance Boilerplate.

Before creating a Manufacturing Instruction, you can apply an approval procedure for the *Advance Boilerplate* on the *Approval Template* screen.

Go To: Main Menu → Administration → Setup → Process Mfg Appr. Proce. → Approval Template

In the *Approval Template* screen, on the *Documents* tab, select the *Advance Boilerplate* checkbox.

Associate an appropriate approval template with the *Advance Boilerplate* and *Update* the settings.

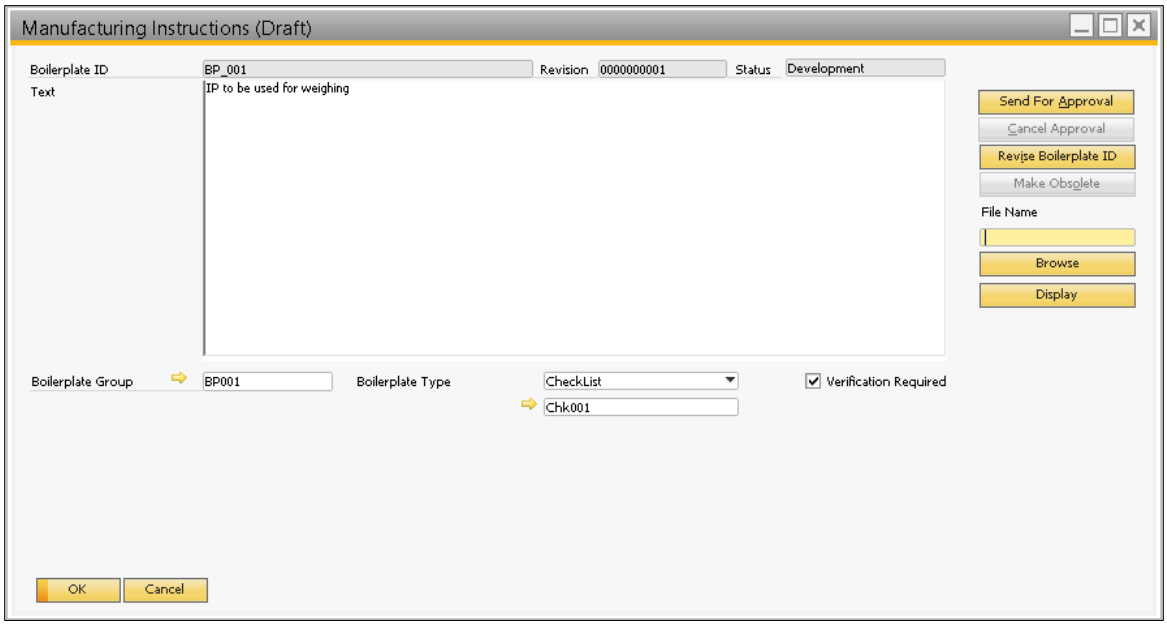


8.2 Manufacturing Instructions

The Advance Boilerplate is specifically designed to define different types of boilerplate, such as *Inspection, Checklist, Boilerplate* and *Require user Input.*

On the *Manufacturing Instruction* screen you can specify the type of boilerplate you need to create. To access the screen,

Go To: Formulation → Manufacturing Instructions



Boilerplate ID: Enter a unique identification key for the Boilerplate here.

Revision: Displays the approved revision number of the boilerplate.

Status: Shows the current status of the boilerplate.

Send for Approval: Click this button to send the record for approval.

Cancel Approval: Click this button to cancel the document approval.

Revise Boilerplate ID: Use this button to generate the new revised boilerplate.

Make Obsolete: Use this button to obsolete the record.

Browse: Click to search and select the file you need to attach to the manufacturing instruction record.

Display: Use this button to view the attached file.

Boilerplate Group: Select an applicable boilerplate group here.

Boilerplate Type: Using the dropdown, select the boilerplate type as one of *Boilerplate, Inspection, Checklist* or *Require User Input*. If you select the Inspection/Checklist option then in the field below you need to associate the required Inspection/Checklist plan. For the option Required User Input a grid is displayed to specify the parameters for user input.

Verification Required: This checkbox functionality is related to BatchMaster WMS.

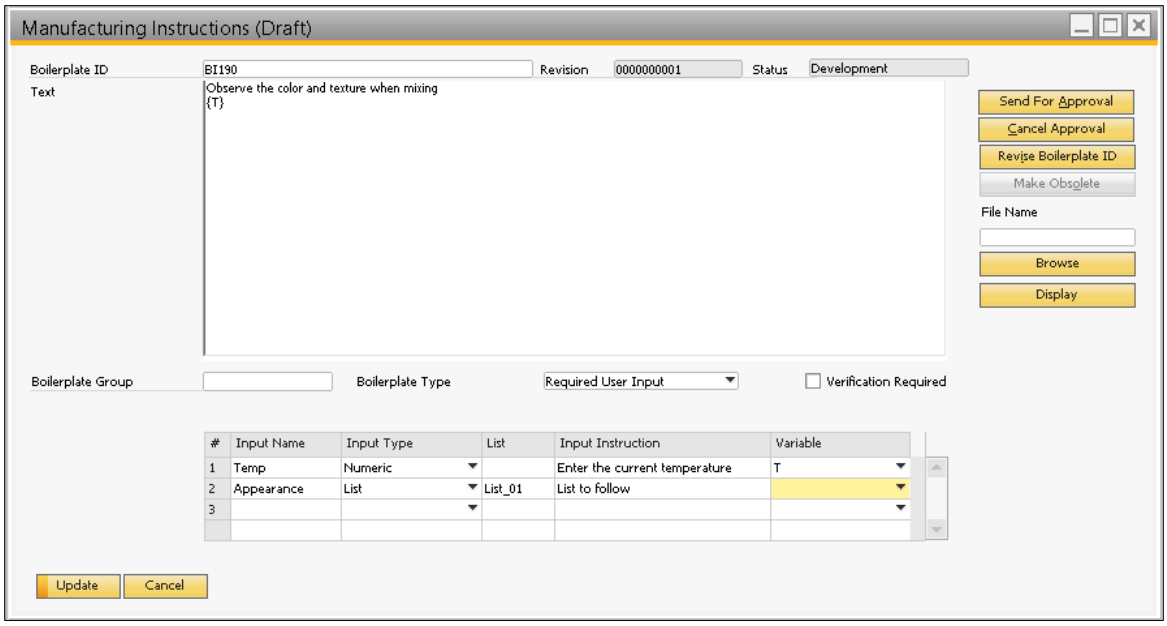
OK: Use this button to save the record with the required modifications.

Cancel: Click this button to exit from the screen without saving the record.

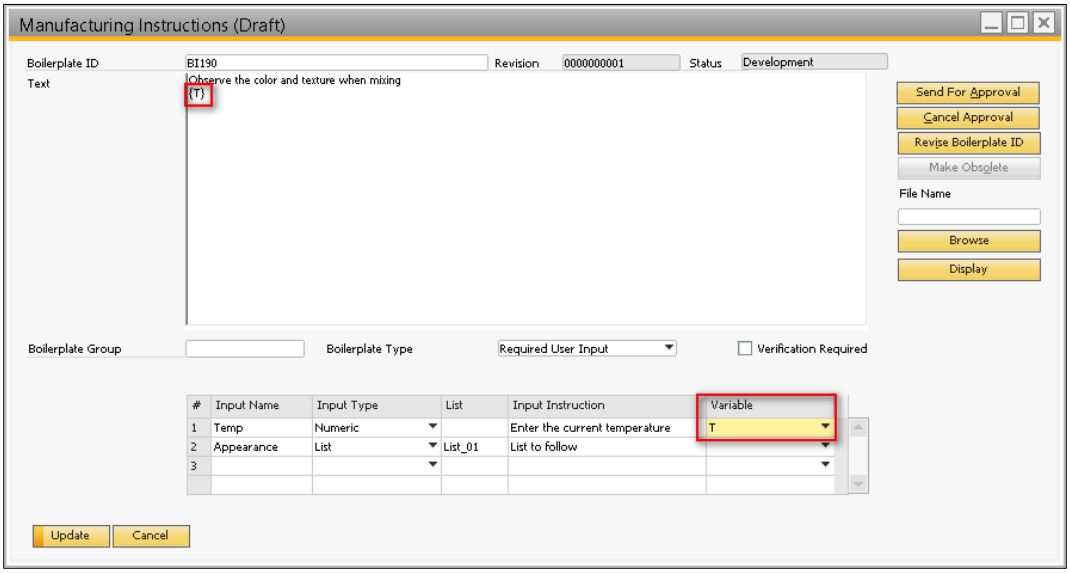
8.2.1 Defining different types of Advance Boilerplate

On the Manufacturing Instruction screen you can define the following types of Boilerplate:

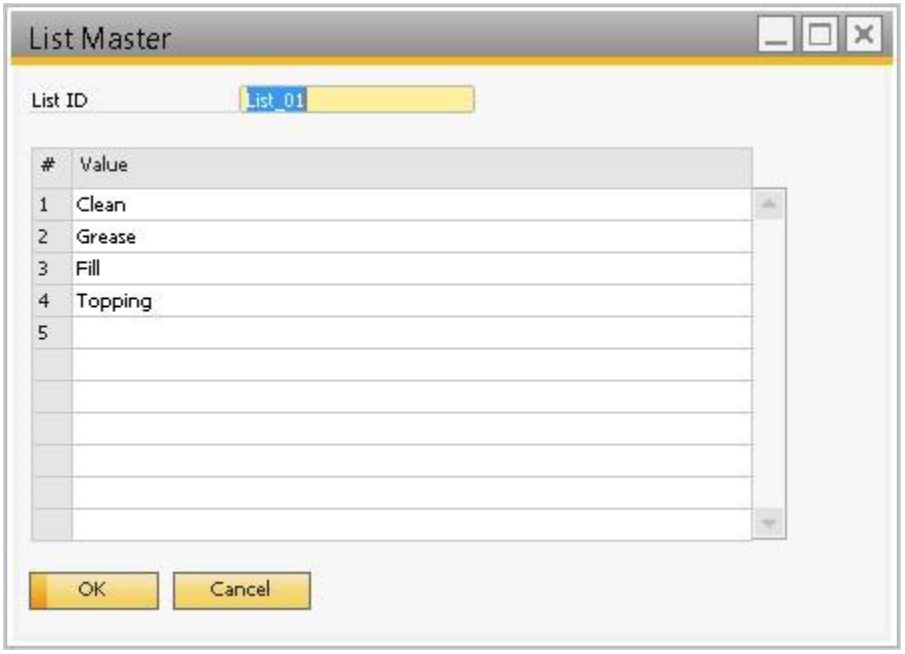
1. **Boilerplate Type as *Require User Input***: This boilerplate type is useful if you want to take input from the user. Choosing this option shows a grid in the below area where you can define an input parameter and details.



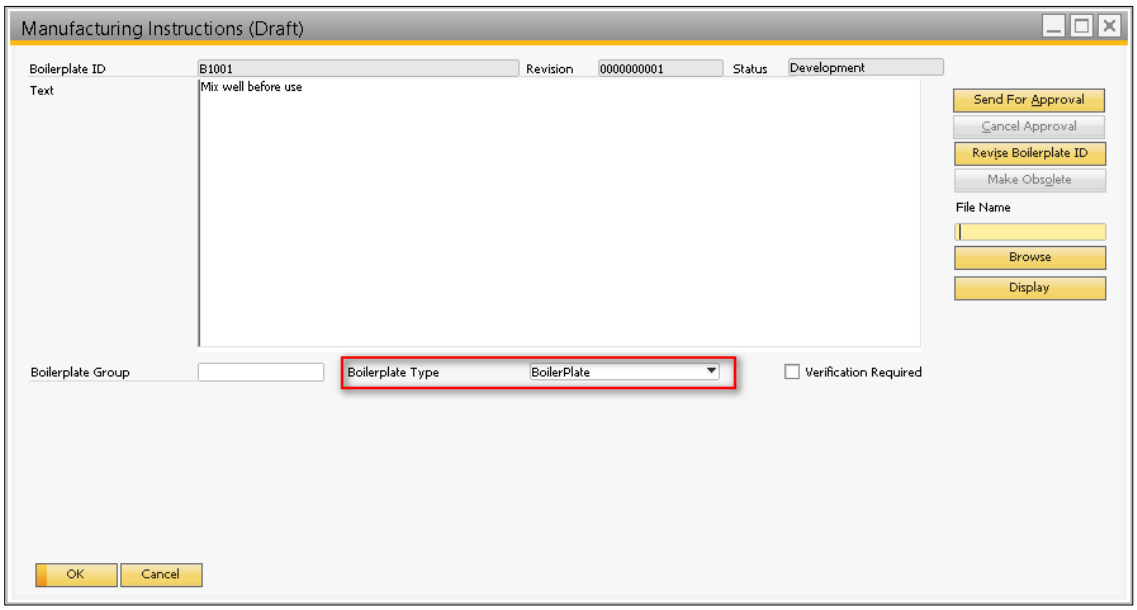
You can define a variable in Curly braces in the *Text* field. Say, the variable {T} is defined to store a temperature. The defined variable can be selected using the respective drop down in the grid.



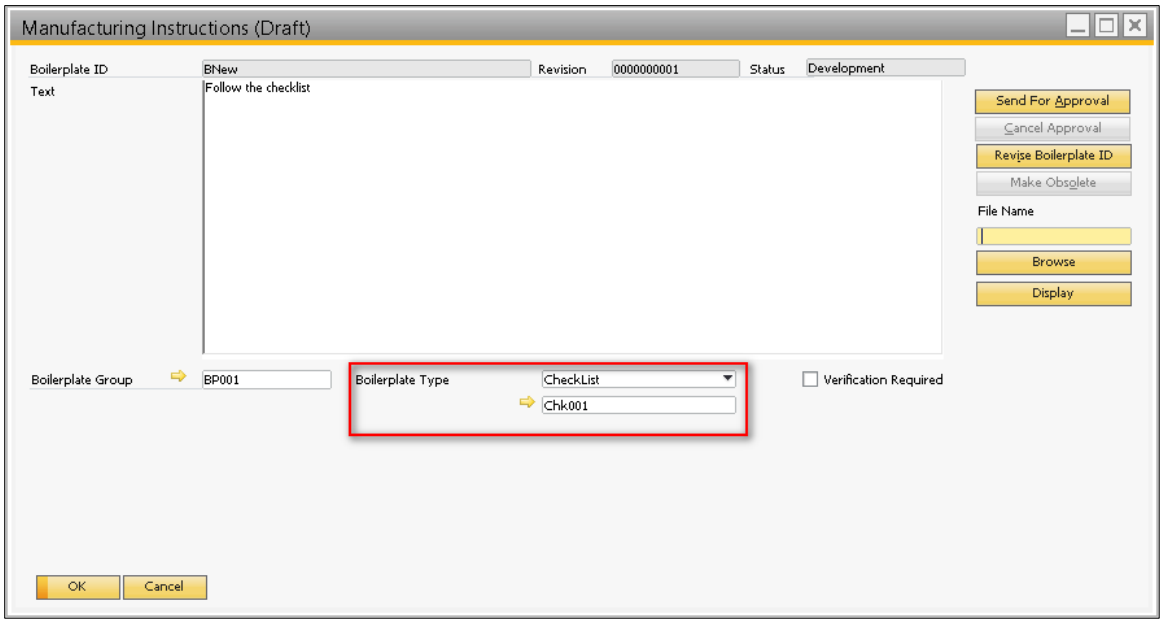
The available Input types are *Alphanumeric, List, Numeric, Date/Time* and *Boolean*. For a list type of *Input* you can pre-define a list through a *List Master*.



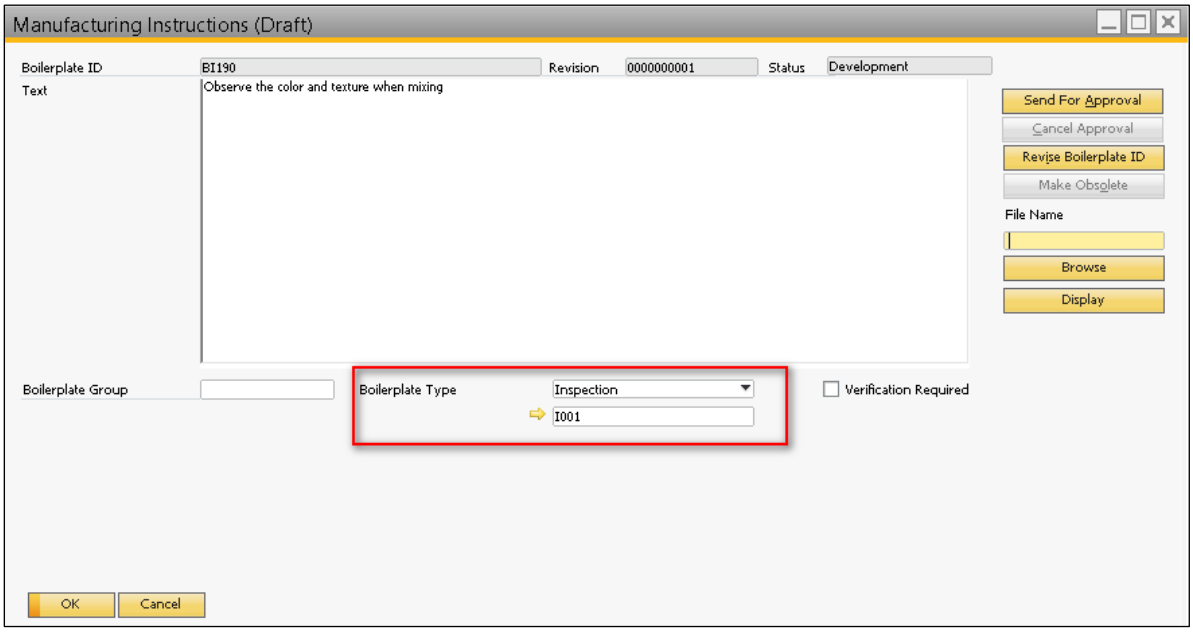
2. **Boilerplate Type as *Boilerplate***: With this option as selected you can create a simple Boilerplate to be used as text.



3. **Boilerplate Type as *Checklist***: For the Boilerplate Type as *Checklist*, you can attach a Checklist as a boilerplate, to be followed as an SOP (Standard Operating Procedure) for batch manufacturing.

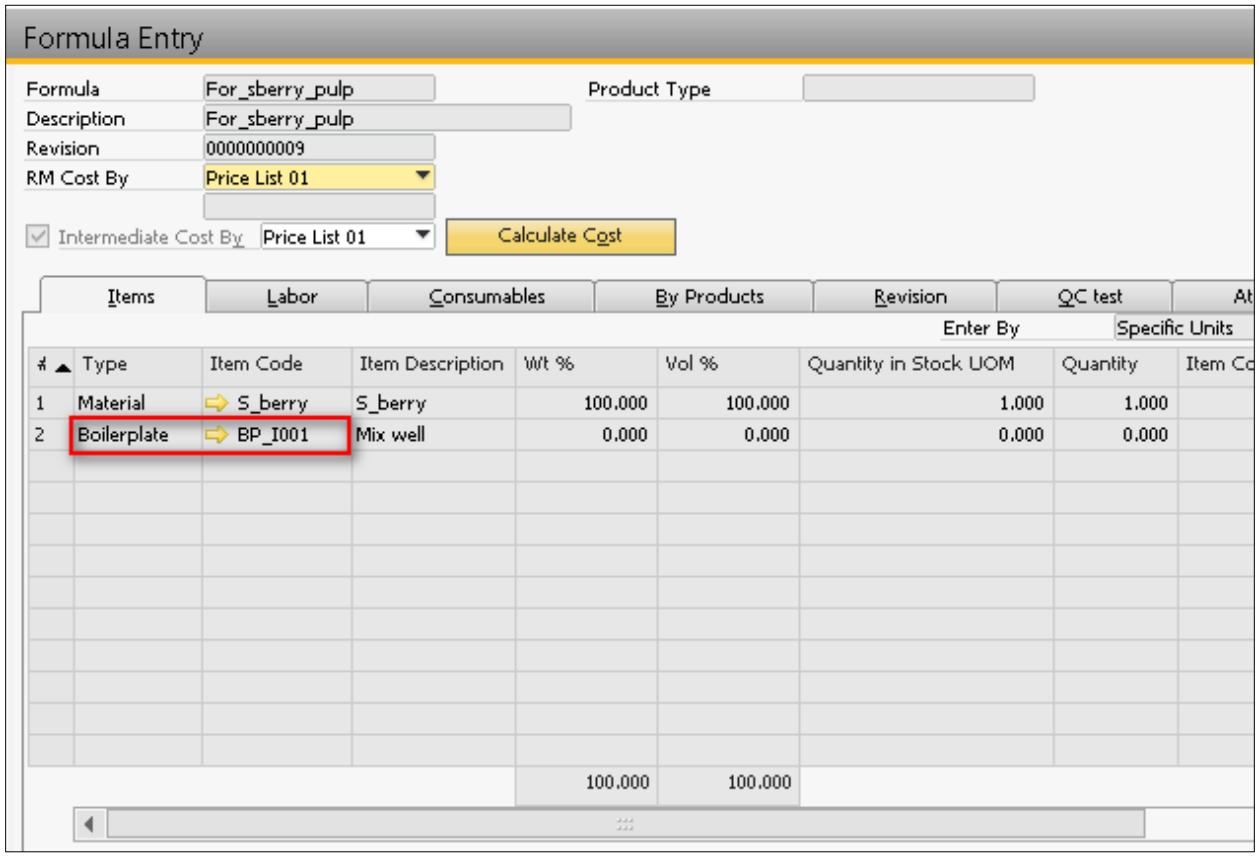


4. **Boilerplate Type as *Inspection***: With this Boilerplate type you can attach an Inspection plan as a boilerplate, containing different activities to undertake for product examination during production.

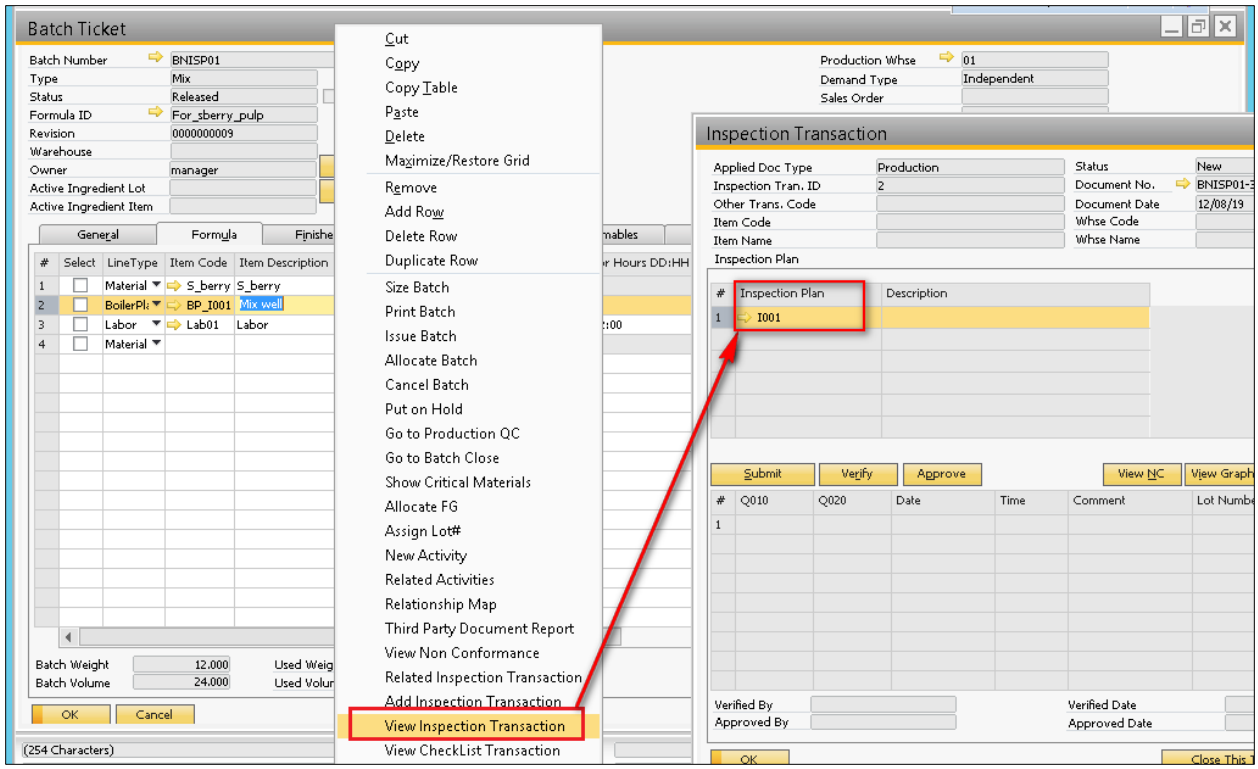


Inspection Plan/Checklist Type of Boilerplate

You can attach the Inspection Plan/Checklist Type of Boilerplate with the formula at the *Formula Entry* screen.



Using the options, *View Inspection Transaction/View Checklist Transaction*, the attached *Inspection Plan/Checklist* can be viewed at the *Batch Ticket, Batch Close, Super Batch Close* screen.



The checklist if attached with the formula can be viewed on the batch using the *View Checklist Transaction* option.

9 Business Partners

As a Nutraceutical or Pharmaceutical manufacturer, your vendors/suppliers must be qualified as per cGMP requirements. For supplier qualification, you need to:

- Write an SOP that includes steps for qualification;
- Maintain required documentation;
- Develop procedures for ongoing monitoring of suppliers and ensure that they are qualified.

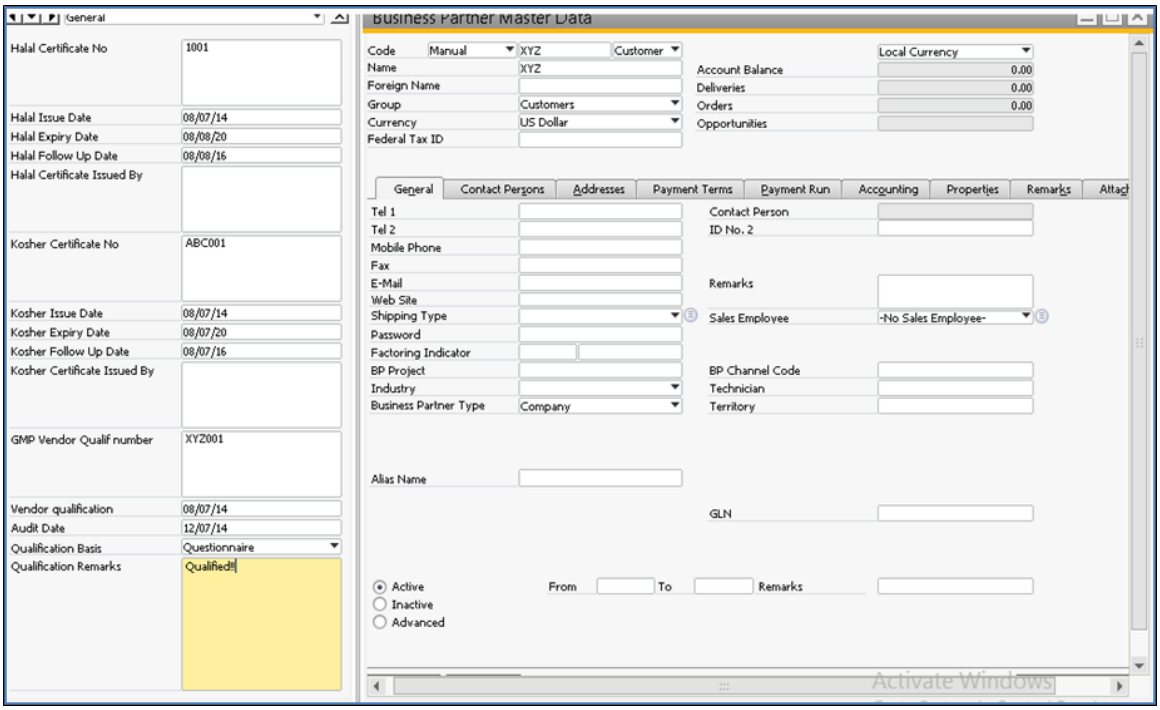
Documents required to qualify a supplier include: supplier's response to quality system questionnaires, raw material specifications, supplier's documents such as specification sheets and BPRs, documents related to supplier's GMP compliance, supplier's certificate of analysis, QC test results performed to verify COA information, and supplier's terms and conditions.

9.1 Business Partner Master Data

The Business Partner Master Data screen is now enhanced to accommodate vendor/supplier qualification details.

Go To: Business Partners → Business Partner Master Data.

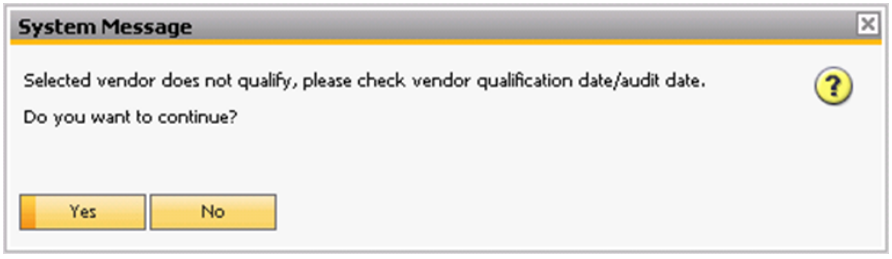
On the Business Partner Master Data screen, select your category as *Vendor* and select an appropriate vendor *code*. Next, you need to enable user-defined fields by clicking on *User-Defined Fields* under the Windows "View" menu. Alternatively, you can press **Ctrl + Shift + U.**



One of your vendors has been qualified as per cGMP requirements, and you want to add relevant information along with the vendor information.

In the GMP Qualification Number field, enter the cGMP vendor qualification number. Next, enter the date on which the vendor was qualified, in the Qualification Date field. Also, enter the next Audit Date.

If the Qualification Date/Audit Date falls on or before the system date, then the system displays a warning message. This is only for reference purposes so you can decide if you want to re-qualify the vendor.



Using the drop-down key on the Qualification Basis field, select the factors based on which a vendor can be qualified. The drop-down includes:

- Questionnaire
- COFA
- BMR
- Certification
- Other

You can enter any additional information or notes in the Qualification Remarks field.

As a part of prerequisites, *BatchMaster ERP* recommends you create a relationship between business partners and items using the Business Partner Catalog Numbers screen.

You can add any document relevant to vendor qualification, on the *Attachments* tab. Click the *Browse* button on the *Attachments* tab to select the desired document.

You will be able to attach any document on the Business Partner Master Data screen if you have enabled the Attachment Folder on the Path tab of the *General Settings* screen.

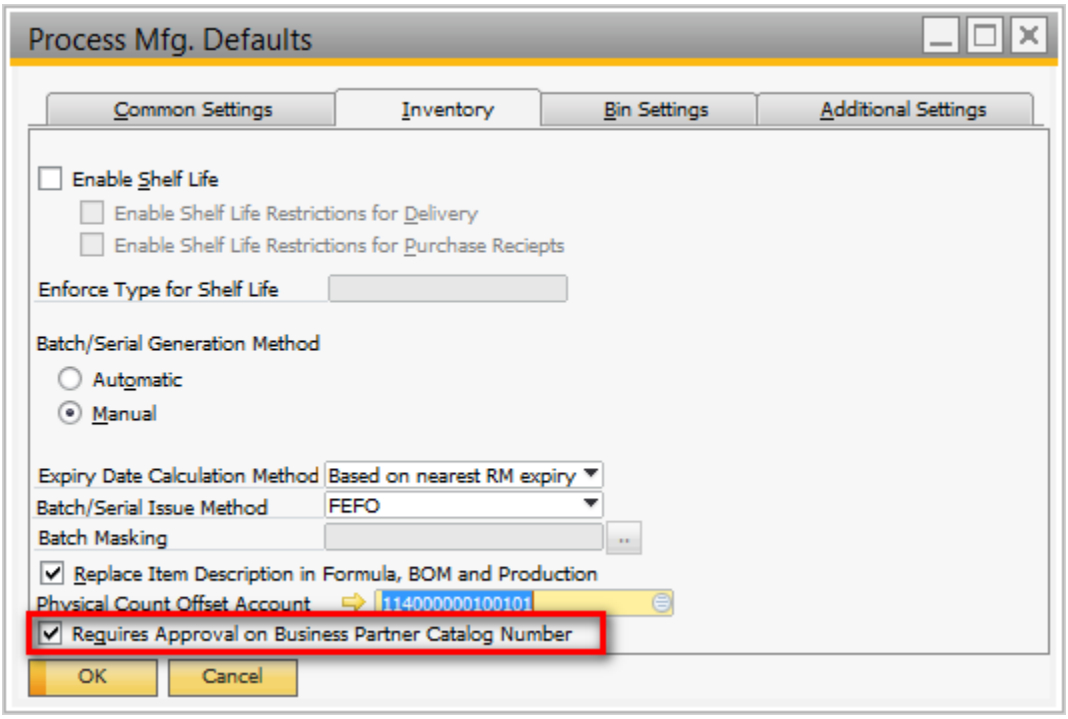
(Administration → System Initialization → General Settings)

Click the *Update* button to save the information added.

9.2 Business Partner Catalog Number-Draft

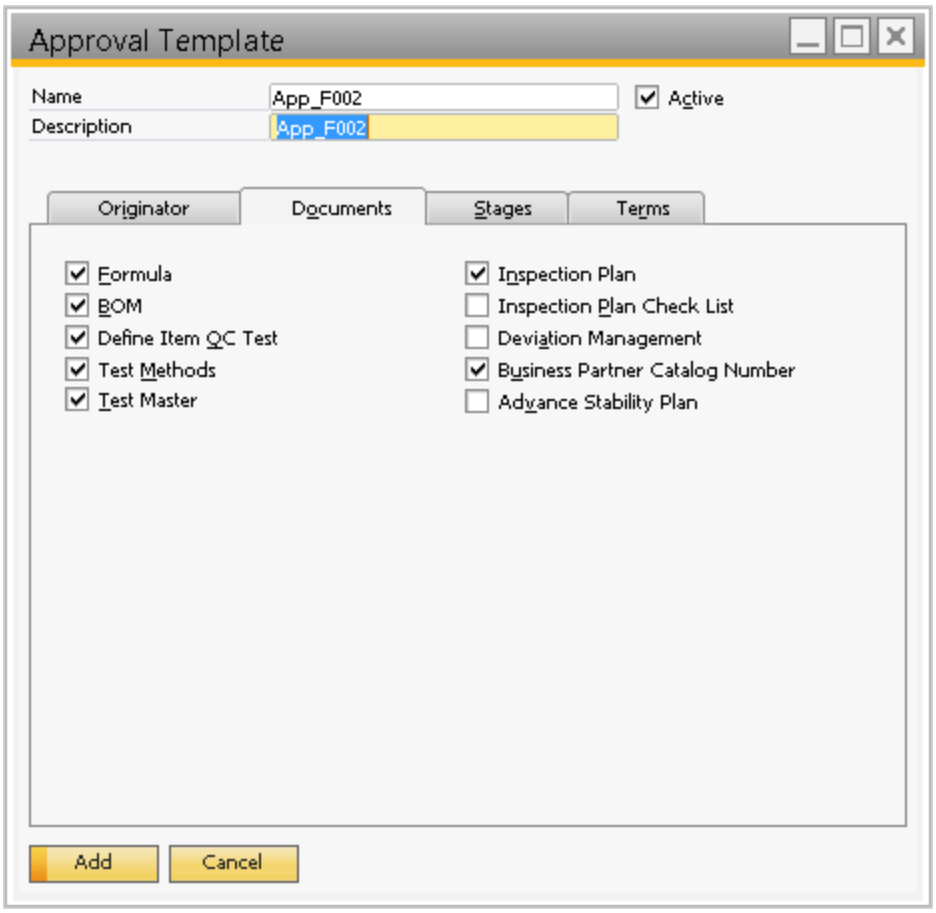
The Business Partner Catalog Number Screen is available to configure your item number or code to vendor/customer catalog number. BatchMaster ERP offers you a capability to implement Approval workflow on BP Catalog No.

On the *Process Mfg. Defaults Screen*, the '*Require Approval on Business Partner Catalog Number'* checkbox is available. Once selected, approval procedure is applied on it.



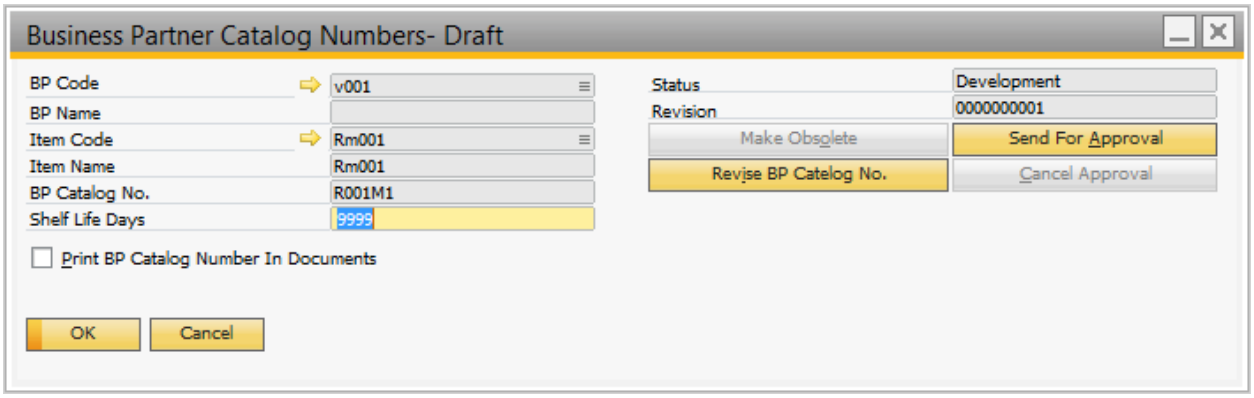
Associate an appropriate approval template with the BP Catalog number.

Go To: Main Menu → Administration → Setup → Process Mfg Appr. Proce. → Approval Template



Applying approval on Business Partner Catalog Number, the Business Partner Catalog Number-Draft screen gets activated. On the screen you can configure Business Partner item code with your item and send it for approval.

Go To: Main Menu → Inventory → Business Partner Catalog Numbers-Draft.



On the *BP Code* field, select the business partner for whom you wish to define catalog number. Choose the item for which you are defining a catalog. In the BP Catalog No field, specify the business partner catalog number for the item. Next, mention the shelf life of the item in the *Shelf Life Days* field and click

the *Add* button. The *Send of Approval* button gets activated, click on it to initiate the approval process. Follow the approval cycle. Once the document is approved by all authorized user, its status changes to Active. You can create a new revision of BP catalog number using the Revise BP Catalog No button. The Cancel Approval button is available to cancel the approval request.

10 Sampling Management

This sales and opportunities-driven function leverages on the capabilities of the sampling techniques to derive product samples and present them for approvals on sales opportunities.

10.1 Sampling Setup

Use this screen to auto-generate project IDs and assign the default specification template. To access this screen, choose:

Go To: Administration → Setup → Sales Request Management → Sampling Setup

10.2 Sales Request Management

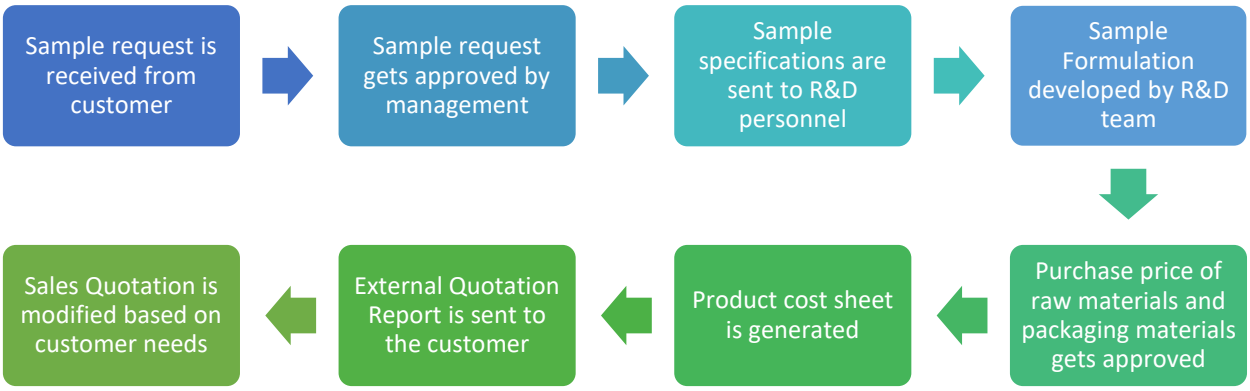
BatchMaster ERP's Sales Request Management feature is designed specifically to systematize, streamline, and speedup the sales process. It assists you in managing your sales project from opportunity to sales closure. Using this feature, you can efficiently manage new sales requests and can also make changes in existing sales requests. In addition, you can add project details, sample information, and other product development activities. This gives you better visibility on the progress of request. You can also generate formal quotation for customers, view pricing information of raw materials and packaging materials, and print a product cost sheet for samples.

1. Customer sends you a sales quotation request. This request may require you to develop sample product with specific formulations /specifications.
2. Sales team creates a record for the customer request and enters customer details.
3. Sales team gets approval from appropriate authorities to proceed with the sales quotation request.
4. After obtaining approval, the sales team asks the formulator to provide them with product's formula, developed based on customer specifications. In addition, they request for other details about the formula such as claim quantity, overage, potency, batch size, and packaging details.
5. R&D personnel/ formulators send the required information to the sales department.

6. Sales department adds packaging information, if not provided by R&D Personnel /formulator, and requests price approval from the purchasing department.
7. Purchasing department checks the price of all raw materials and packaging materials and updates the requested items' price based on volume. They send this information back to the requester (sales department).
8. Sales department then generates the product cost sheet and gets it approved by appropriate authorities.
9. Once approved, sales department sends the quotation with sample, to the customer.
10. Sales team negotiates with the customer and if approved, generates the sales order.
11. There can be exceptions to the above sequence of events (requirement). If the customer demands quotation for existing formulation (with no sample request) with some changes in the packaging material, then the sales department gets price approval from the purchase department and generates an internal quotation. Once this quotation is approved, they make an external quotation.

SRM Process Flow

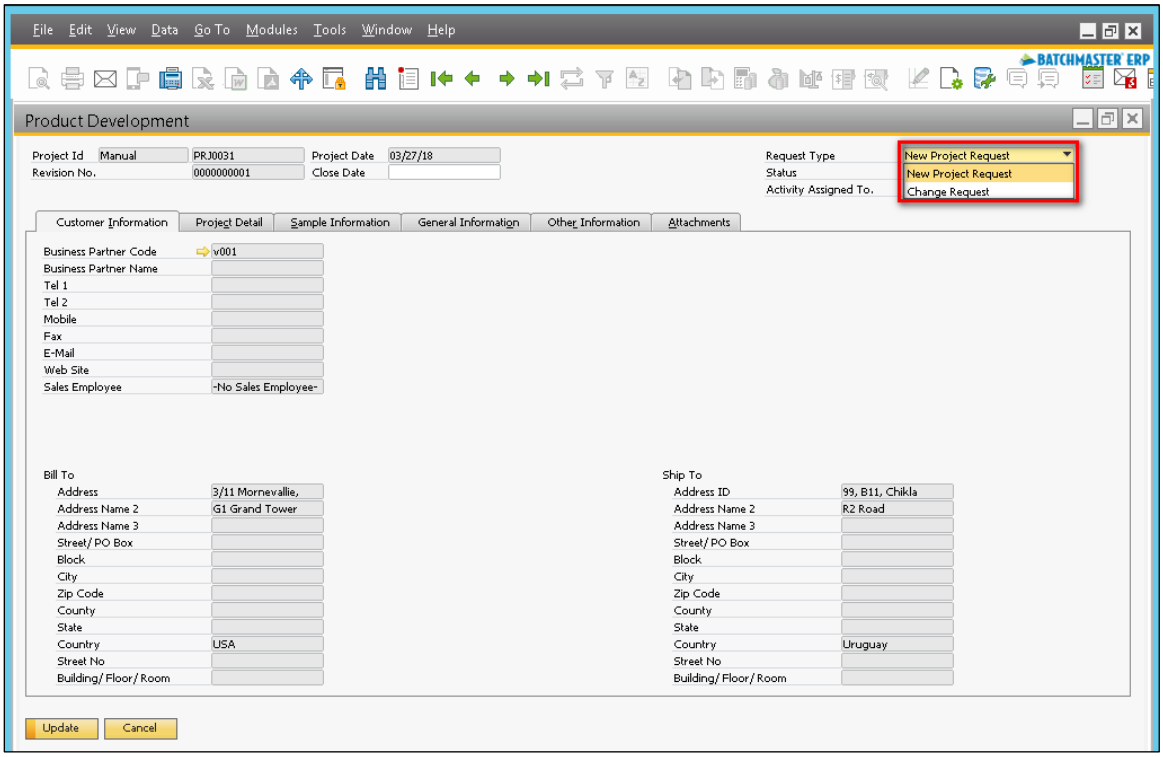
BatchMaster ERP provides you the *Product Development* screen to record a customer request.



10.3 Product Development

Using the *Product Development screen,* you can efficiently record and track the sample development life cycle. Here you can record project details, sample information, and other development activities of a product. This will provide better visibility on the progress of sample request. Also, you can view pricing details of product components, print product cost sheets, and generate a quotation for your customer.

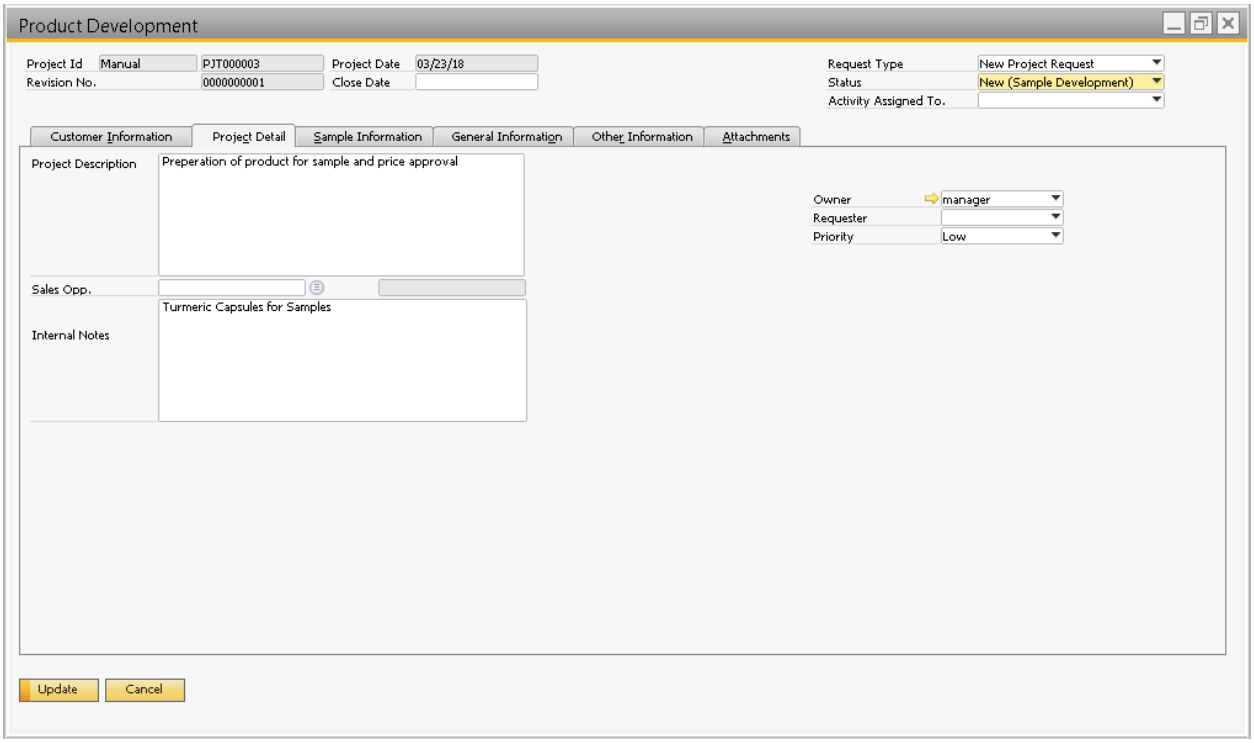
Go To: Sales Request Management → Product Development



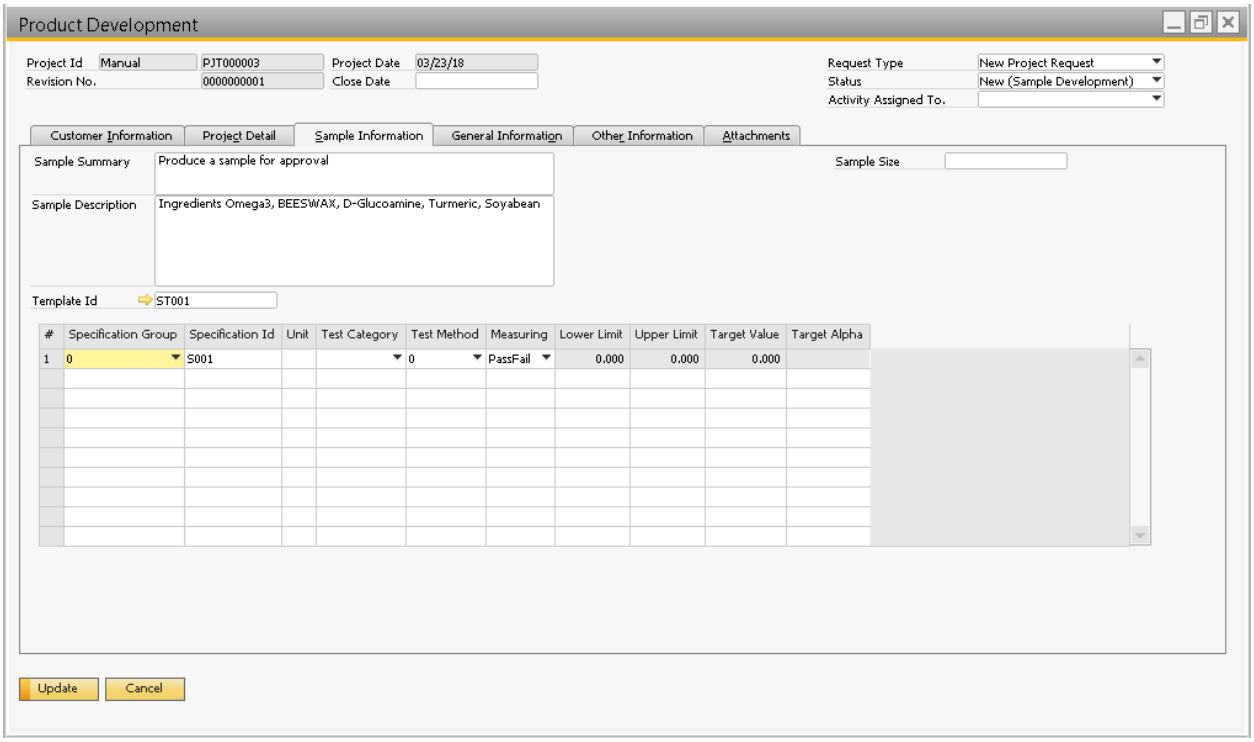
For a new sample request, you can enter the *Request Type* as *New Project Request*, while if you need to modify any existing request you can choose the *Change Request* option.

On the Customer Information tab you can recall and display a Business Partner already maintained on the *Business Partner Master Data* screen, or can directly define a new one. You can also maintain Bill To/Ship To details. When you close the project, the details will be automatically updated on the *Business Partner Master Data* screen.

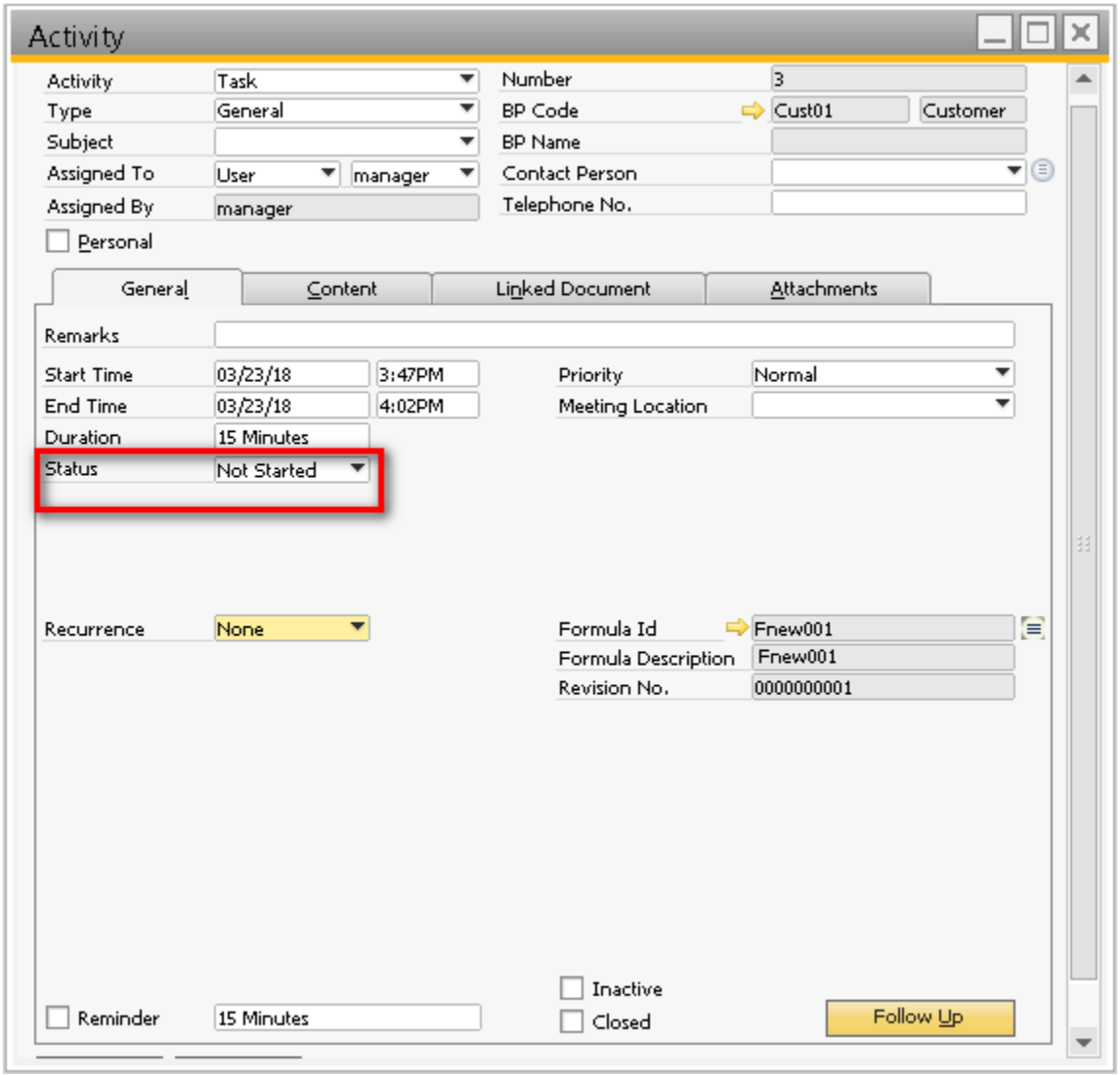
On the *Project Details* tab, you can store basic details of a project. If the project request reaches through a sales opportunity, then enter the opportunity number in the corresponding field. Also, you can enter the user who is responsible for this project in the *Owner* field and set the urgency level of the project using the *Priority* dropdown.



All sample-related details such as sample summary, size and description, can be specified on the *Sample Information* tab. If your customer or prospect has any specific requirement for the product sample, then you can add these requirements in the screen of a specification template and use that template in the *Template ID* field.

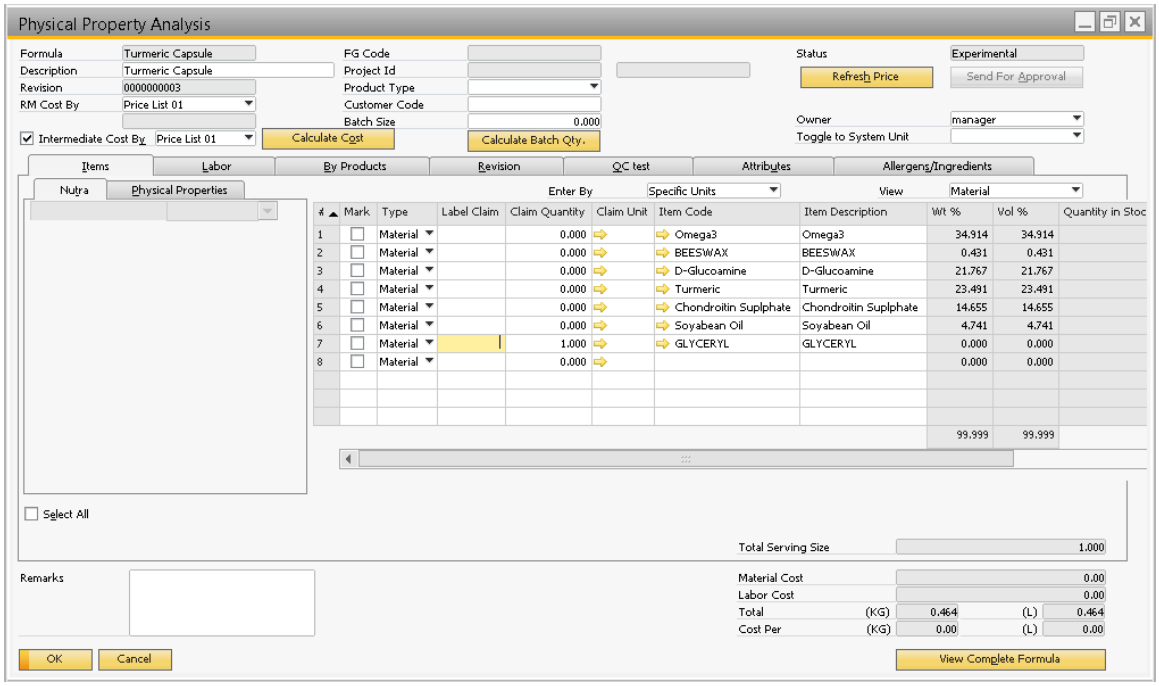


Click the *Add* button to add the recorded sample request. By default, the project status is set to *New (Sample Development)*. Now, the sales team will look for approval from appropriate authorities, before proceeding with the quotation. At this phase, you should set the project status as *Approval to Create Sample*. When you update the record, an activity for the approval of the sample development will be created and will be assigned to the user specified in the *Activity Assigned To* field.

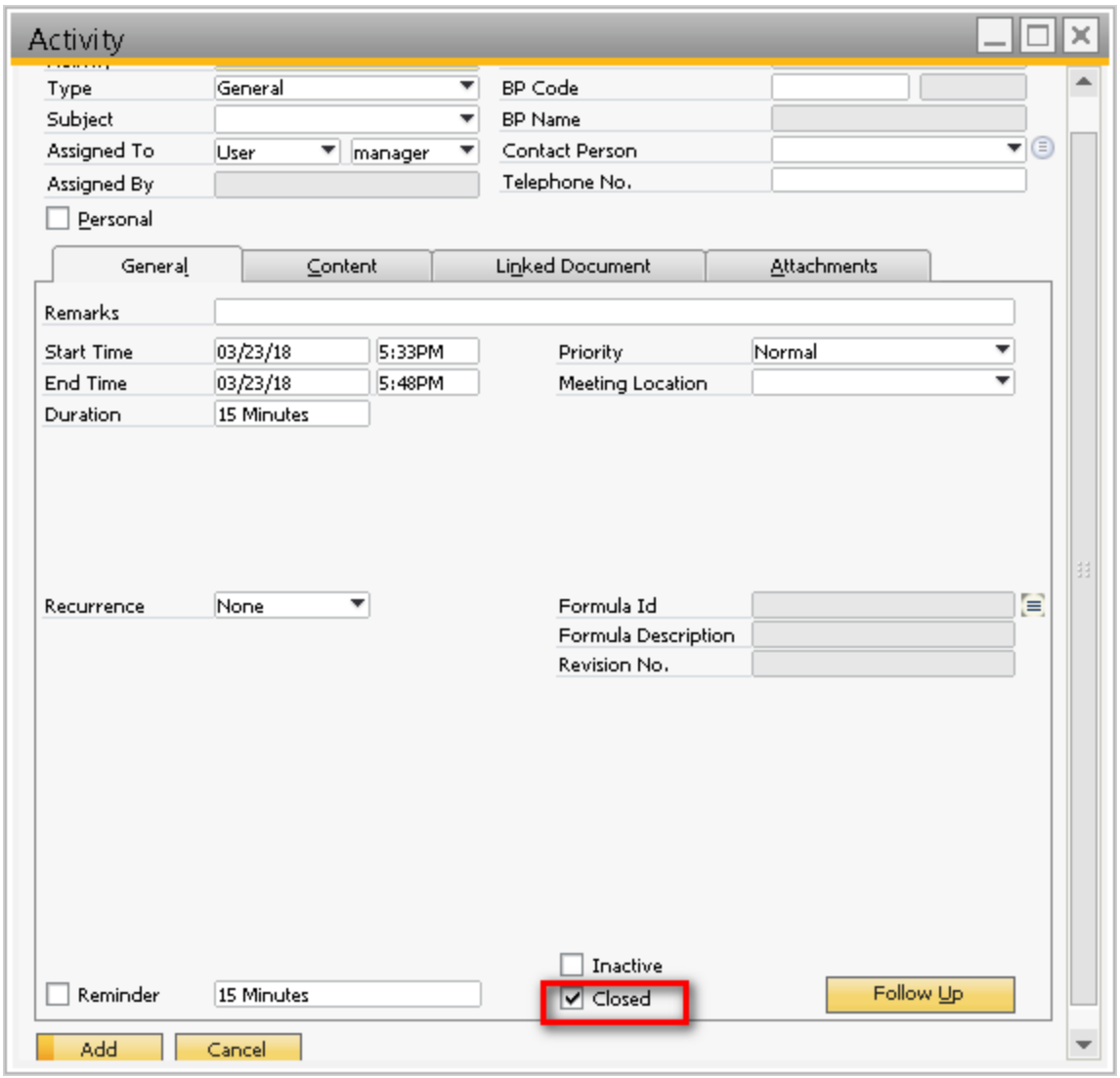


Once the sample creation is approved by the responsible sales personnel, the corresponding activity can be closed and the project owner can change the project status to *Request for Formula Development*. By doing so, a new activity for sample formulation will be created and assigned to the user specified in the *Activity Assigned To* field.

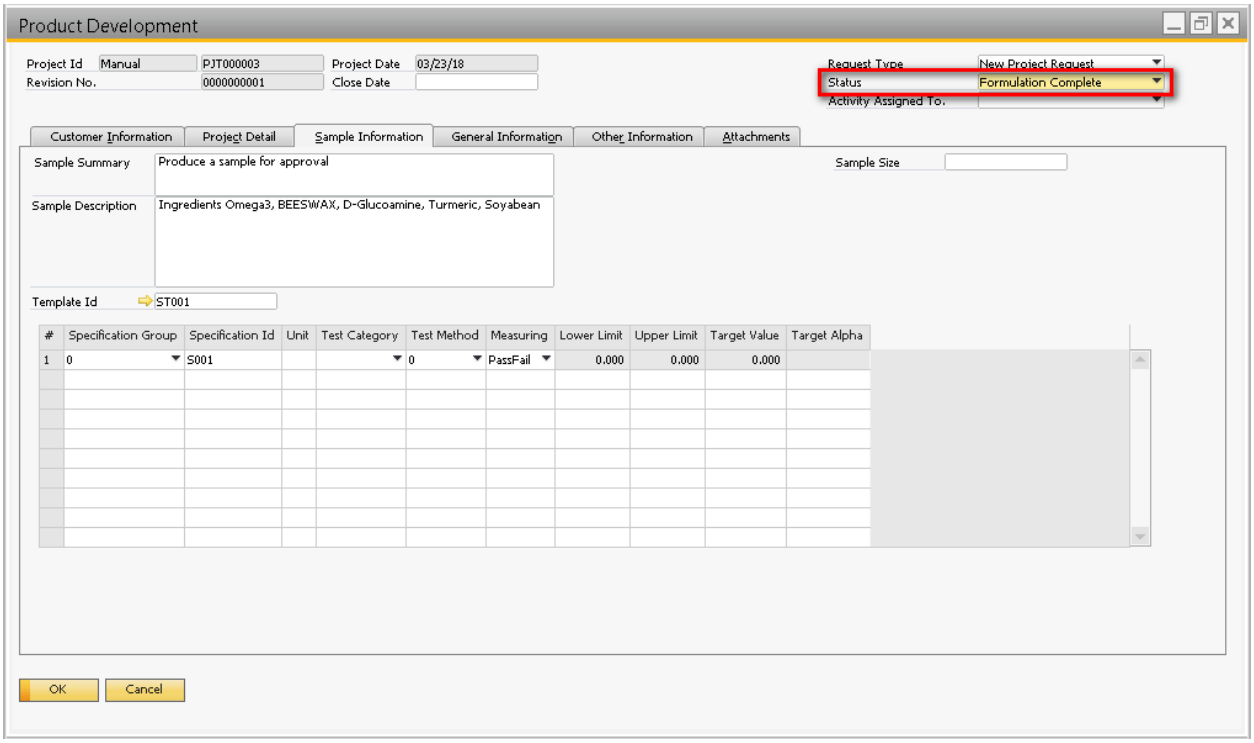
As a formulator, you can prepare the formula using the *Physical Property Analysis* screen.



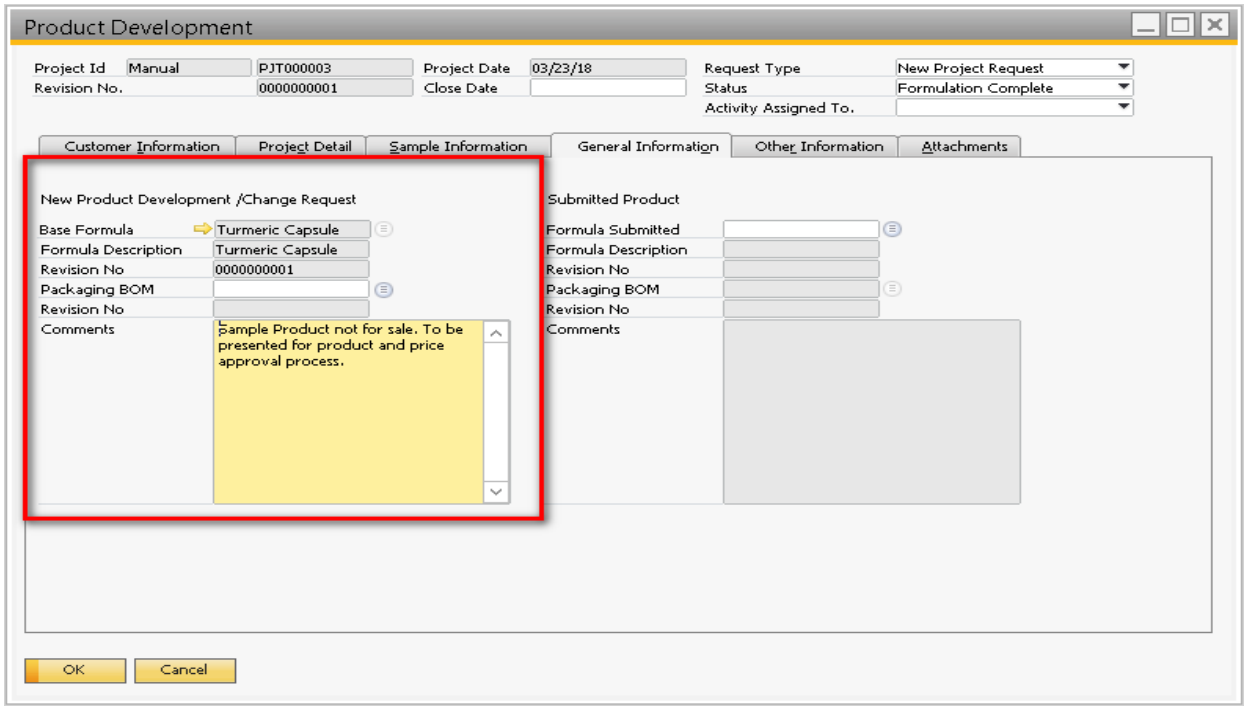
Once the sample formula is ready with an *Active* status in the *Physical Property Analysis* screen, then you must close the corresponding activity. Once the activity is closed the system will update the created formula on submitted formula.



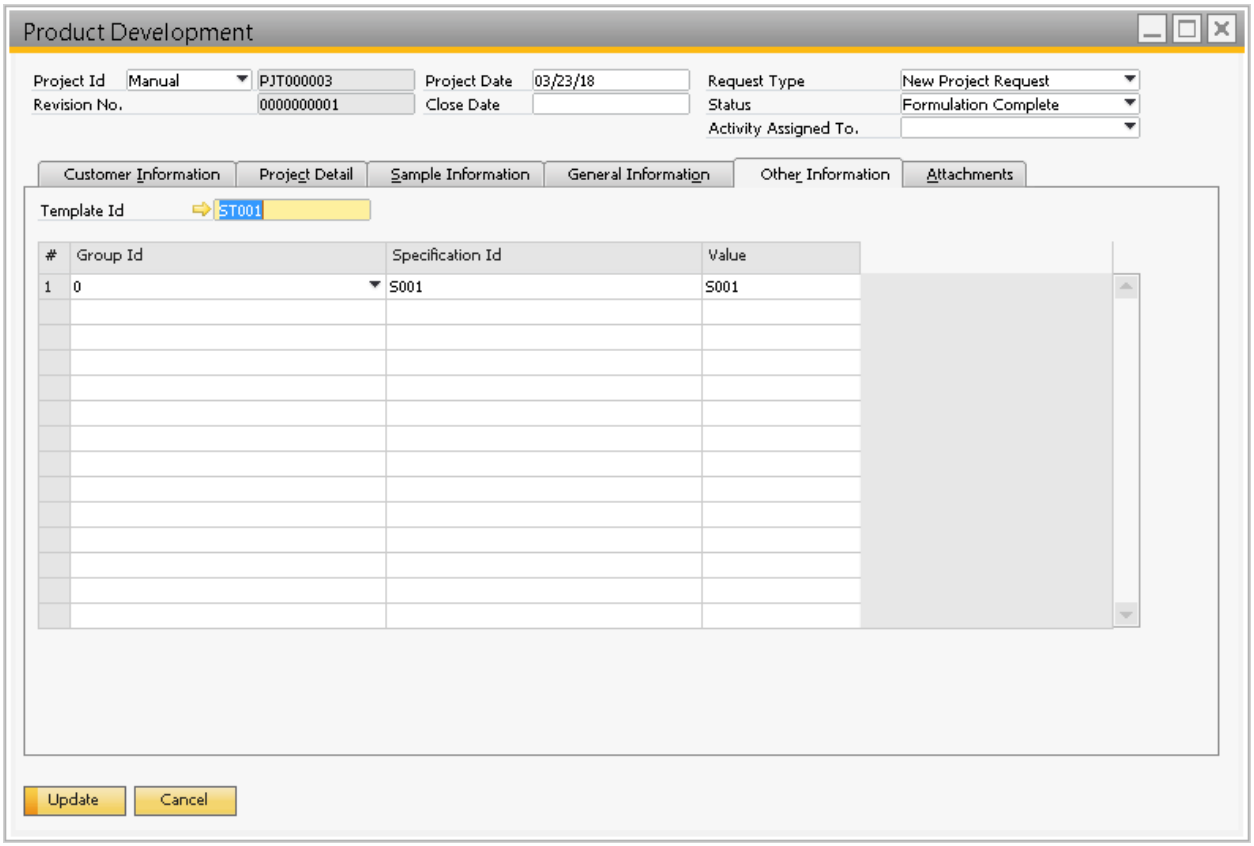
As a result, the project status on the *Product Development* screen changes to *Formulation Complete*.



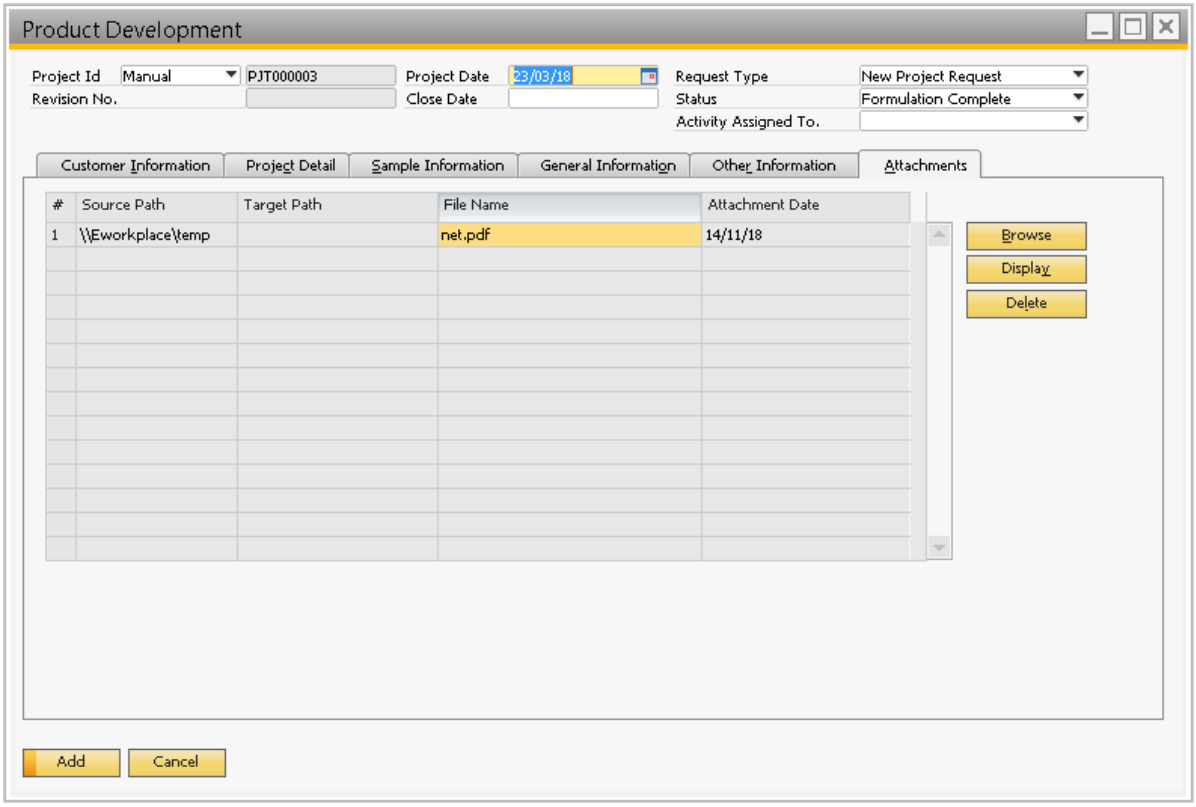
Next, on the *General Information* Tab, you can enter the *Base formula* and *Packaging BOM* that should be used for the sample product. The *Base formula* field is editable when status of product development is *Request For Formula Development*. Additional data can later be added about the submitted product.



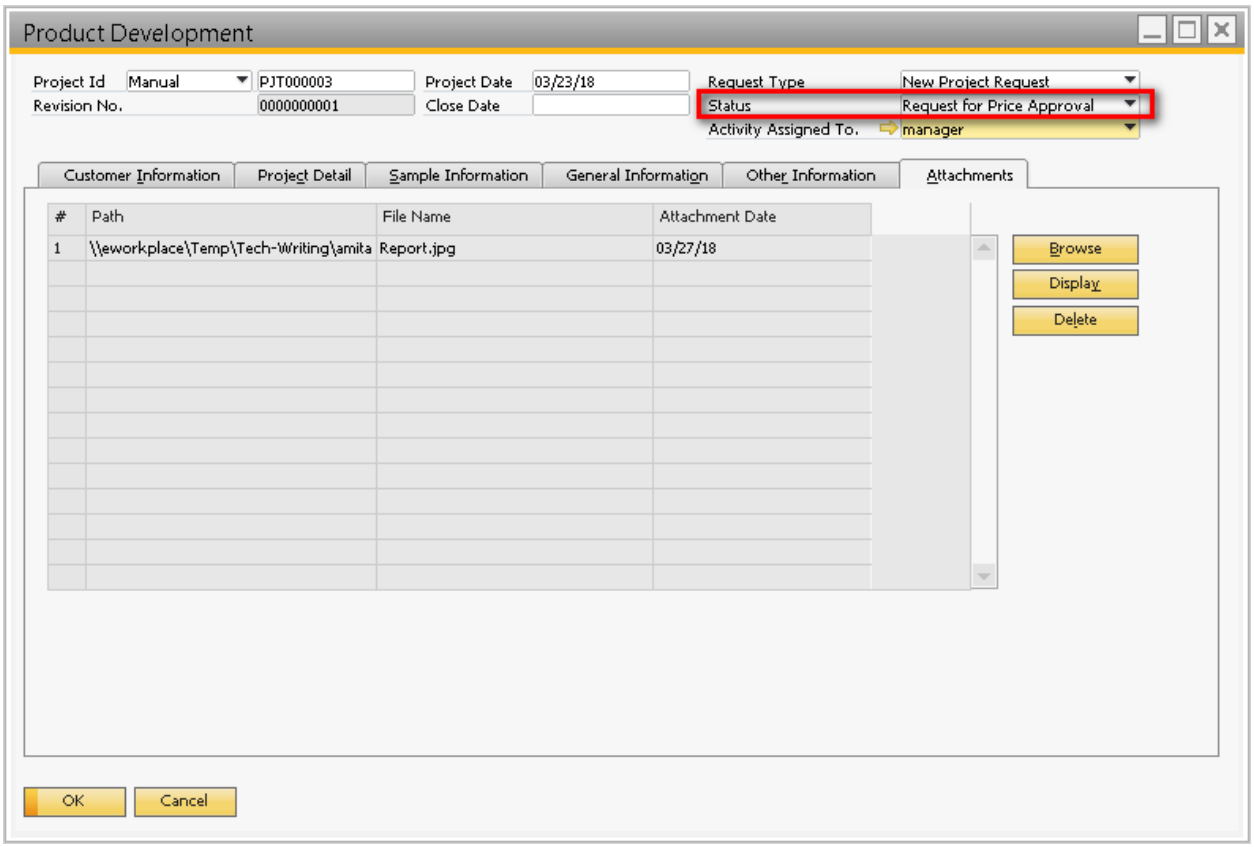
Additional sample-related information can be entered on the *Other Information* tab.


Product Development
Project Id
Manual
PJT000003
Project Date
03/23/18
Request Type
New Project Request
Revision No.
0000000001
Close Date
Status
Formulation Complete
Activity Assigned To.
Customer Information
Project Detail
Sample Information
General Information
Other Information
Attachments
Template Id
ST001
#
Group Id
Specification Id
Value
1
0
S001
S001
Update
Cancel

You can use the *Attachment* tab to attach any supporting file or document with the project. You need to ensure that the document is available in a network location.

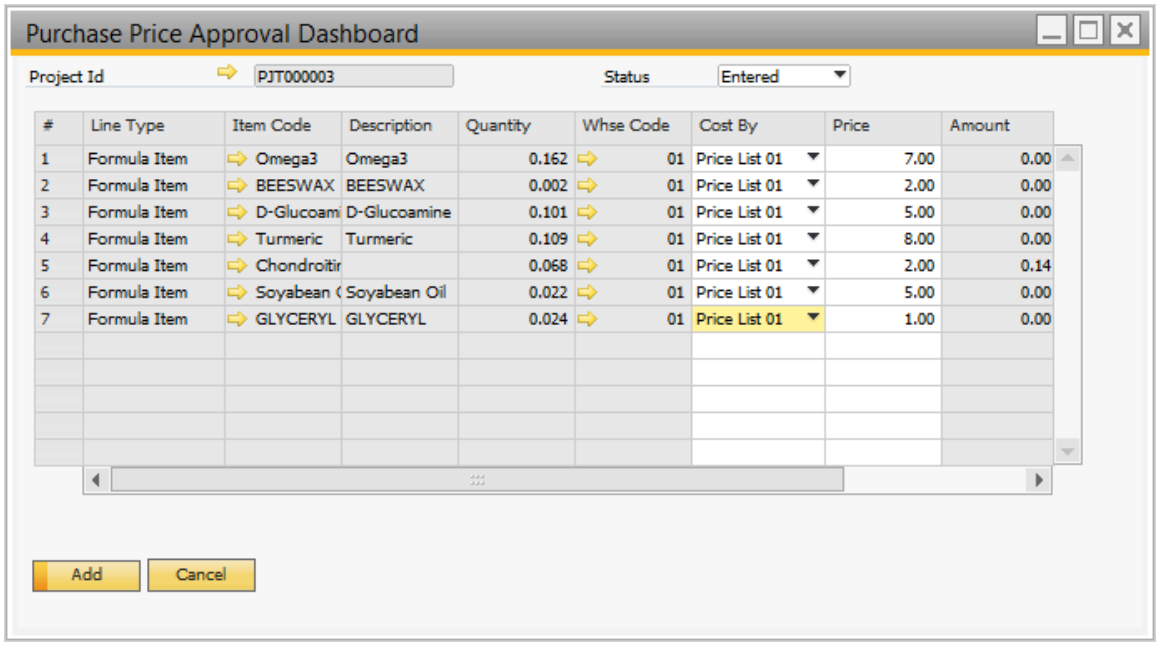


Once the formula is ready, based on the feedback from the formulator, you will project the cost of raw materials and packaging required to prepare sample. You can also request the purchase department to give price approval. At that point, you can set the project status to *Request for Price Approval* and in the *Activity Assigned To* field specify the code of the user to whom this activity needs to be assigned.

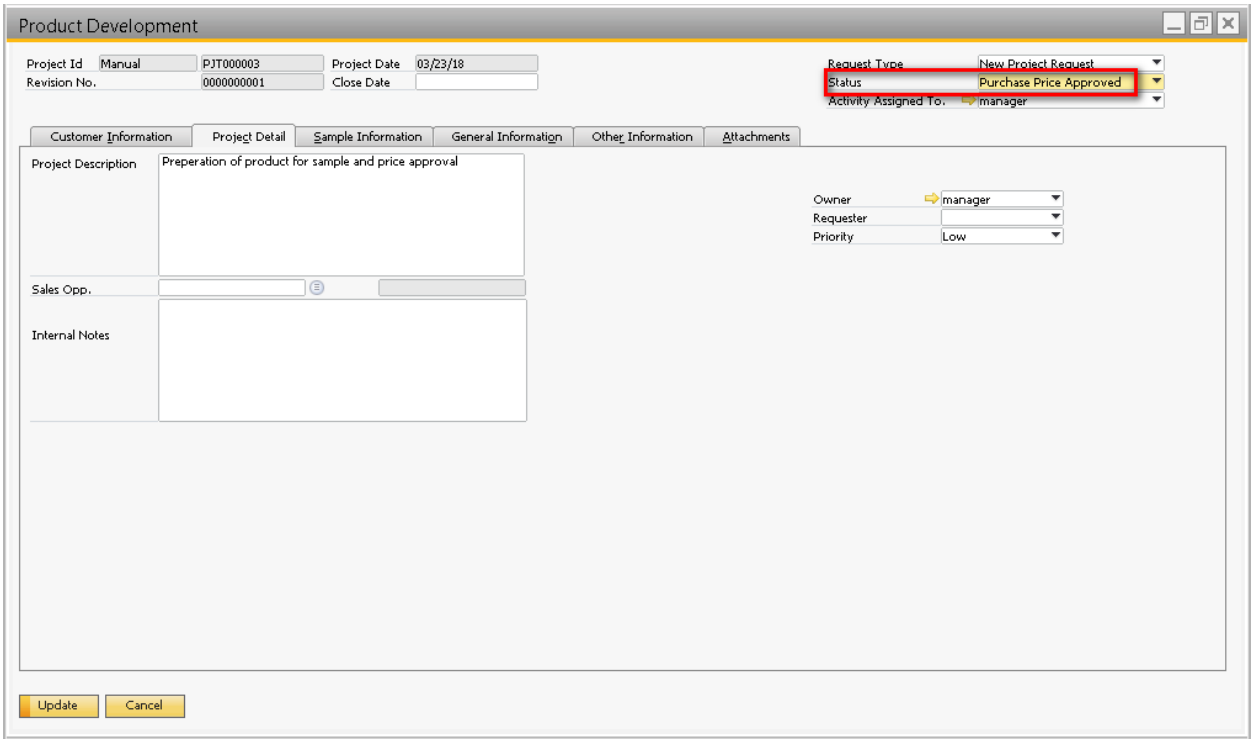


Through the *Purchase Price Approval Dashboard,* the purchasing manager can select the desired price list in the *Cost By* field and quote the price of materials.

Go To: Purchasing → Purchase Price Approval Dashboard

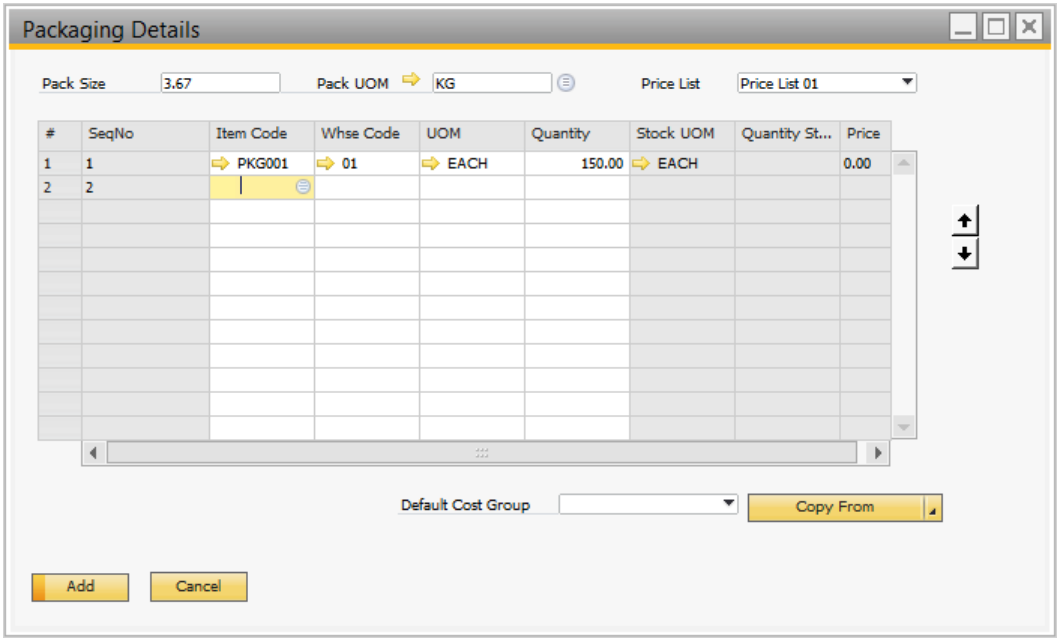


Once the material prices are approved, then you can close the corresponding activity for price approval. As a result, the project status on the *Product Development* screen changes to *Purchase Price Approved*.

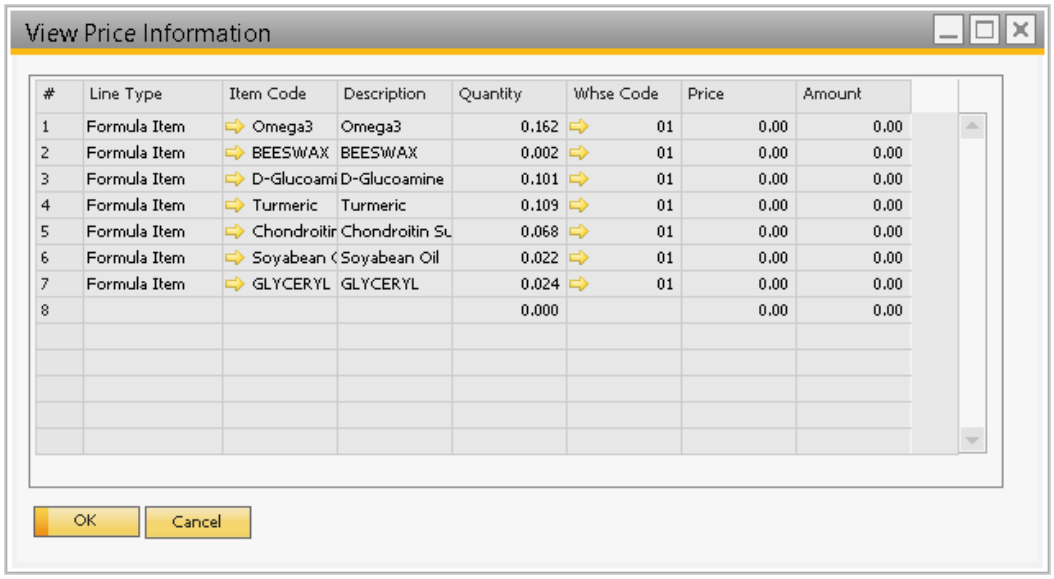


You can define packaging of a sample manually or you can copy the BOM assembly items or container items. To accomplish this, right-click on the *Product Development* screen and select the option *Packaging Details*.

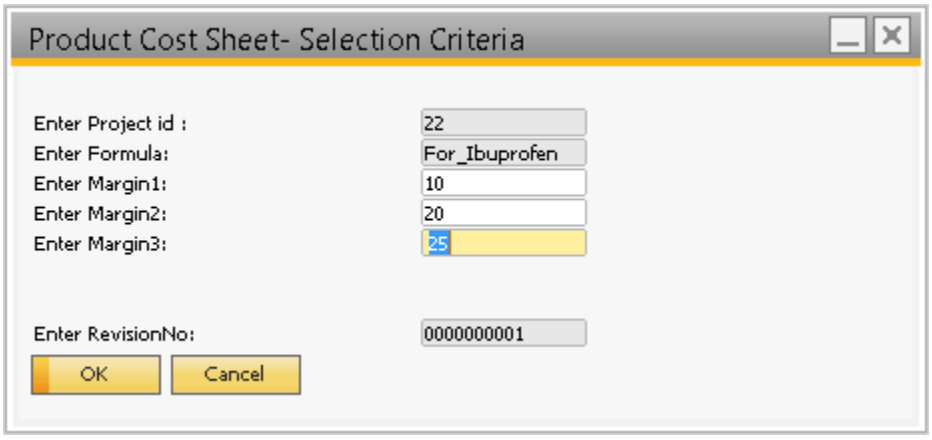
On the *Packaging Details* screen, you can manually enter packaging details of your sample or else select the Copy from BOM/Container BOM. Additionally, you can also use *Default Cost Group* drop-down menu to set the default price list that can be used to print the *Product Cost Sheet*.



You can view the purchase price information of formula ingredients using the *View Price Information* option (right-click to display.)



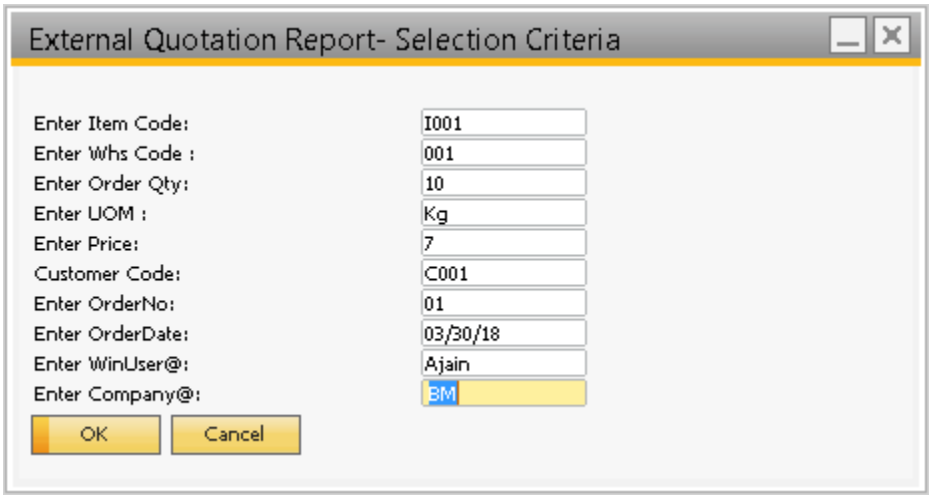
Before preparing the sales contract, a sales manager will need the statement of cost incurred in sample preparation. You can generate a cost sheet using the *Product Cost Sheet* screen, which can be accessed by right-clicking on the *Product Development screen* and choosing the option *Product Cost Sheet*.



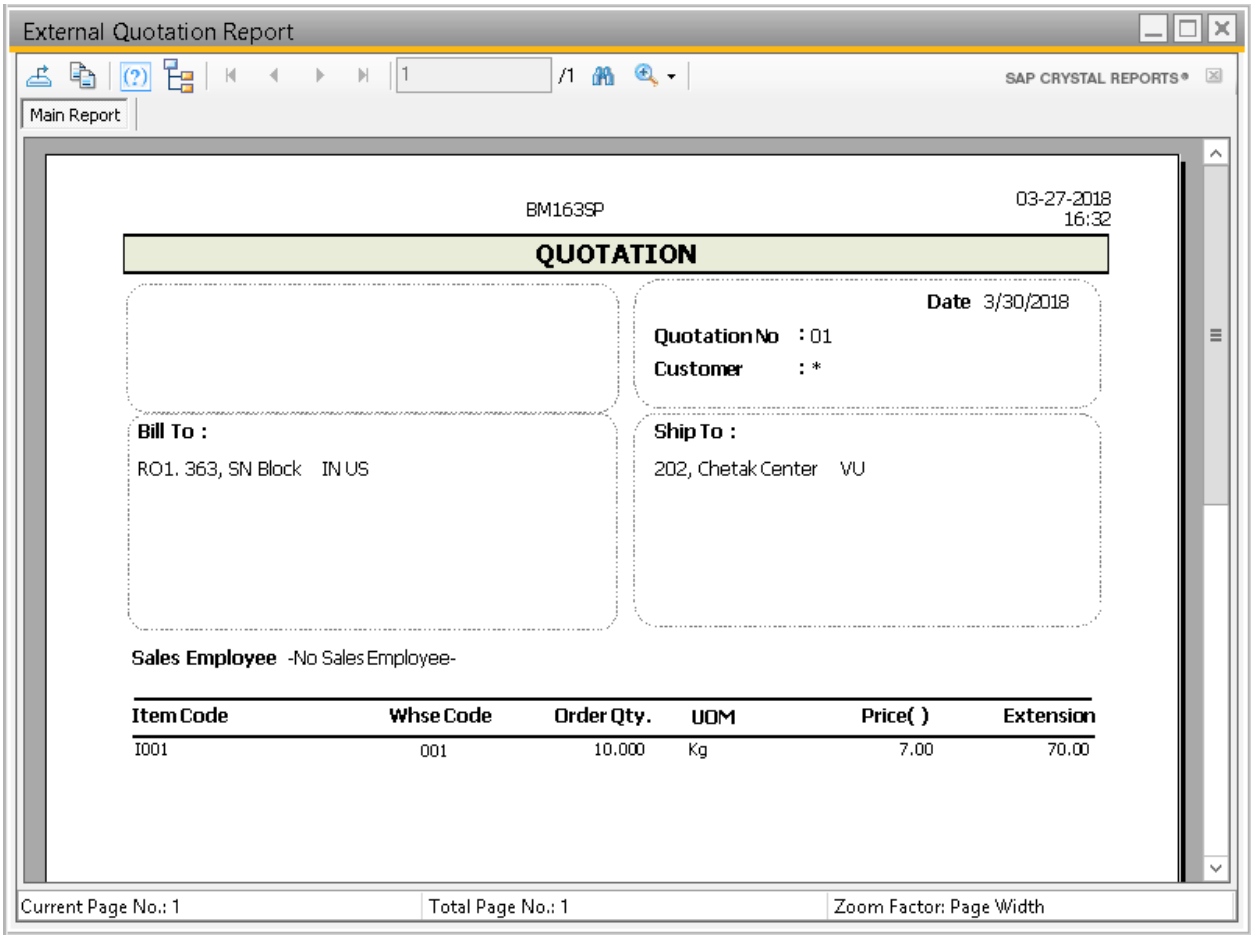
The total cost displayed on the Product Cost Sheet report will include the Labor cost (Formula Labor + Fixed Cost Labor + Setup Cost Labor) defined for the formula.

Once the sales manager approves the cost sheet, you must close the corresponding activity. As a result, the project status on the *Product Development* screen changes to *Price Cost Sheet Approved*.

Finally, the sales department will need to send a quotation to the customer/prospect. To generate the quotation, right-click on the *Product Development* screen and choose the option *External Quotation.*

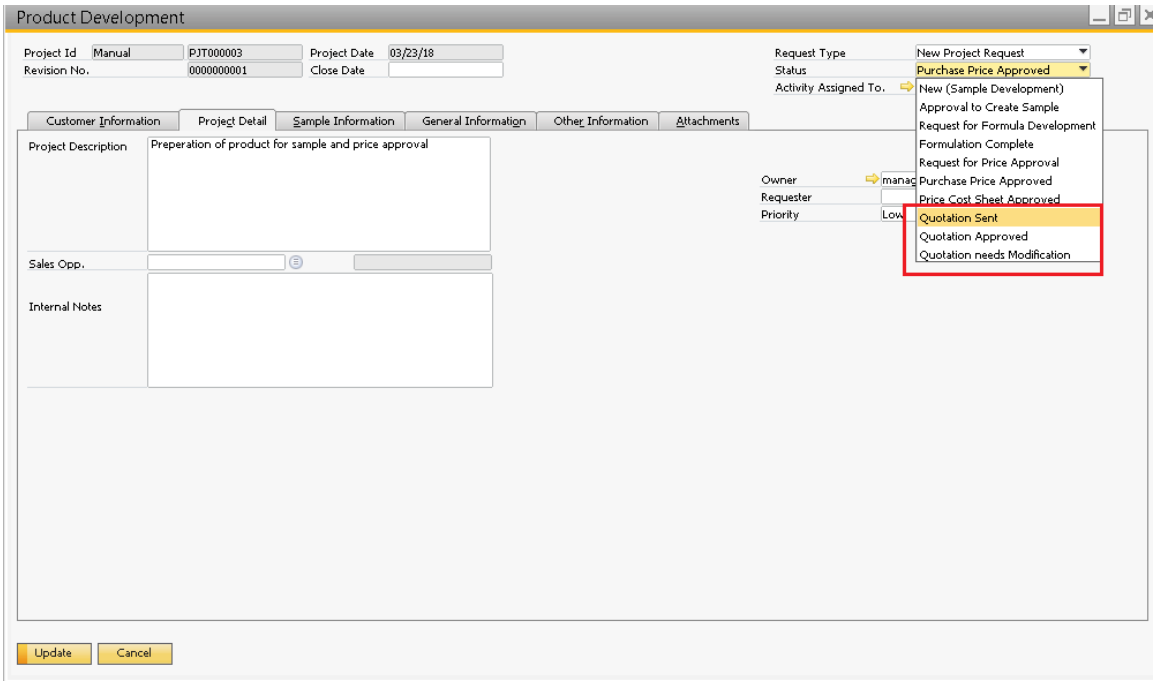


Using this screen, you can enter the desired pricing for the customer and generate the report. The project person can generate and send external quotation based on the quoted price from the last sent quotation to the customer. The quotation report generated appears as in the following screen.



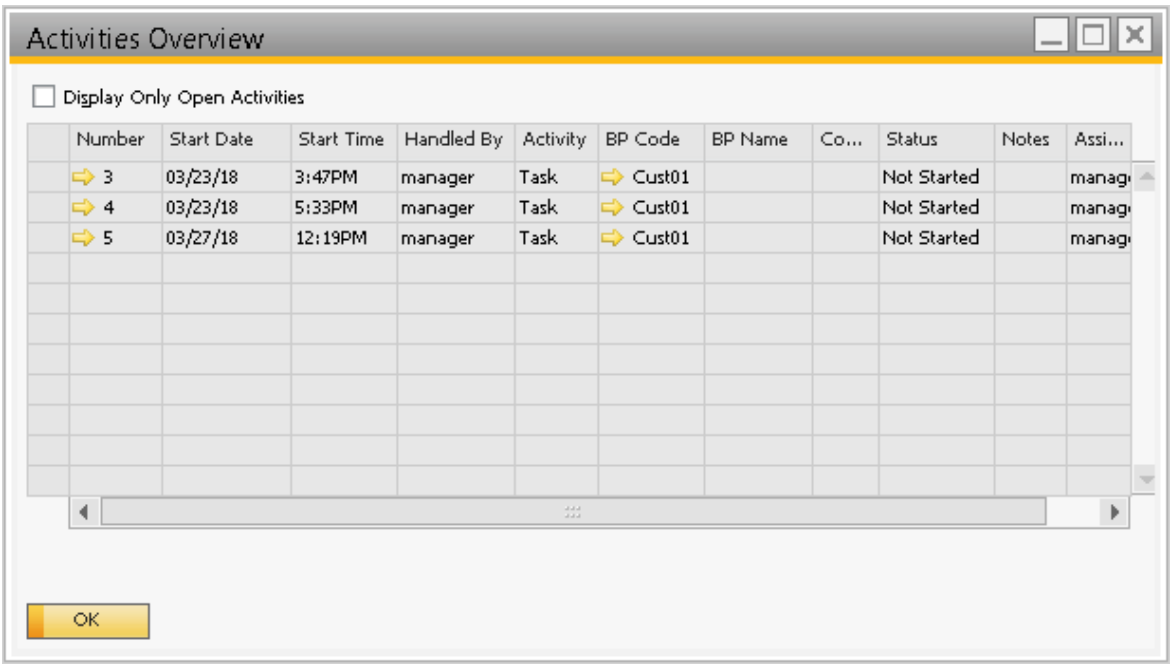
At this stage, you can set the project status to *Quotation Sent*.

If the customer/prospect approves the quotation and is ready to place an order, then the project owner can set the project status to *Quotation Approved*. If the customer needs modifications to the quotation, then you need to set the project status to *Quotation needs Modification*. In this case, the entire product development cycle needs to be repeated from *Approval to create the sample* to *Quotation sent*.

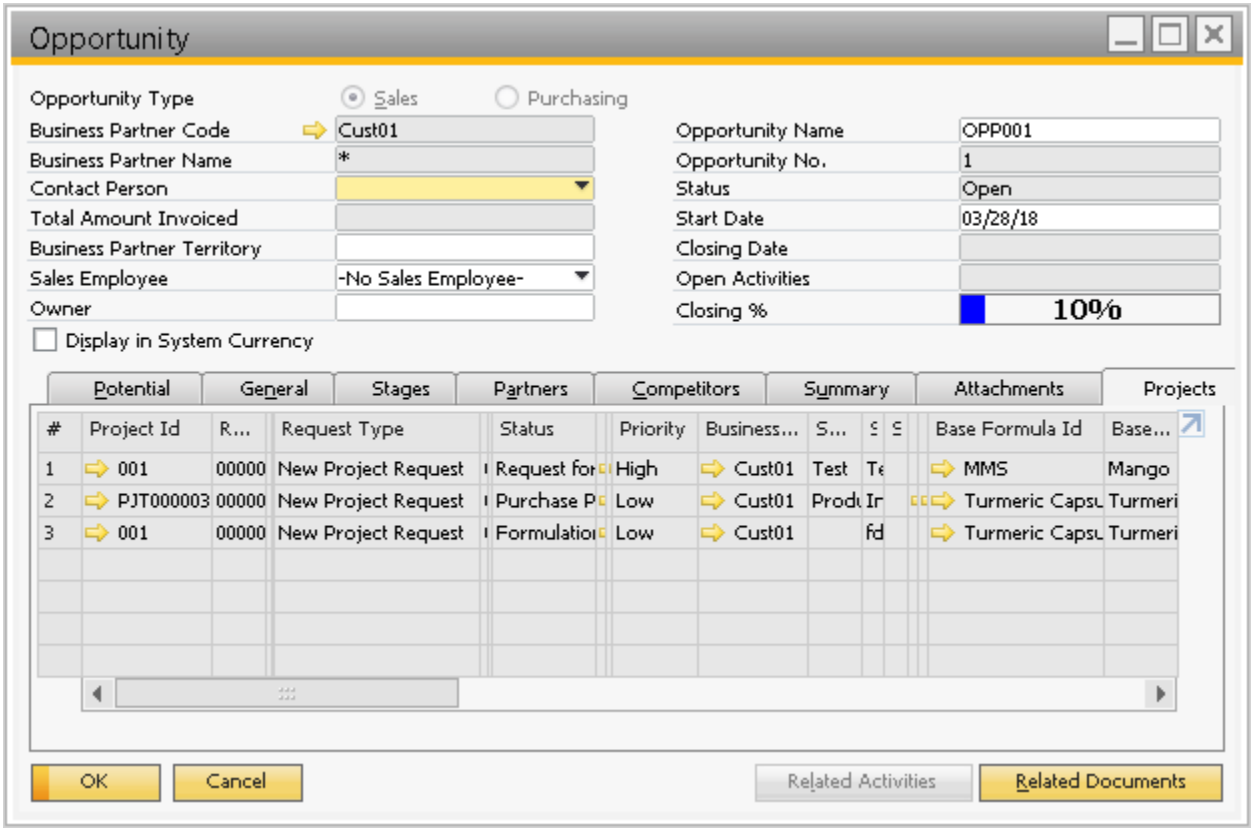


During the entire project development process, BatchMaster ERP automatically creates activities as and when needed. To access the Activity screen, right-click on the *Product Development screen* and choose the option *New Activity*.

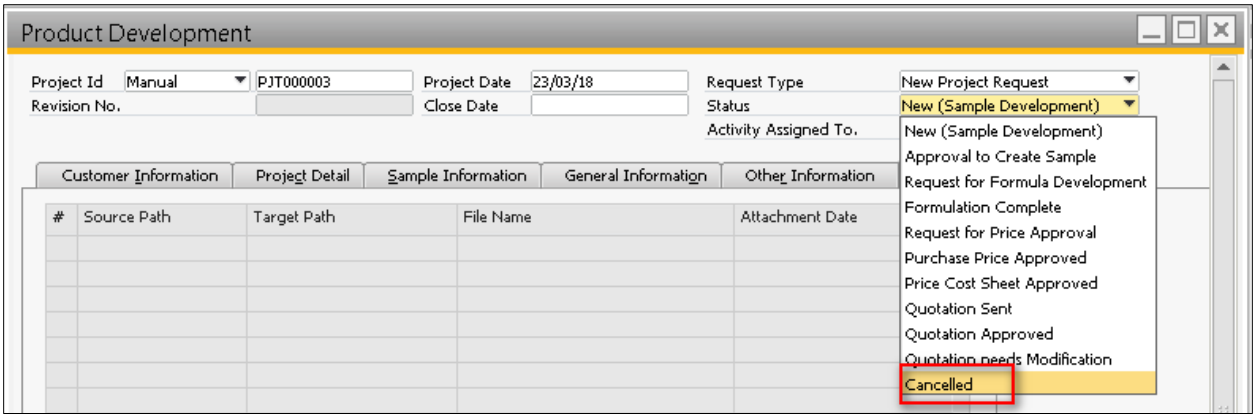
Activities that have been added already for a product development process can be viewed by choosing the *View Related Activity* option from the right-click menu of the *Product Development* screen.



If the Product Development record is associated with a sales opportunity you can also view project details on the *Opportunity* Screen. On this screen, the *Projects* tab shows all the sample project records created against the sales opportunity. The hyperlinks provided within various fields help you to easily navigate to specific records and view their details.



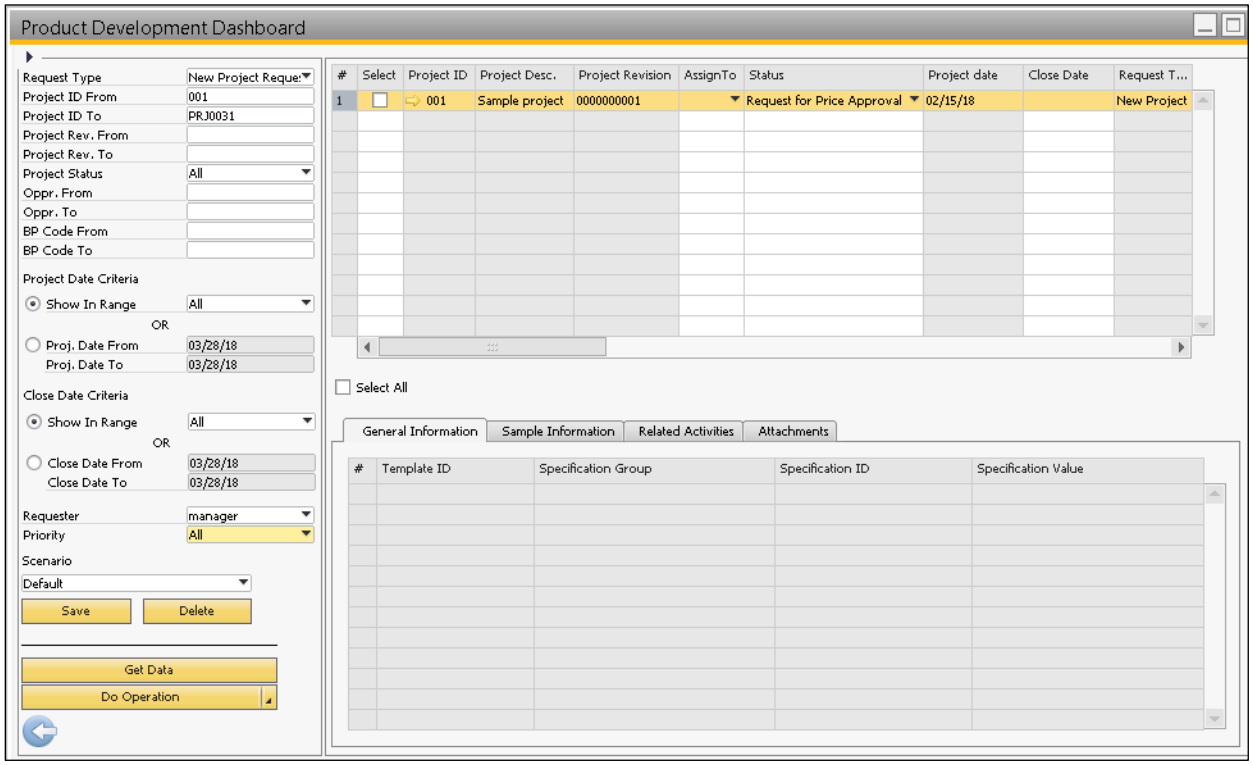
You can cancel the Sample request any time just by setting its status as *Cancelled*. Setting this status disables the record and so you cannot work on it further.



10.3.1 Product Development Dashboard

The Product Development Dashboard is specifically designed to track and analyze the progress of sample requests. You can view sample requests along with their status, and perform different operations such as: view/modify pricing of raw materials and packaging materials; open the Purchase Price Approval dashboard; print a product cost sheet for samples; generate formal quotations for customers. Hyperlinks are provided to easily navigate to particular details.

Go To: Process Manufacturing → Production Utilities → Product Development Dashboard



From the left pane, you can apply suitable filter criteria and click the *Get Data* button. The sample projects fulfilling the criteria you specify will be displayed in the dashboard grid.

In the grid you can view all details of the project such as Project id, revision number, status, requestor, request type, project date, owner, Base formula and packaging details, sales opportunity number if the project is created against any opportunity. In the lower grid, you can view project General Information, sample information, Related Activities and Attachments details.

From the dashboard you can perform the following business operations:

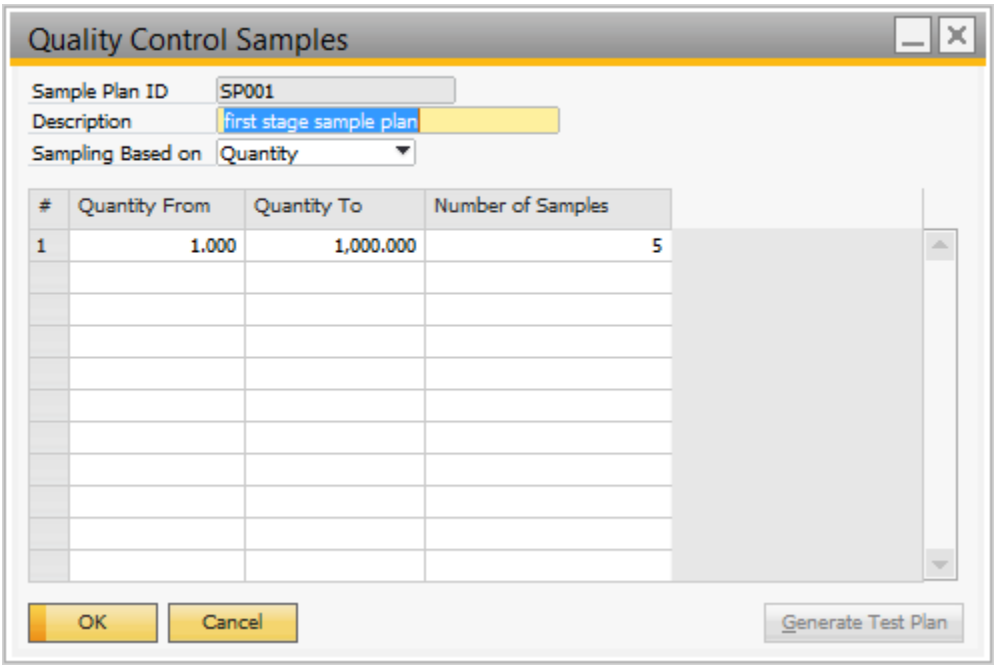
- Print Product Cost sheet
- Print external quotation report
- Change project status
- Close projects
- Open the purchase price approval dashboard
- Open packaging detail
- View price information

10.4 Quality Control Samples

Based on the regulatory norms set by the FDA and ICH, there could arise a need to track the quantity of raw materials drawn from multiple material lots received in different containers. Typically, any organization with such a need should set sampling standards. These standards can then be used while drawing samples for performing quality tests on raw materials.

Before you draw samples, you need to perform a series of steps beginning with the *Quality Control Samples* screen.

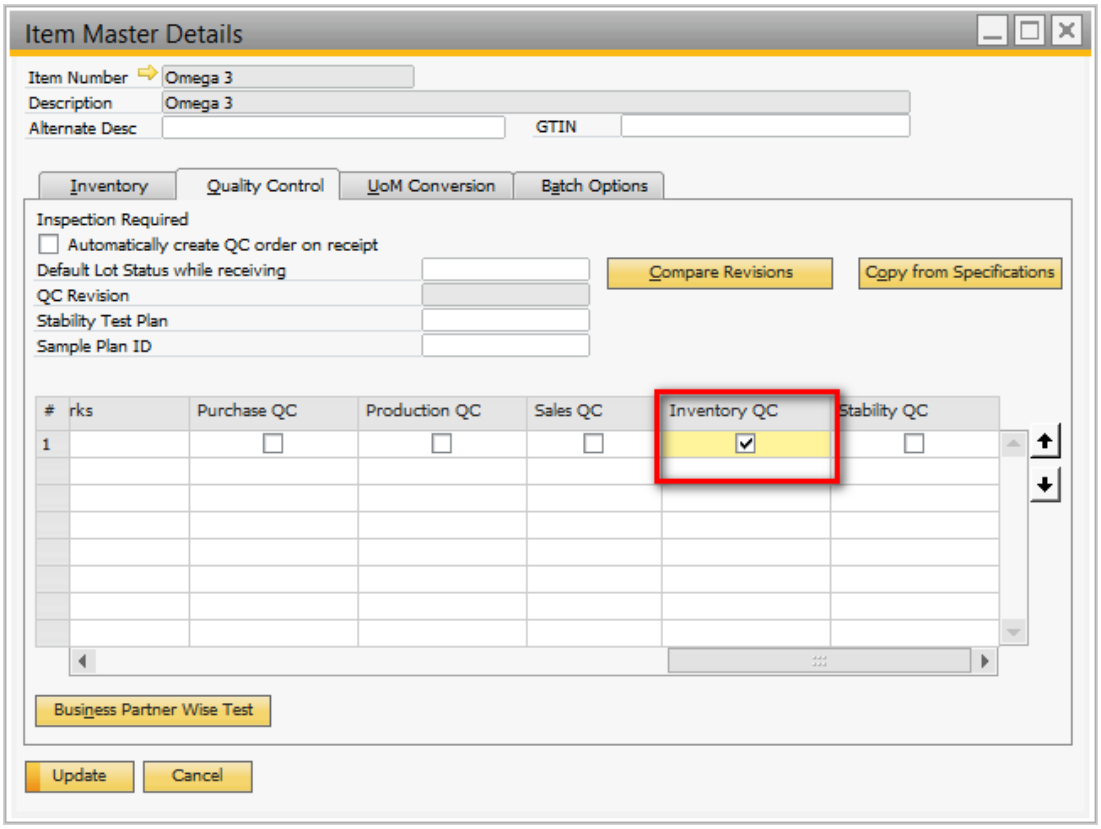
Go To: Administration → Setup → Quality Control Setup → Quality Control Samples



Use the table in the screen to set the number of samples to be drawn while performing quality control tests on lots that are received in different containers. Also, as part of the prerequisites to draw quality control samples, create a QC control order for the item for which samples need to be drawn.

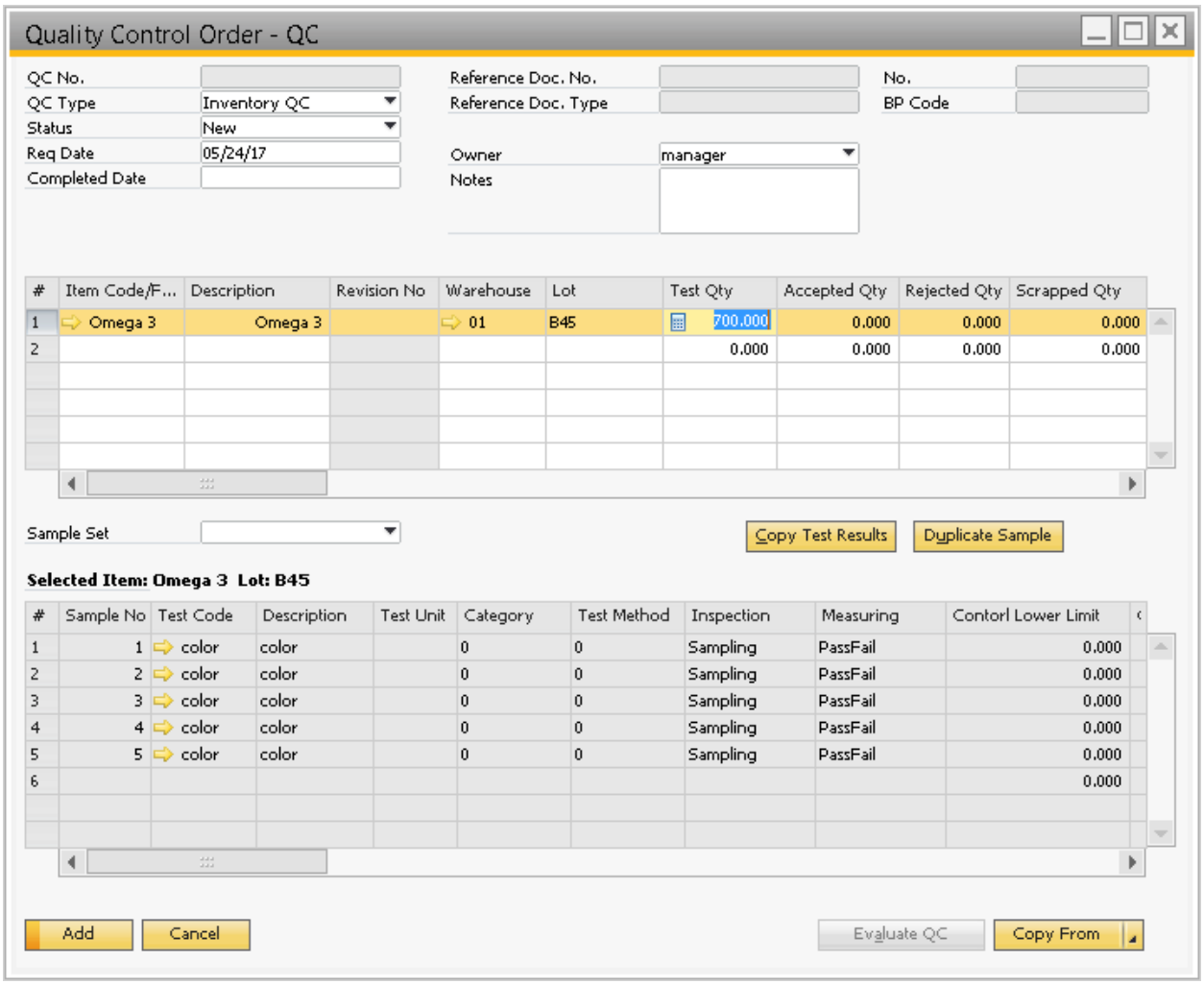
Create an item using *Item Master Data.* Provide the costing method for the item. The available choices for the costing method are: *FIFO*, *FEFO*, and *LIFO*.

Additionally, in the *Quality Control* tab of the *Item Master Details* screen, enter the quality control test, and select the checkbox for the *Inventory QC* option to perform quality control tests on the item.

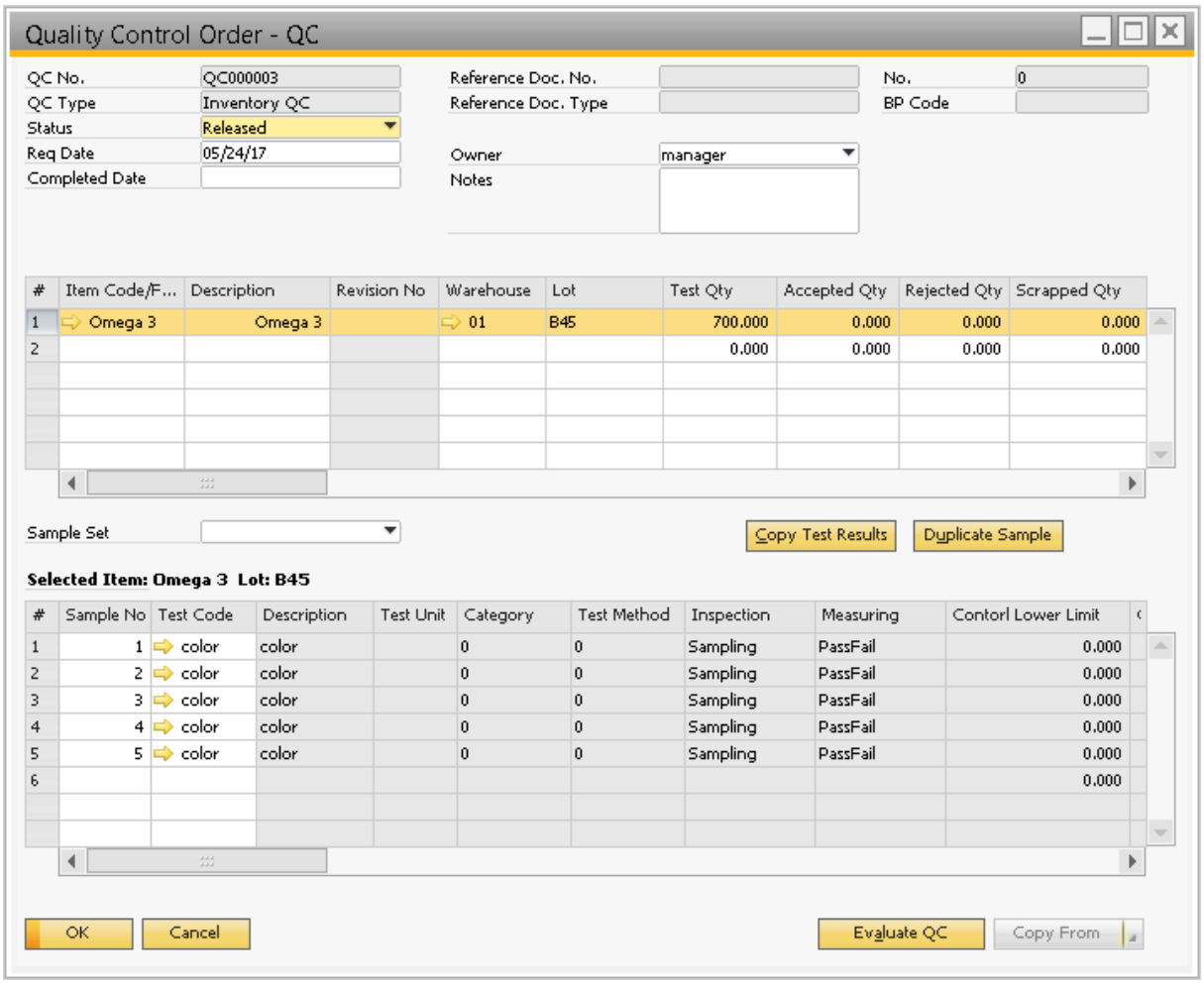


Receive lots for this item.

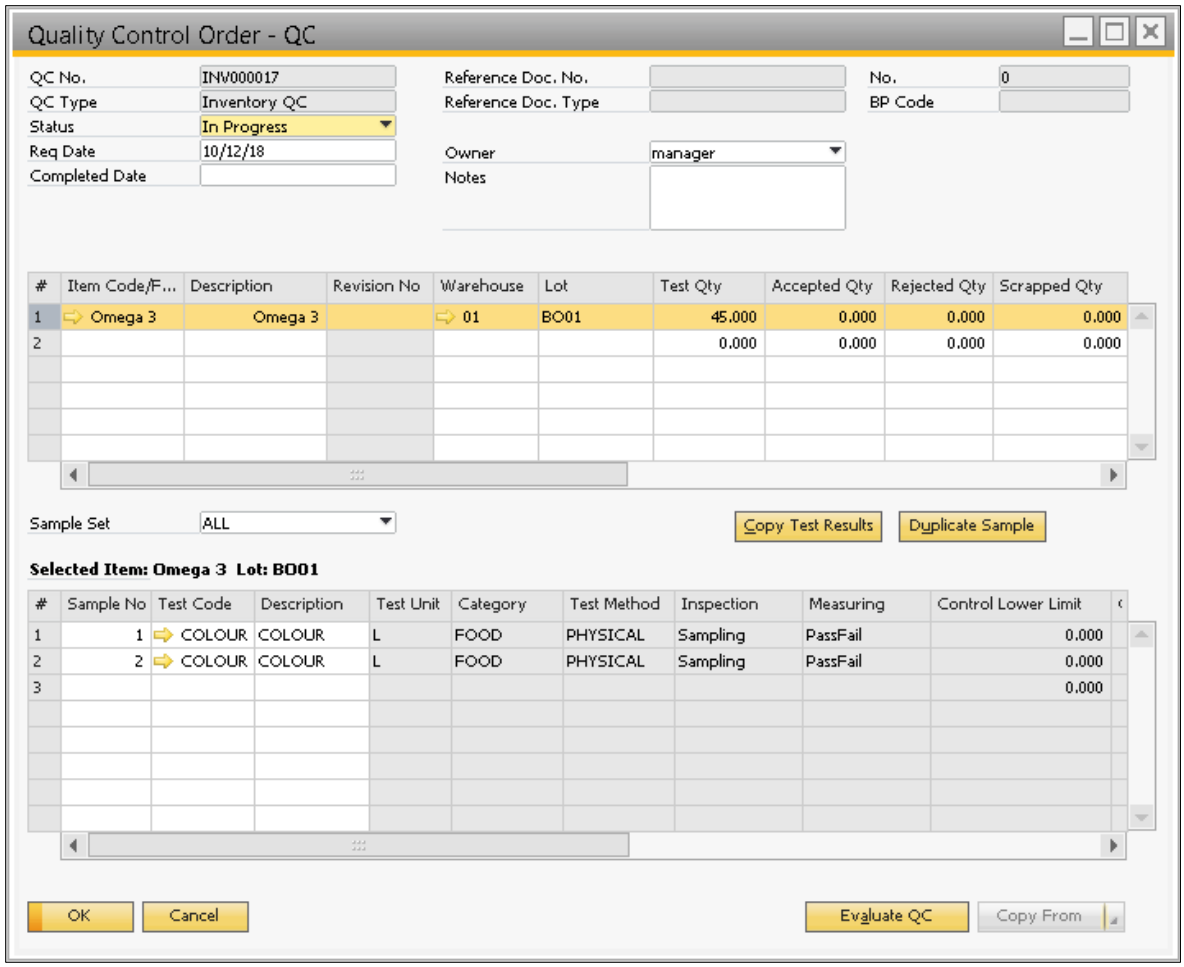
Now, go to Q*uality Control - QA*, *Quality Control - User*, or *Quality Control – QC* and create a quality control order for the item which you have received. For example, we have taken the *Quality Control Order – QC* screen. Create an inventory-type quality control order for the item, by selecting the required options from the screen.



Once the changes are saved, change the status of the Quality Control order from *New* to *Released*.



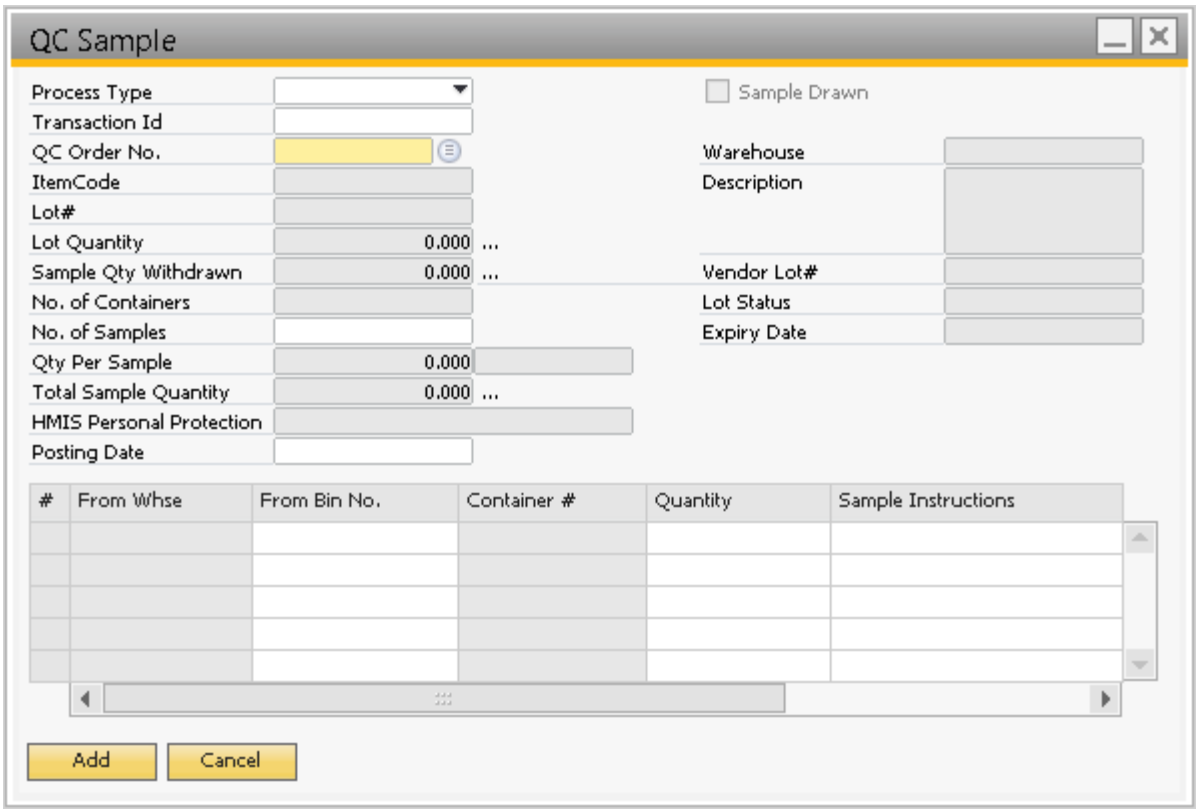
Perform the QC test, enter the test result obtained for the sample and *Update* the record. The QC Order status changes from *Released* to *In Process*.



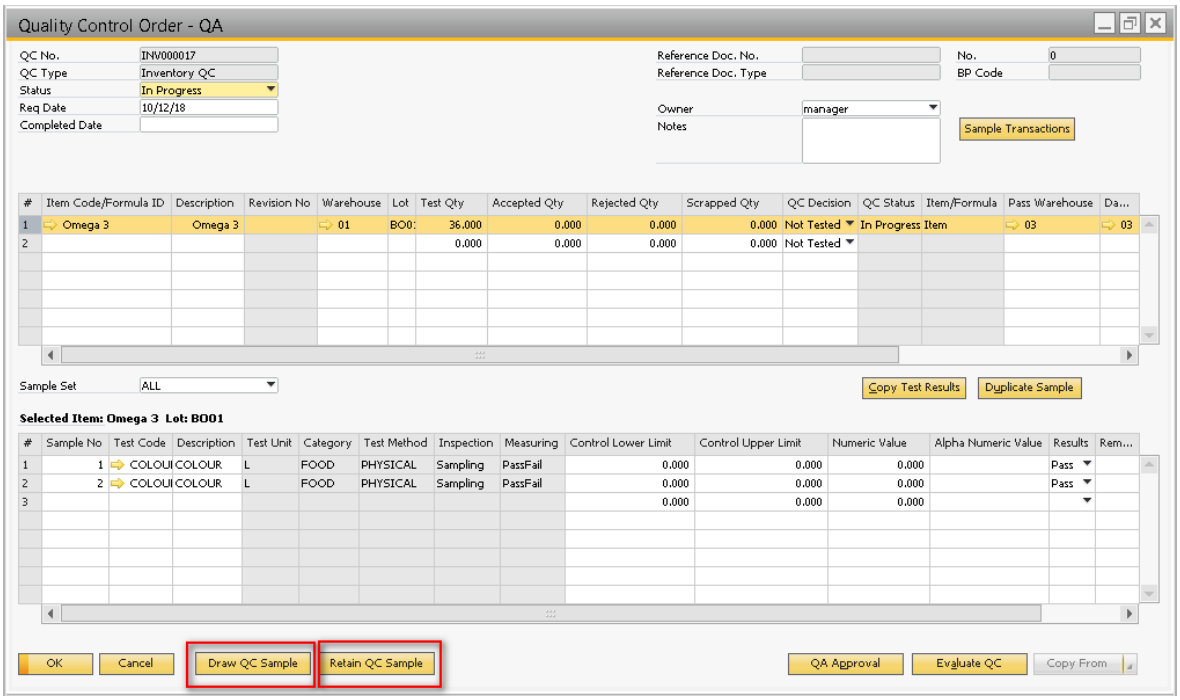
Now if you wish to keep a track of sample lot quantities used in QC, then BatchMaster ERP provides you options to *Draw QC Sample* and *Retain QC Sample*. If you draw the QC Sample lot then system will perform the Goods issue transaction for the drawn quantity. While if you Retain the QC Sample lot then the sample quantity will be transferred to specified warehouse.

Use the *QC Sample* Screen to perform the action. To access the screen

Go To: Quality Control → QC Sample



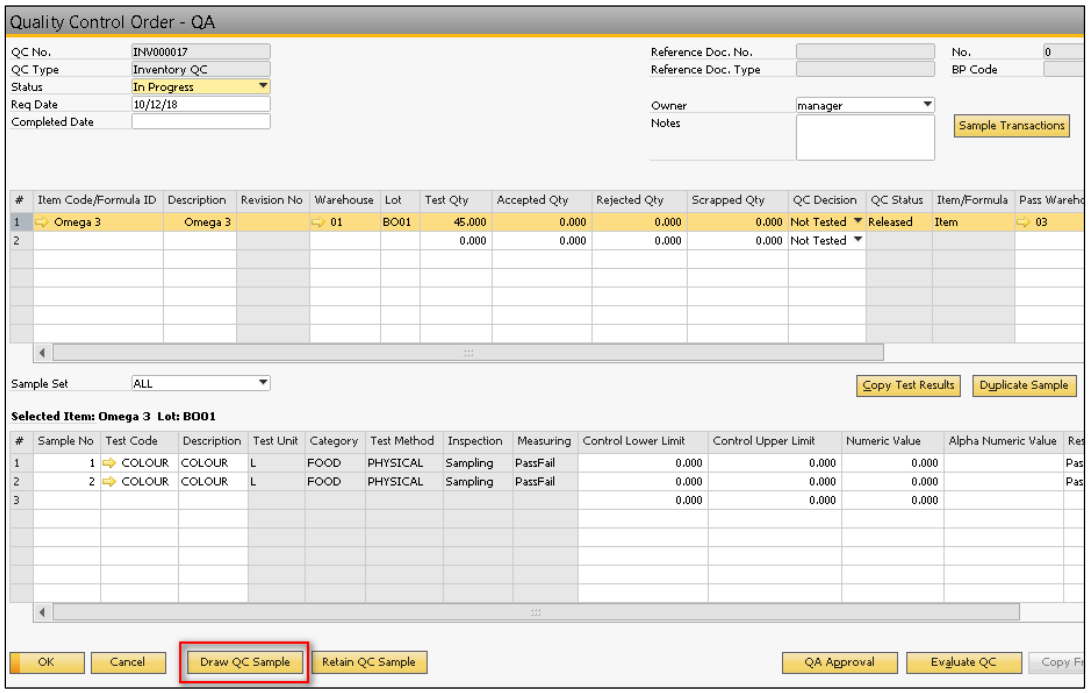
The *QC Sample* screen can either access directly from the *Quality Control Order-QA* screen, using the *Draw QC Sample/Retain QC Sample* button.



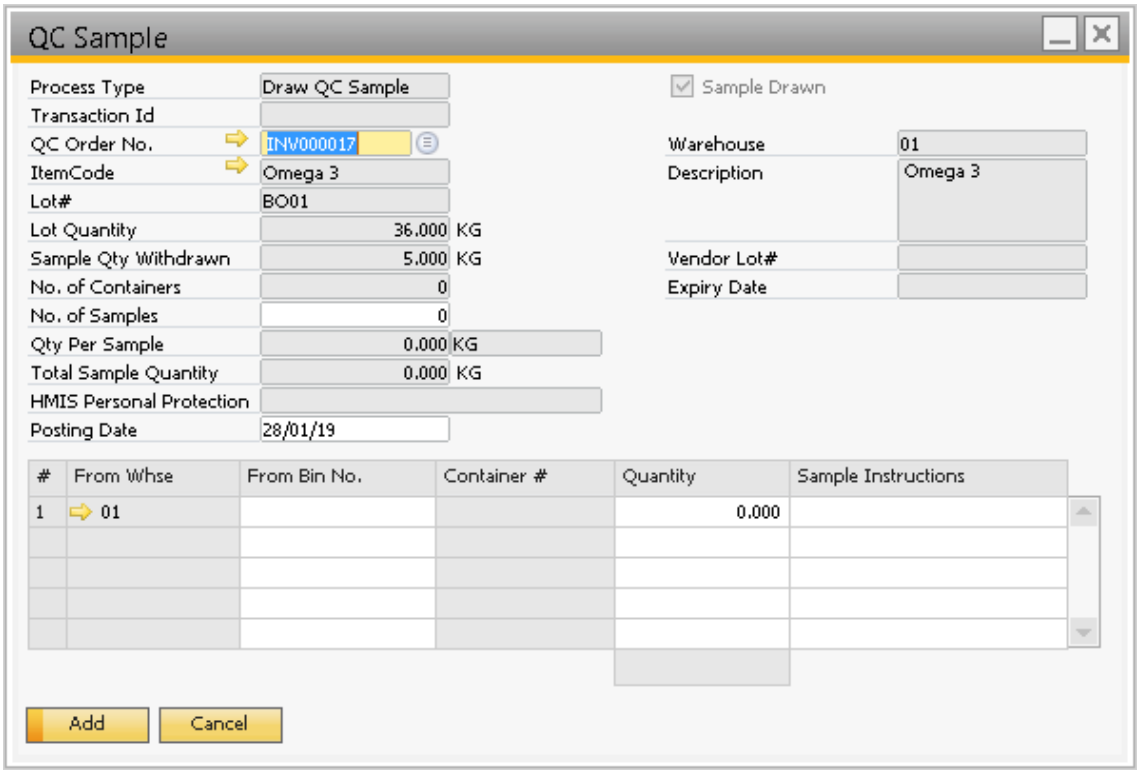
If you open the *QC Sample* screen directly from the *Quality Control Order-QA* screen then sample details get auto filled on the basis of respective QC order. While, if you open the screen from the menu then the *Process Type* and *QC order* needs to be specified.

Draw QC Sample

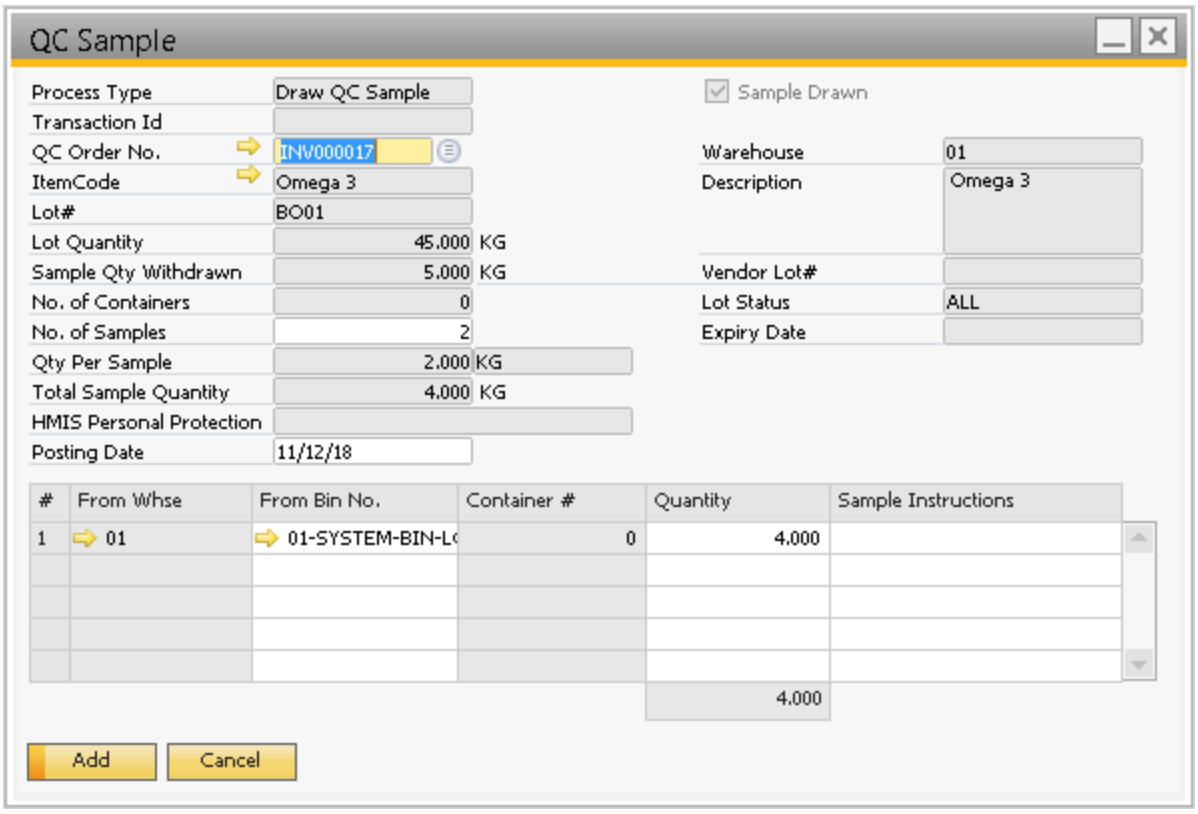
Let's first perform the *Draw QC sample* of the sample lot used in QC. For this click on the *Draw QC Sample* button available on the *Quality Control Order QA* screen.



On the *QC Sample* Screen, observe that the *Process Type* as *Draw QC Sample*, *QC Order number* and lot details get auto filled.

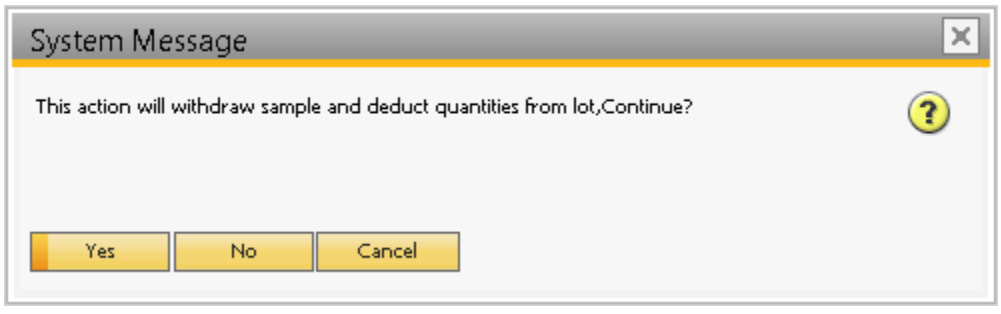


In the grid, specify the *Bin/Container No* and the *Quantity* of the sample lots needed to be drawn. Also, specify the *No of samples* in the respective field.

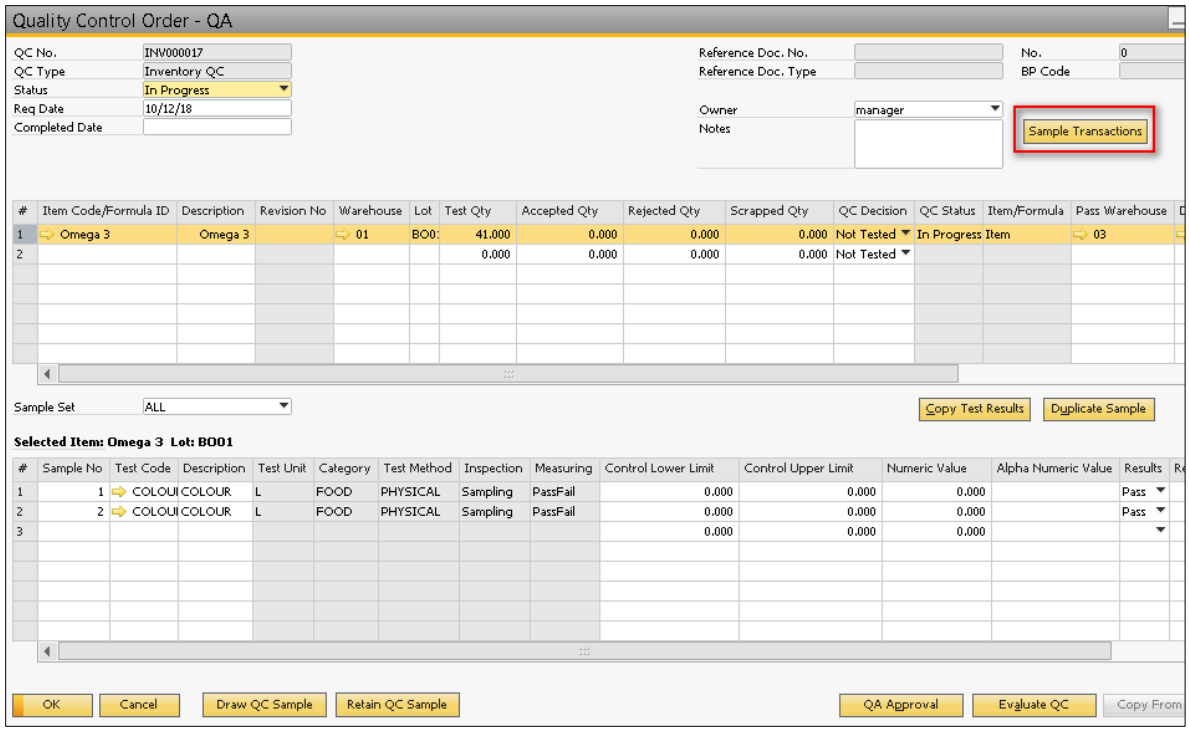


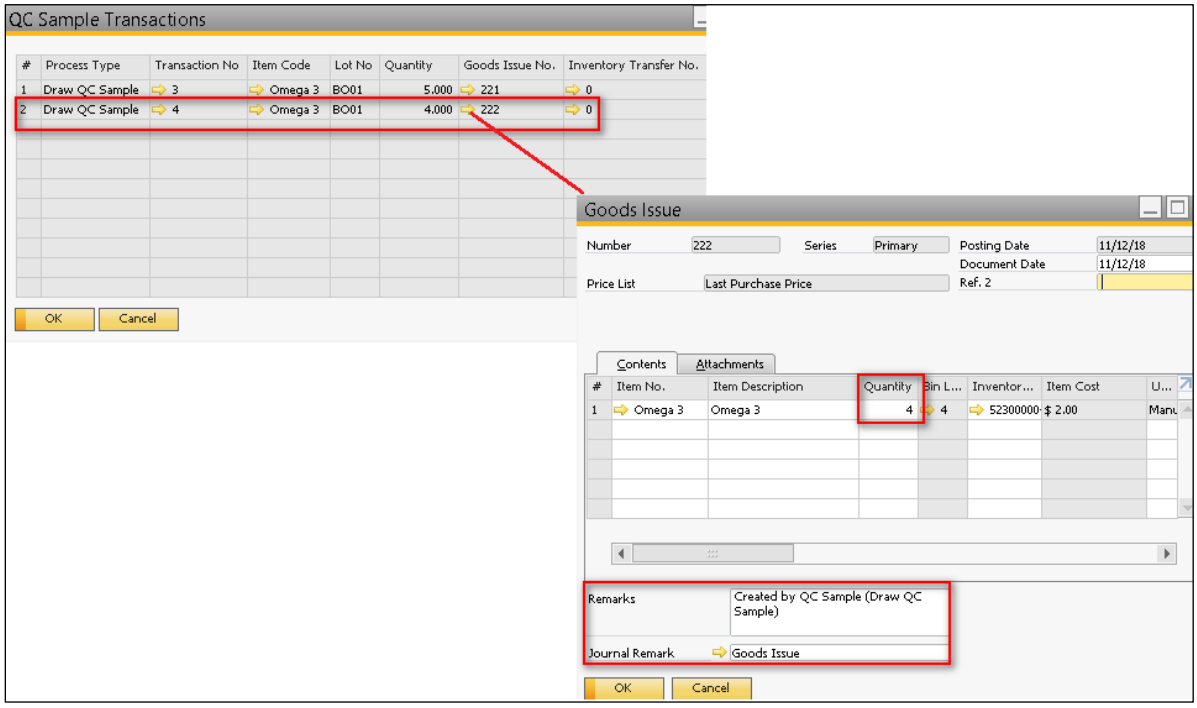
The Lot Quantity field will show only that quantity of lots whose status will allow inventory transfer.

Click on the *Add* button. The system displays a message as below before withdrawing the sample quantity from the lot. Click on *Yes* to confirm.



The System will perform the *Goods Issue* transaction for the drawn lot quantity. You can view *Sample Transaction* details from the *Quality Control Order QA* screen.



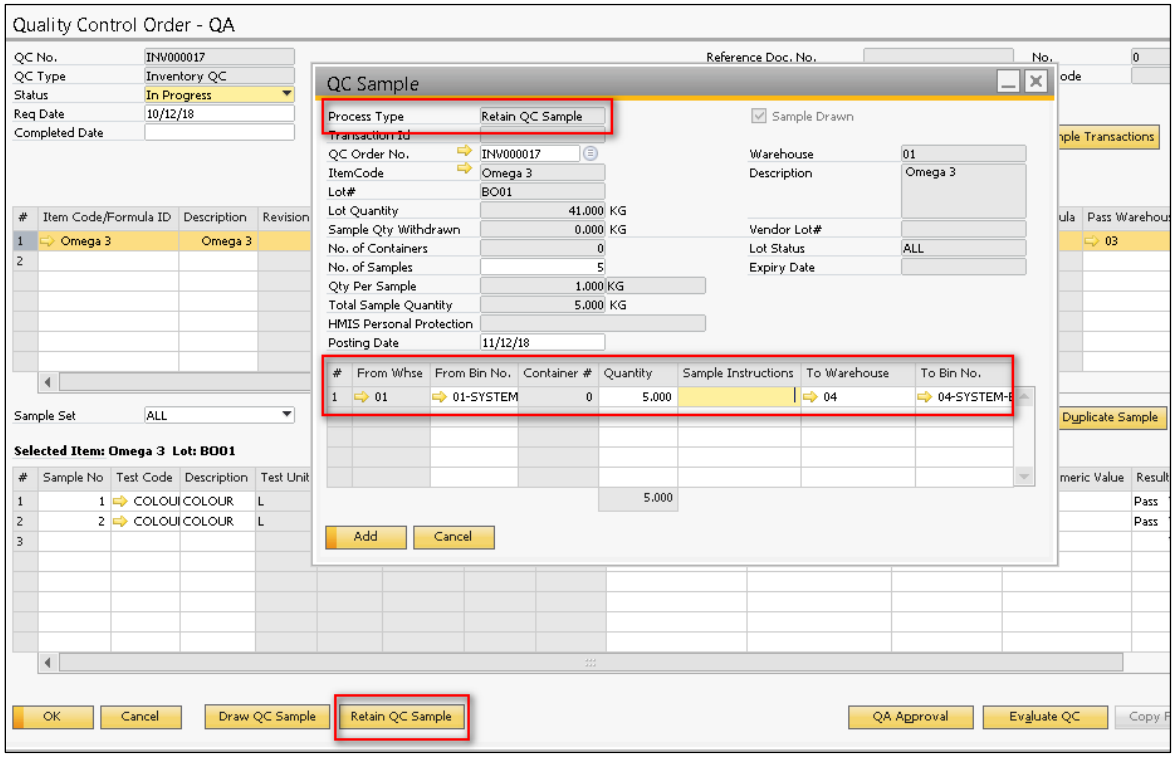


The Issue document *Posting Date* is the *Posting date* you specified on the *Draw QC Sample* screen.

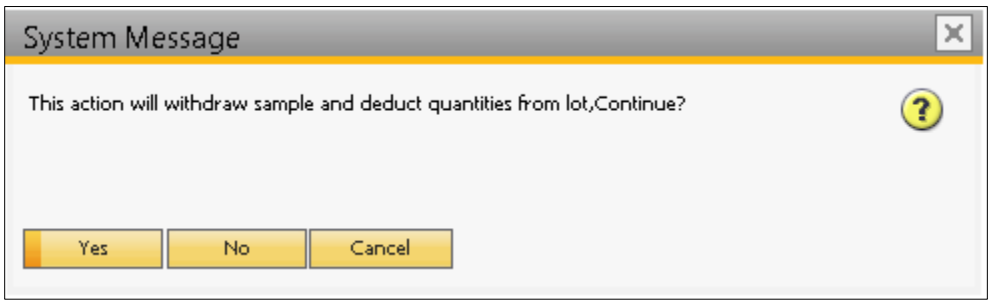
Retain QC Sample

Retaining the QC Sample is helpful if you wish to keep the sample lot quantity at particular warehouse. Thus, to perform the *Retain QC sample* process you are required to specify an exact location where the sample lot will be transferred. For this, on the *QC Sample* screen, enter the *To warehouse* and *To Bin No*.

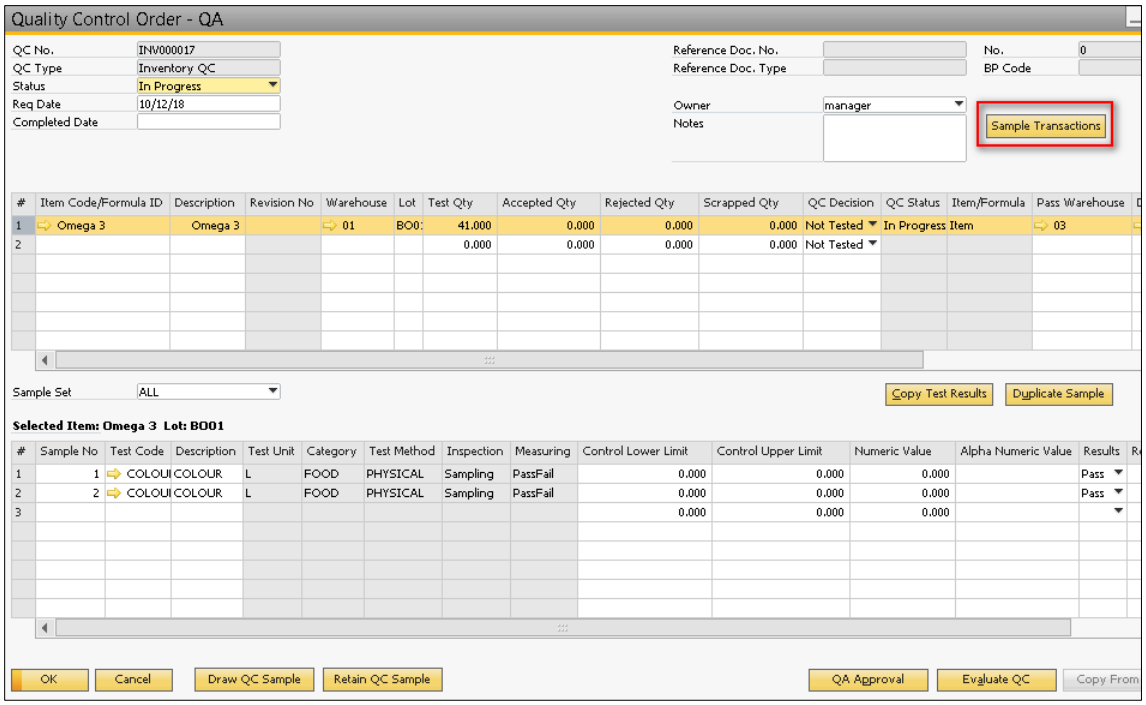
ANY QC Rejected lot will not be included when you perform the Retain Sample.

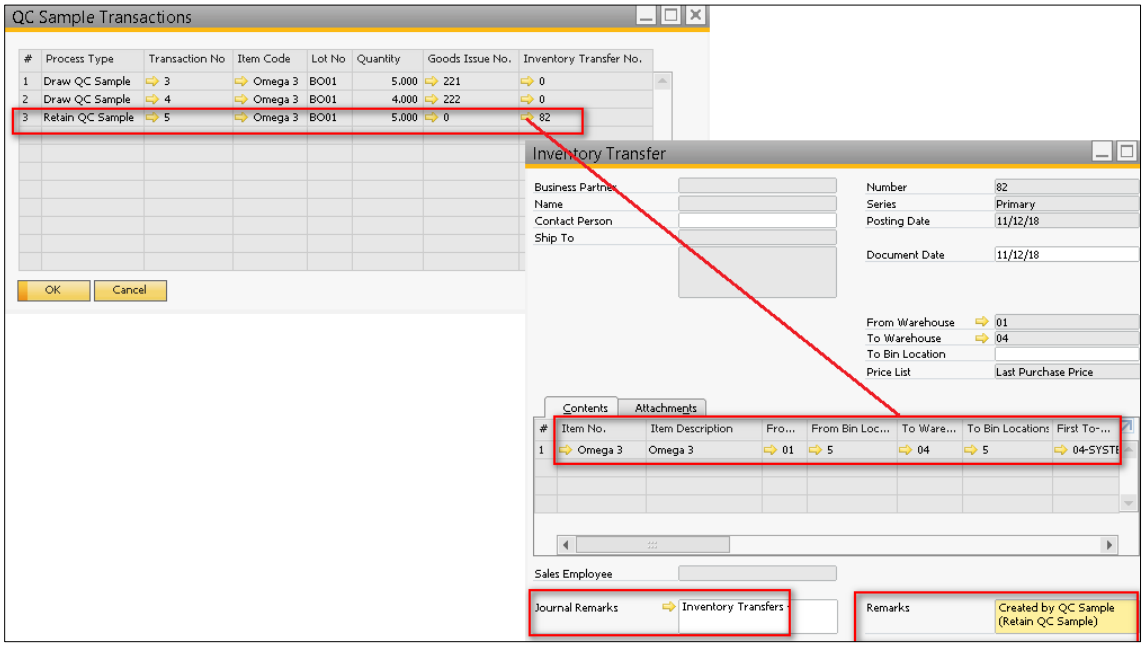


Click the *Add* button. The system displays a message as below before withdrawing the sample quantity from the lot. Click *Yes* to confirm.



The System performs an inventory transfer of the *QC sample* lot to the specified warehouse bin location. You can view *Sample Transaction* details from the *Quality Control Order QA* screen.


Quality Control Order - QA
QC No. INV000017
QC Type Inventory QC
Status In Progress
Req Date 10/12/18
Completed Date
Reference Doc. No.
Reference Doc. Type
No. 0
BP Code
Owner manager
Notes
Sample Transactions
Item Code/Formula ID Description Revision No Warehouse Lot Test Qty Accepted Qty Rejected Qty Scrapped Qty QC Decision QC Status Item/Formula Pass Warehouse
1 Omega 3 Omega 3 01 BO0 41.000 0.000 0.000 0.000 Not Tested In Progress Item 03
2 0.000 0.000 0.000 0.000 Not Tested
Sample Set ALL
Copy Test Results
Duplicate Sample
Selected Item: Omega 3 Lot: BO01
Sample No Test Code Description Test Unit Category Test Method Inspection Measuring Control Lower Limit Control Upper Limit Numeric Value Alpha Numeric Value Results
1 1 COLOUI COLOUR L FOOD PHYSICAL Sampling PassFail 0.000 0.000 0.000 Pass
2 2 COLOUI COLOUR L FOOD PHYSICAL Sampling PassFail 0.000 0.000 0.000 Pass
3 0.000 0.000 0.000
OK
Cancel
Draw QC Sample
Retain QC Sample
QA Approval
Evaluate QC
Copy From


QC Sample Transactions
Process Type Transaction No Item Code Lot No Quantity Goods Issue No. Inventory Transfer No.
1 Draw QC Sample 3 Omega 3 BO01 5.000 221 0
2 Draw QC Sample 4 Omega 3 BO01 4.000 222 0
3 Retain QC Sample 5 Omega 3 BO01 5.000 0 82
OK
Cancel
Inventory Transfer
Business Partner
Name
Contact Person
Ship To
Number 82
Series Primary
Posting Date 11/12/18
Document Date 11/12/18
From Warehouse 01
To Warehouse 04
To Bin Location
Price List Last Purchase Price
Contents
Attachments
Item No. Item Description Fro... From Bin Loc... To Ware... To Bin Locations First To-...
1 Omega 3 Omega 3 01 5 04 5 04-SYSTE
Sales Employee
Journal Remarks Inventory Transfers
Remarks Created by QC Sample (Retain QC Sample)

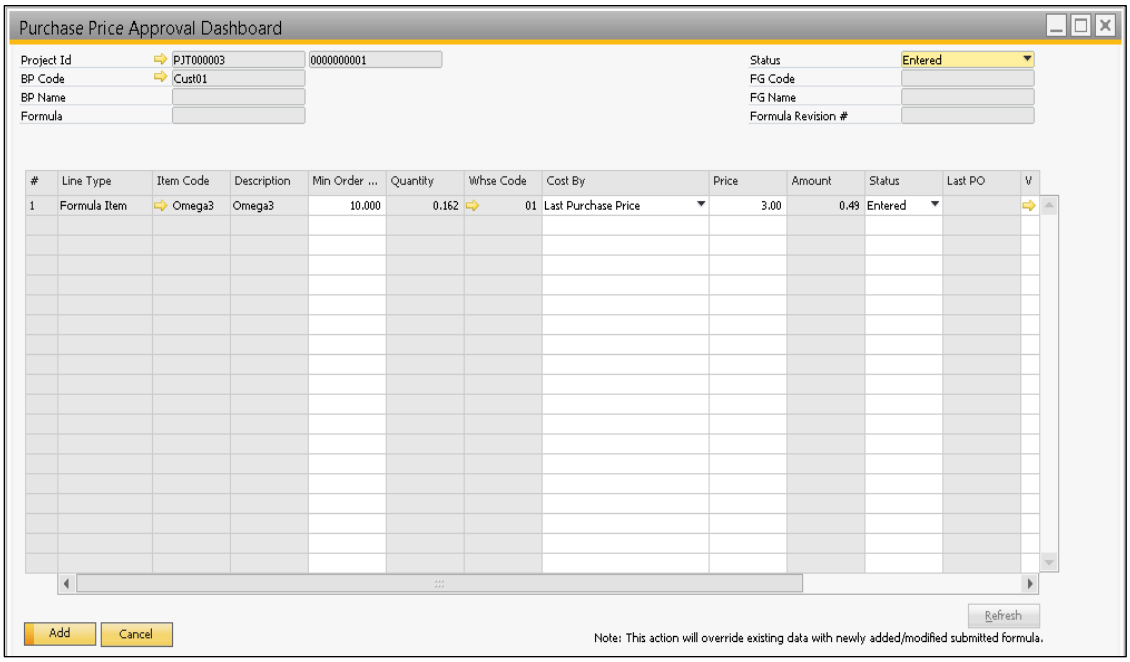
11 Purchase Price Approval Dashboard

Once you have added formula and packaging details on the *Product Development* screen, you need to prepare a purchase price list for the formula ingredients and the packaging materials and get it approved. You can do so using the *Purchase Price Approval Dashboard*. You can access the screen directly from the Purchase-A/P module or open it from the *Go To* menu of the *Product Development* screen.

On the dashboard, select the sample whose purchase price list should be approved. You can observe that the raw materials and packaging materials along with prices appear on the dashboard.

Your purchasing manager can review the price of materials on this dashboard and approve individual material cost as well as the entire price list.

Go To: Purchase – A/P → Purchase Price Approval Dashboard



On the *Purchase Price Approval Dashboard*, select the *Status* of the purchase price approval. The status indicates whether or not the purchase price list has been approved.

The *FG Code/Name* are defaulted from the Project.

The grid or the table stores cost details of individual items required in making the sample. Using the *Cost By* field, you can define the price list that decides the cost of each item, choose the *Last Purchase Price, Last Evaluated Price or Item Cost* option.

Alternatively, you can manually enter the price of the item, in the *Price* field. For lab items, the approved price will be updated on the *Physical Property Analysis* screen, and when posted by converting the experimental formula to development it is reflected on the formula as well.

Based on *Quantity* and *Price*, system will automatically calculates the product of two and displays the value as the total price of the item, in the *Amount* field.

Next, enter the *Status* of the price approval for every item. This status is different from the *Status* in the header, which indicates the status of purchase price approval for the sample, in whole. The available statuses are: *Entered*, *Hold*, and *Approved*.

You can directly drill down to the Purchase Order from the Last PO # field.

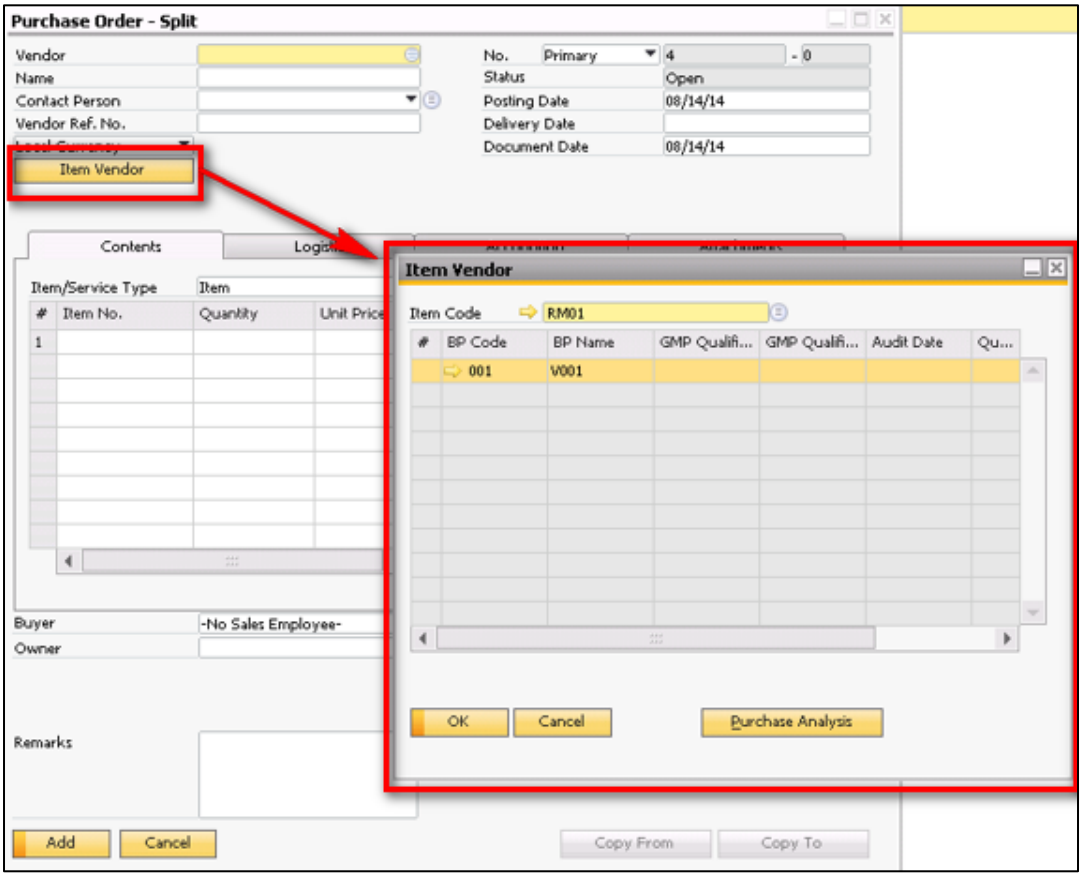
Finally, you can enter the unique identification code of the vendor who has quoted this price for the item, in the *Vendor Code* field. This option provides you a lookup of approved vendors or all vendors based on the setup option.

Use the *Refresh* button to refresh the prices approved for the Base Formula with the prices of the newly submitted formula (if submitted on the Product Development Screen).

Click the *Update* button to save the changes. As soon as purchase price of sample is approved and you close the respective activity, the status of the sample request changes to *Purchase Price Approved.*

11.1 Buying from an Approved Vendor

Use the Item Vendor button on the Purchase Order screen to spot approved vendors from whom the item can be purchased. Clicking this button displays the Item Vendor screen, which facilitates you to get the list of approved vendors for the selected item as maintained on the Business Partner Catalog numbers screen.



When you choose the desired vendor-item combination from the screen, the item details get auto-populated in the grid of the *Purchase Order* screen.

12 Third Party Manufacturing

Third Party manufacturing, also known as sub-contracting or outsourcing, can provide the following benefits:

- Free up capacity for other manufacturing needs
- Provide additional capacity during periods when demand exceeds your ability to supply product
- Take advantage of specialized processing and/or testing capabilities at the sub-contractor
- Potential lower cost per unit than if you make the item in-house
- Integration of labor costs and their impact on finished goods (FG) costs

Like most business opportunities, sub-contracting presents some risks:

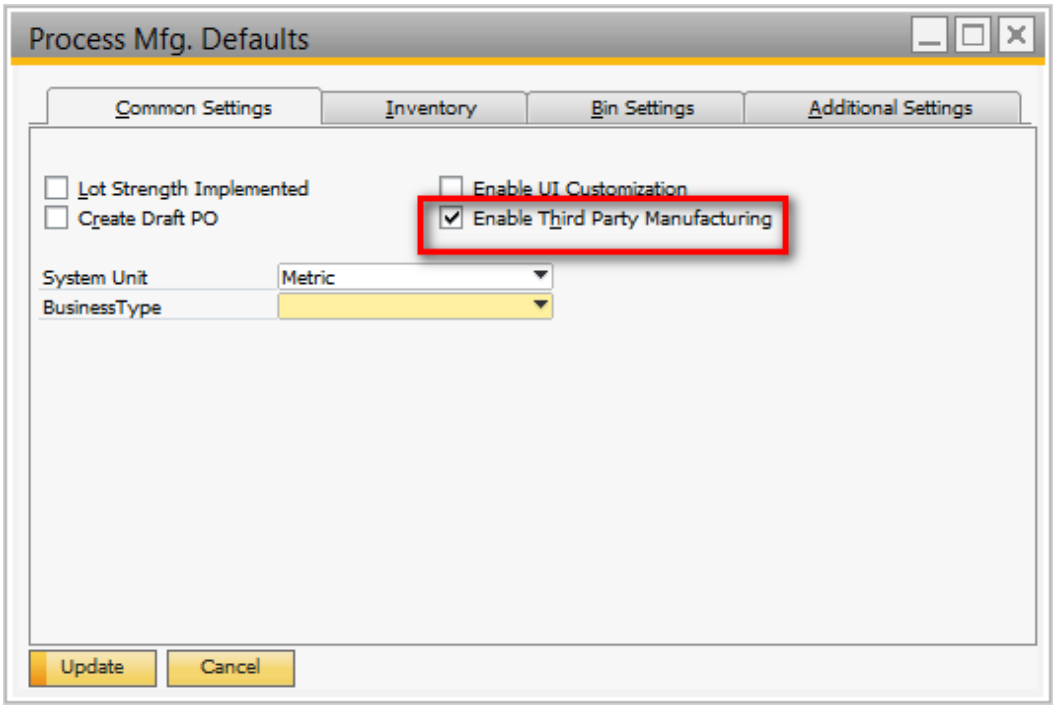
- Loss of control: it's difficult to track off-site production
- Capacity at the sub-contractor may not be available when you need it
- Potential quality and delivery issues
- Exposure of your product and formula to outside parties

The bottom line is you must establish and maintain a relationship of trust and communication.

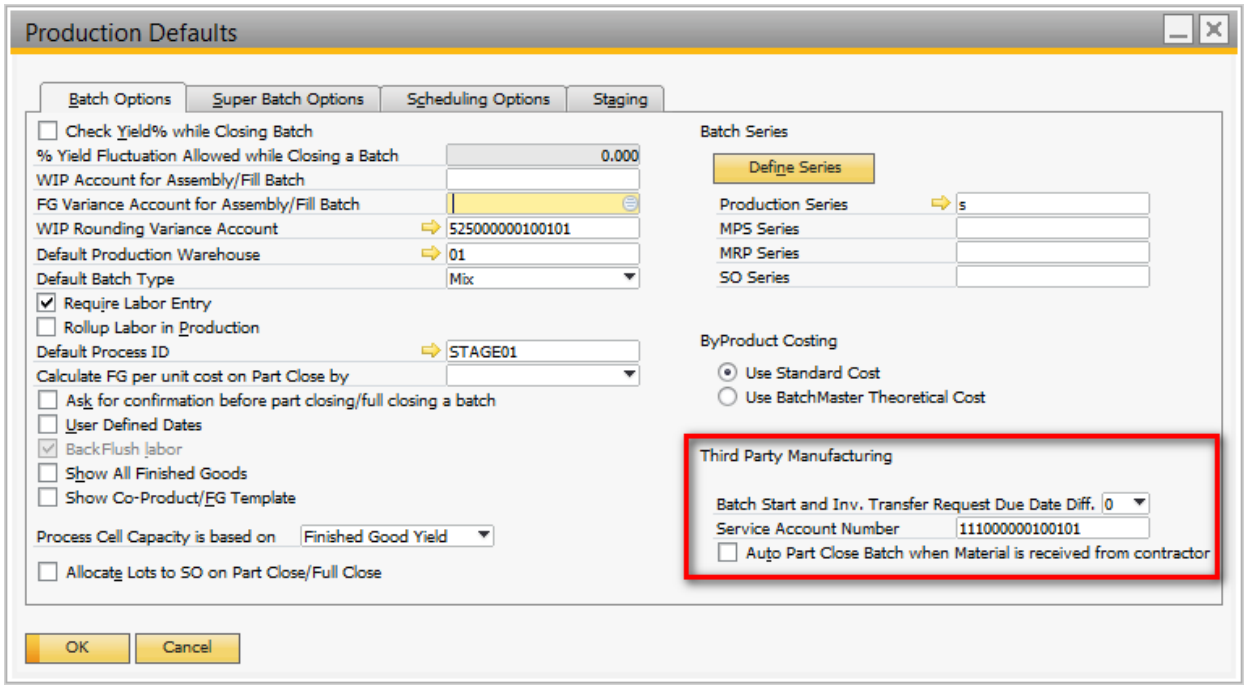
12.1 Set-up Steps: Defaults

On the process manufacturing defaults screen, enable third party manufacturing by checking the box, then click UPDATE to save your work.

Go To: Administration → Setup → System Initialization → Process Mfg. Defaults



Go To: Administration → Setup → Production → Production Defaults.



Batch Start and Inv. Transfer Request Due Date Diff: As part of third-party manufacturing, you will create an inventory transfer request to move items from your warehouse to the sub-contractor's warehouse. At the production defaults screen, you instruct the system whether the inventory transfer request is due on the batch start date or the day before.

Service Account Number: Enter the account number for Service PO Liabilities (or a similar description)

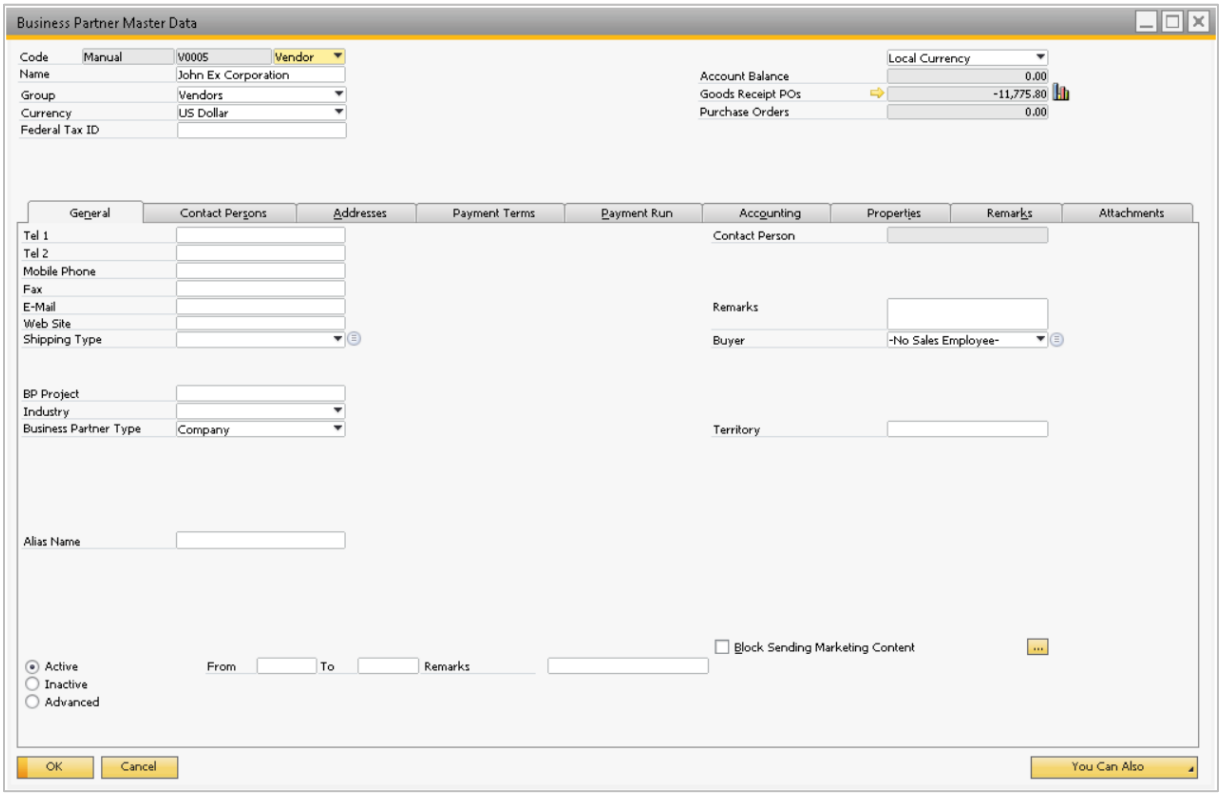
Auto Part Close Batch when material is received from contractor: Leave this option unchecked if you want to use the Third Party Dashboard functionality.

Click UPDATE to save your work.

12.1.1 Business Partner Setup

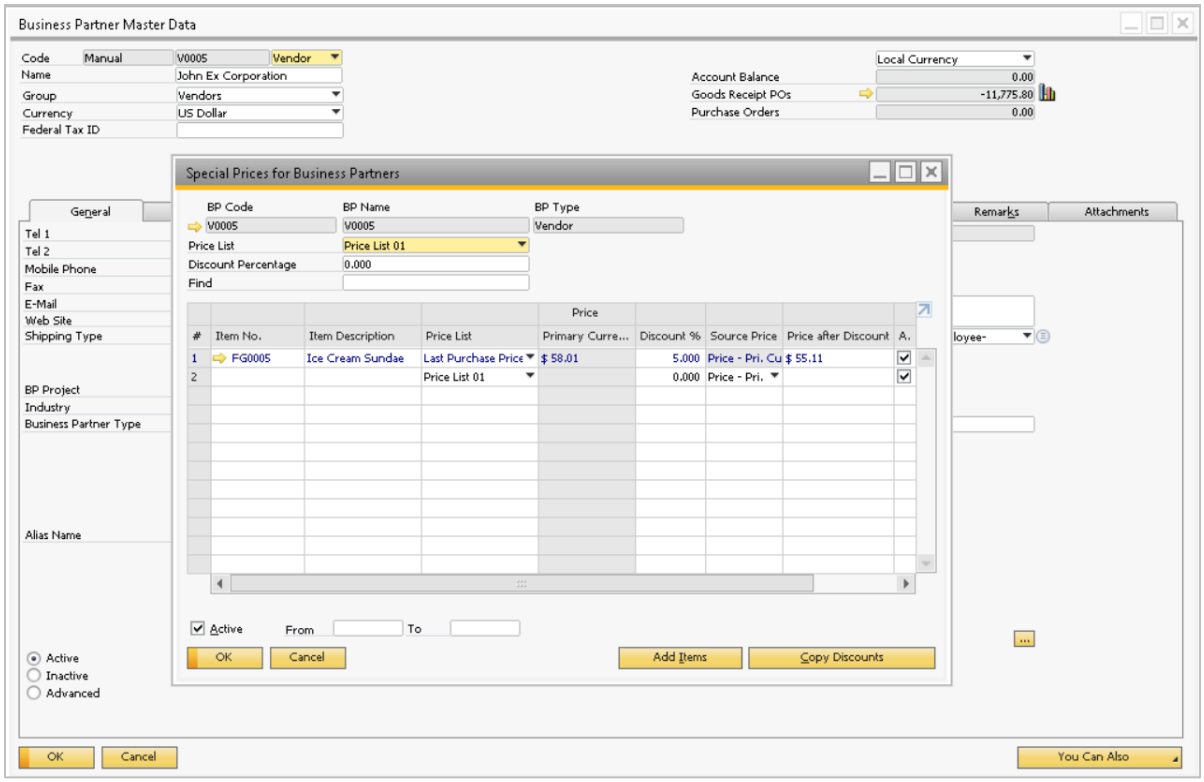
Define the contract manufacturer as a vendor in the Business Partner records.

Go To: Business Partners → Business Partner Master Data.



12.1.1.1 Special Prices For Business Partner

The Special Prices for BP section allow users to map vendors with FG, while the Period Discounts pop-up enables defining service charges for a specific date range. The Volume Discount configuration further allows users to set quantity-based service charges using the Special Price field (SAP standard), ensuring a structured and scalable pricing approach.



If *Consider Special BP Price* checkbox is selected on the *Third Party* Tab of *Bill of Material* screen, the system allows you to associate special pricing with the Vendor linked to the third-party warehouse. This special pricing is applied to the labor cost during batch entry and impacts the standard cost upon batch close.

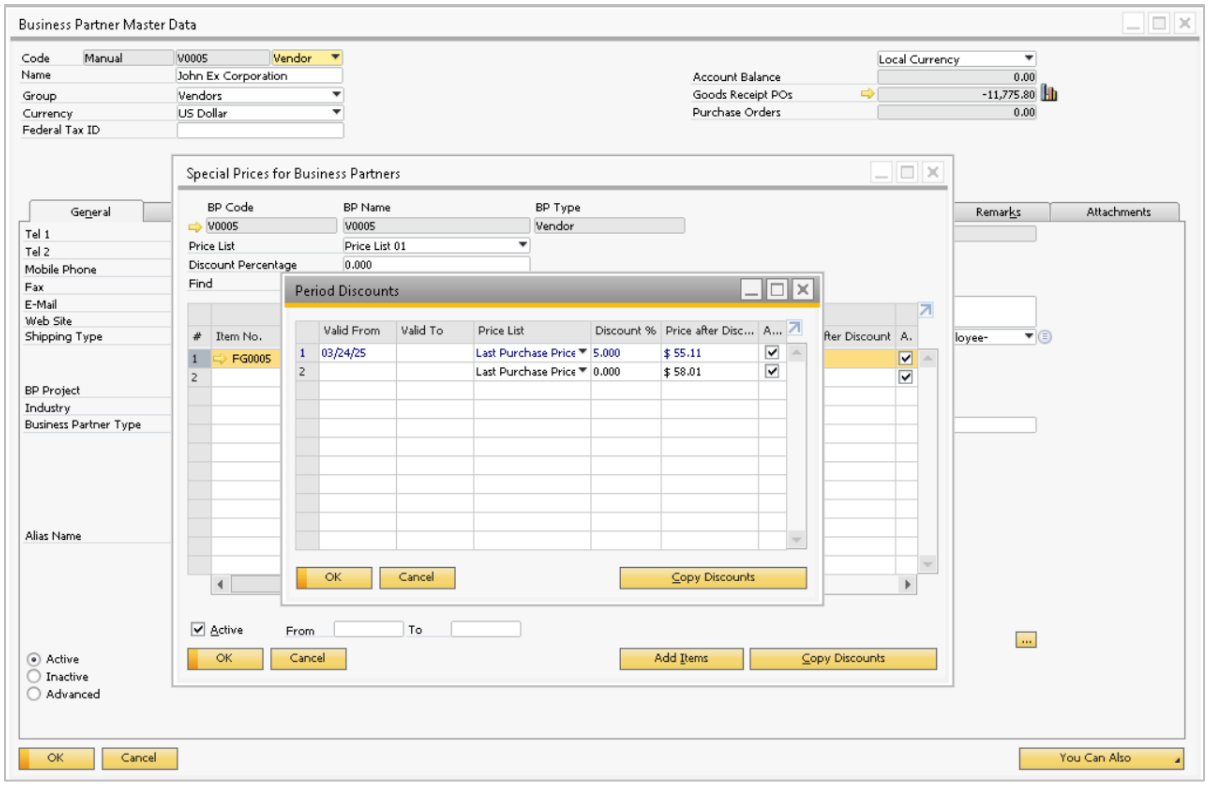
Thus, while closing the production batch, the system automatically calculates third-party service costs based on the posted and updated Service GRPO. It then posts a journal entry (JE) for the service charge, updates the FG unit cost by incorporating the service cost, and clears the work-in-progress (WIP) account, ensuring all costs are transferred to the FG account.

12.1.1.2 Period Discounts

In SAP Business One (SAP B1), managing Period Discounts for a Business Partner (BP) enables time-based special pricing for customers or vendors.

This screen allows mapping service charges by date and quantity using Special BP Partner pricing and defined Period Discount.

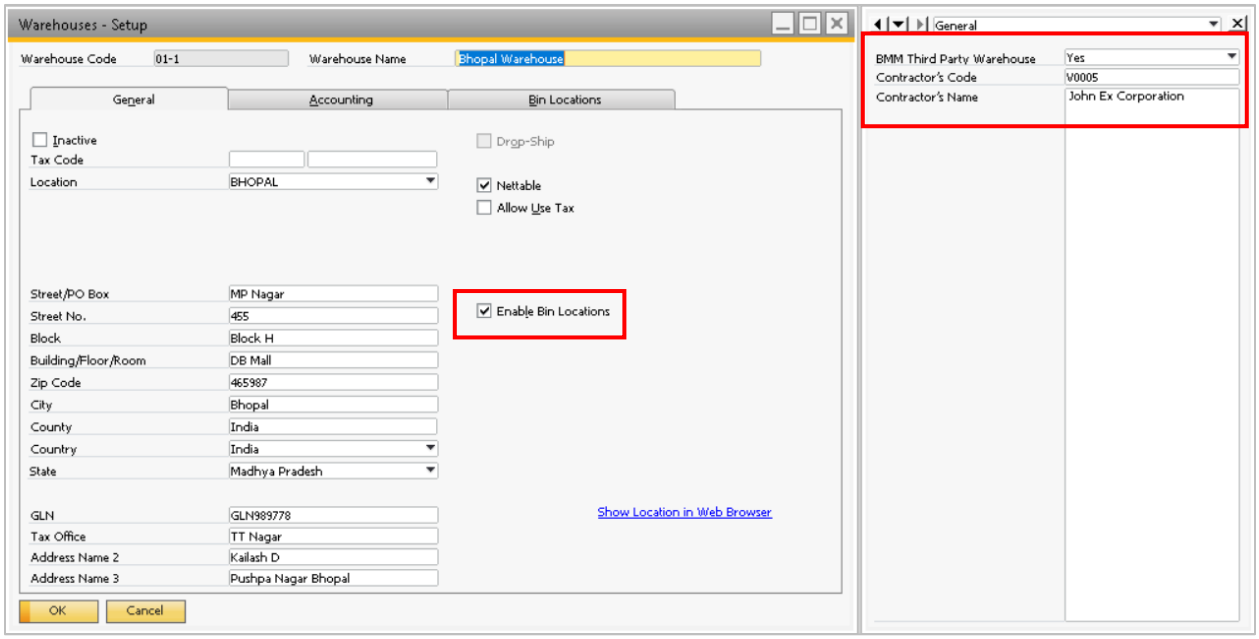
To configure this, navigate Business Partners Master Data. Maintain the data for the Vendor and from the context Menu, select Special Prices For Business Partner Option to maintain price list and select the relevant FG item. Double-click to open the Period Discounts window and define the Valid From and Valid To dates along with the discount percentage or Price After Discount. For Volume Discounts, double-click on a specific period to configure quantity-based discounts using slabs (e.g., 5% for 100 units, 10% for 500 units). Once set, save and apply the discounts, ensuring they are automatically reflected in transactions during the specified period.


Business Partner Master Data
Code
Manual
V0005
Vendor
Name
John Ex Corporation
Group
Vendors
Currency
US Dollar
Federal Tax ID
Local Currency
Account Balance
0.00
Goods Receipt POs
-11,775.80
Purchase Orders
0.00
Special Prices for Business Partners
General
Remarks
Attachments
BP Code
BP Name
BP Type
V0005
V0005
Vendor
Price List
Price List 01
Discount Percentage
0.000
Find
Tel 1
Tel 2
Mobile Phone
Fax
E-Mail
Web Site
Shipping Type
BP Project
Industry
Business Partner Type
Alias Name
Active
Inactive
Advanced
Period Discounts
Valid From
Valid To
Price List
Discount %
Price after Disc...
1
03/24/25
Last Purchase Price
5.000
$ 55.11
2
Last Purchase Price
0.000
$ 58.01
OK
Cancel
Copy Discounts
Item No.
FG0005
Active
From
To
Add Items
You Can Also

12.1.2 Define Contractor Warehouse

Go To: Administration → Setup → Inventory → Warehouses

Make sure to enable bin locations. When the warehouse record is saved, the system will generate a default bin location code. Next, display the user-defined fields by pressing **Ctrl+Shift+U.**

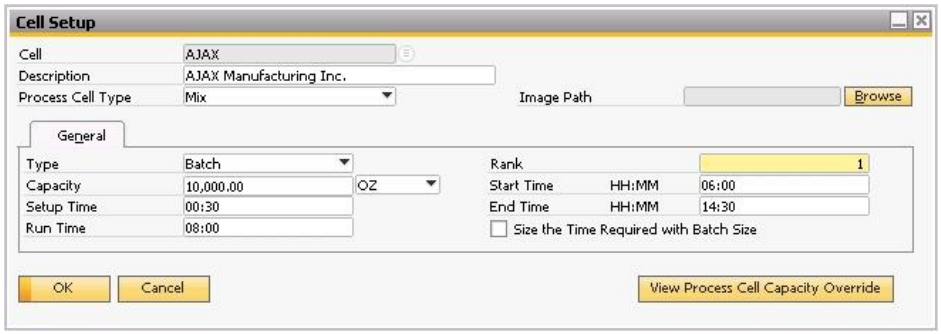


Enter the contractor's business partner code, then select "Yes" to the contractor's warehouse prompt. Click UPDATE.

BatchMaster ERP does not support Multiple Bin Locations on Third Party Warehouse. It creates and supports System Bin Location for tracking purposes. Thus you should not create any additional Third Party Warehouse Bin Location.

12.1.3 Define Outside-Processing Cell

Go To: Administration → Setup → Formula → Cell Setup



Define a unique process cell for the contract manufacturer. Doing so has two main advantages: (1) Batches opened for outside processing will not impact the scheduling of in-house jobs, and (2) you can use the scheduling dashboard to track and manage the load at the contract manufacturer.

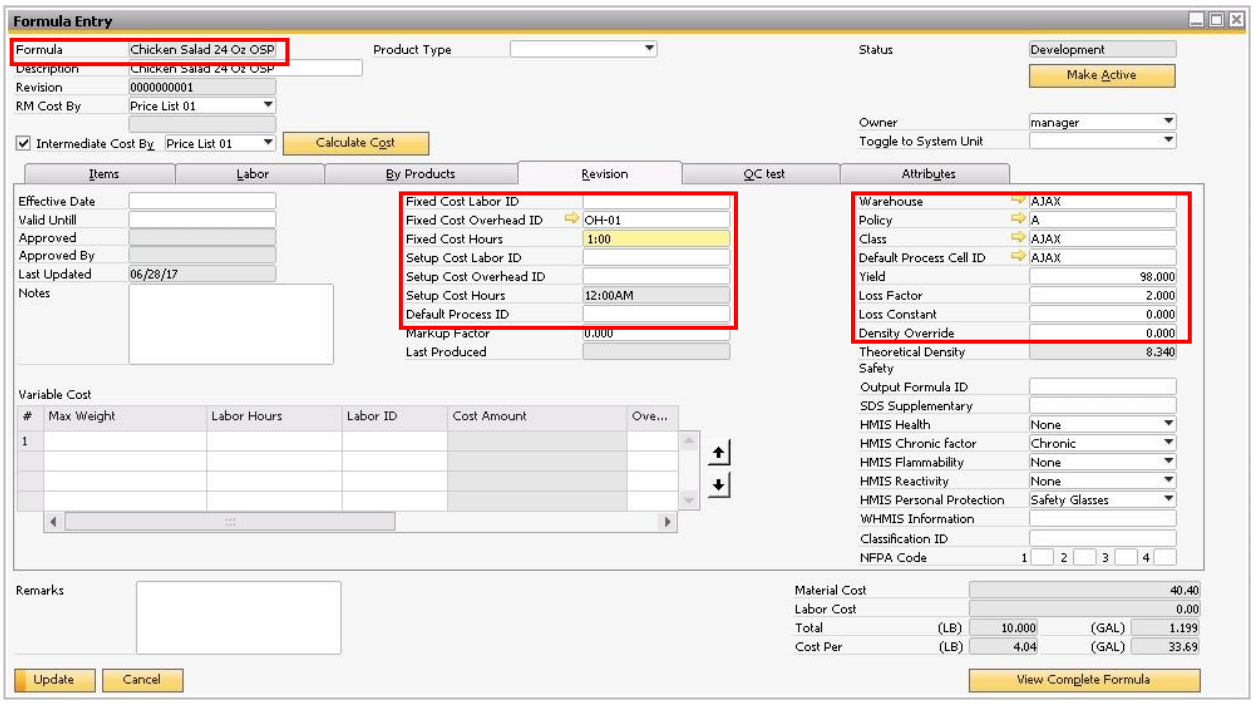
12.1.4 Define Outside Processing Formula

While not required, it may be advantageous to define a unique formula for use by the sub-contractor. Your production formula likely includes in-house labor, overhead, fixed and/or variable costs, and in-house set-up charges. None of these will apply when the product is made outside your facility. Instead, you could choose to apply a different labor and/or overhead code and number of hours to cover the cost of pulling, packing and shipping raw materials and packaging to the contractor. When you define the outside-processing formula, follow these steps:

Go To: Formulation → Formula Entry

1. Use the "find" function to call up the active revision of the desired formula in your production warehouse. Right-click in the top portion of the screen and select "duplicate." When the window is refreshed, enter a formula name that identifies it as an outside-processing formula.
2. Switch to the Labor tab and delete all row entries using the right-click function.
3. Switch to the By-Products tab and delete all row entries.
4. Switch to the QC Test tab and delete all row entries.
5. Switch to the Attributes tab and make any needed changes.
6. Return to the Revision tab (see next page) and enter appropriate data in the fields boxed in red. Pay particular attention to the *warehouse* field – be sure to enter the contractor's warehouse code. After saving the development revision, click the "Make Active" button.

Refer to the *BME-B1 18.2 Formulation User Guide* for more details.

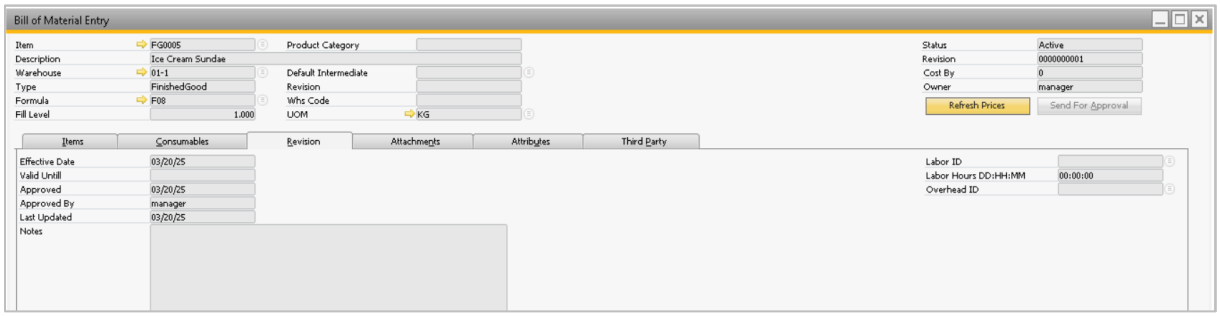


12.1.5 Define Outside-Processing Bill of Materials

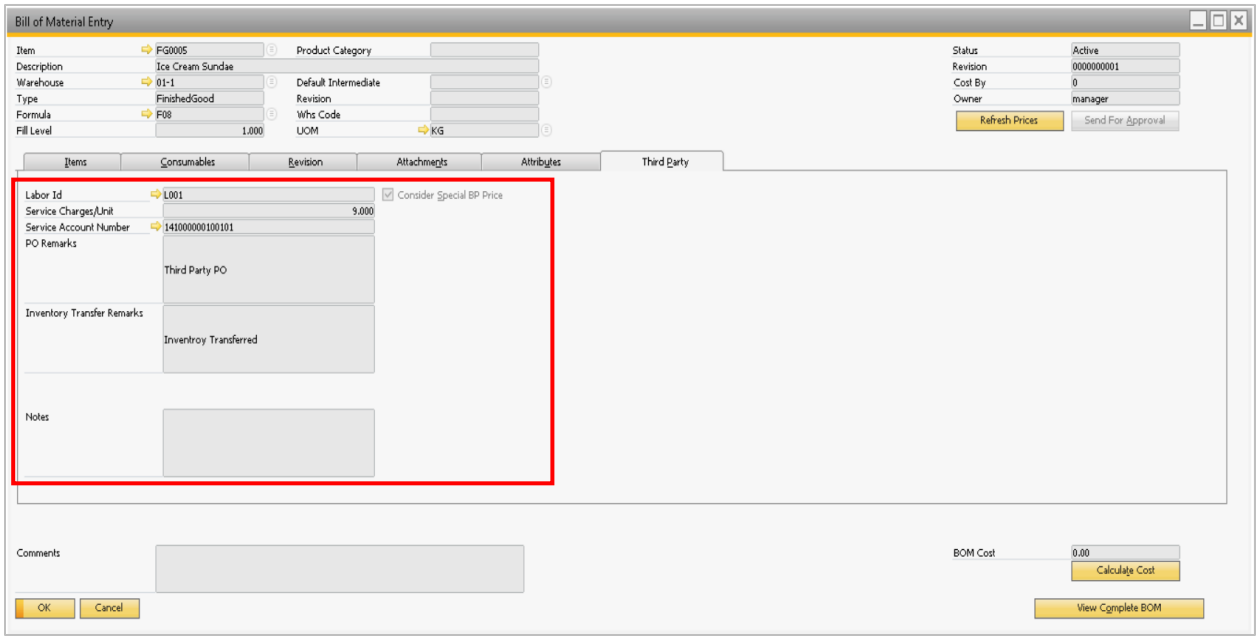
Go To: Bill of Material → Bill of Material Entry

Use the "find" function to call up the active revision of the desired BOM in your production warehouse. Right-click in the top portion of the screen and select "duplicate." When the window is refreshed, re-type the item name or use the look-up function to fill the field. Enter the codes for the outside-processing warehouse and formula. Switch to the revision tab, remove any Labor ID or Overhead ID codes, and zero out any labor hours. Save the development revision, then click the "Make Active" button.

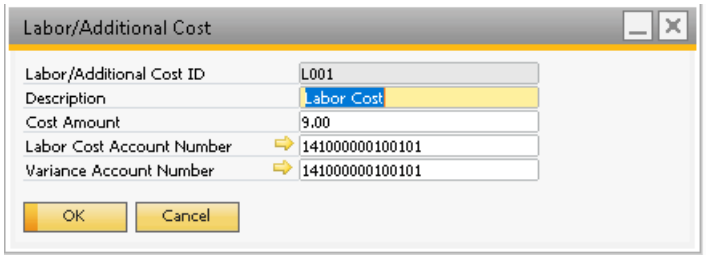
If you enter the raw materials and quantities from the outside-processing **formula** on the items tab of the **BOM** the data will appear in the inventory transfer request for the batch. You can then add or delete items and modify transfer quantities before converting the transfer request to a hard transfer. This process will be covered in detail in a subsequent section of this document.



Switch to the Third Party tab and enter the following information:



Labor ID: This field is used to link the labor created from the *Labor/Additional Cost* master. Selecting a Labor ID via the lookup automatically populates the *Service Charge/Unit* (standard labor cost) and the *Service Account Number* as specified below.



The Labor ID you specify on the *Bill of Material Entry* screen gets populated on *Batch Ticket* screen at the *Formula* tab. When a batch is created for an item with a third party BOM (configured Labor ID), a non-editable labor line is automatically added to *Batch Ticket* Screen. This ensures the labor cost is included in the final finished goods cost without manual adjustments.

Consider Special BP Pricing: If *Consider Special BP Price* checkbox is selected, the system allows for associating special pricing with the Vendor linked to the third-party warehouse.

Service Charges/Unit: this is the price the sub-contractor charges for the product

Service Account Number: defaults from Production Defaults and can be changed here

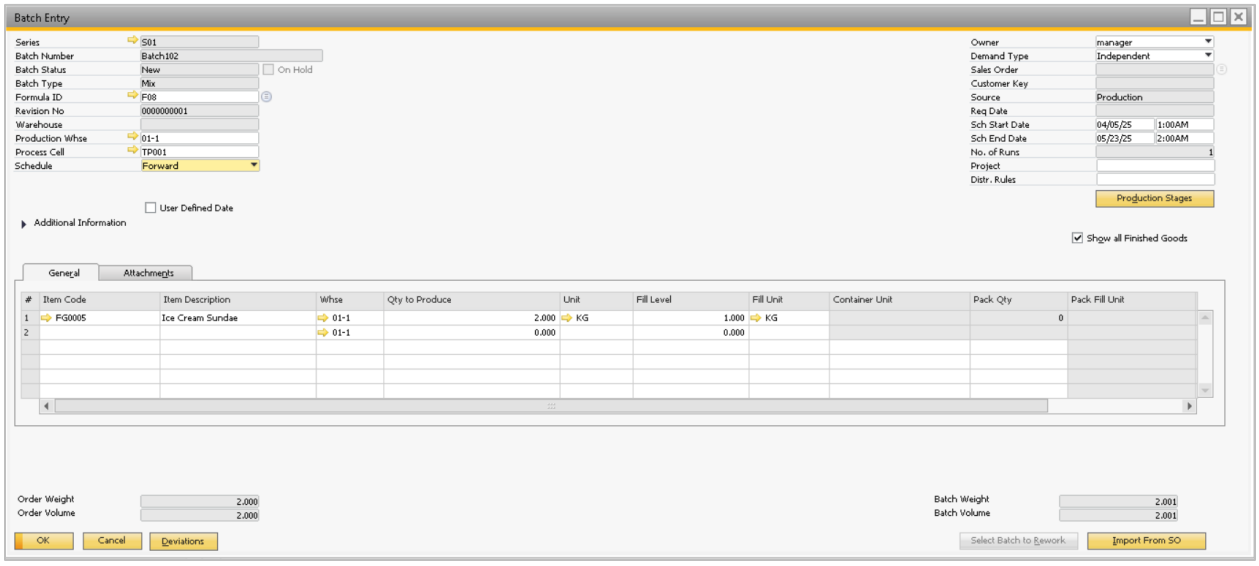
PO Remarks: will print on the purchase order sent to the contractor

Inventory Transfer Remarks: will print on the inventory transfer document

Click UPDATE to save your work.

12.2 Create Outside-Processing Batch

Go To: Process Manufacturing → Batch Entry



Open a production batch using the outside-processing formula. Enter the codes for the contractor's warehouse and process cell. In the lower grid, place your cursor in the top left cell and TAB out. The item code and warehouse information will display, as will the item's unit of measure and applicable fill data. Enter the quantity to produce and click on ADD button.

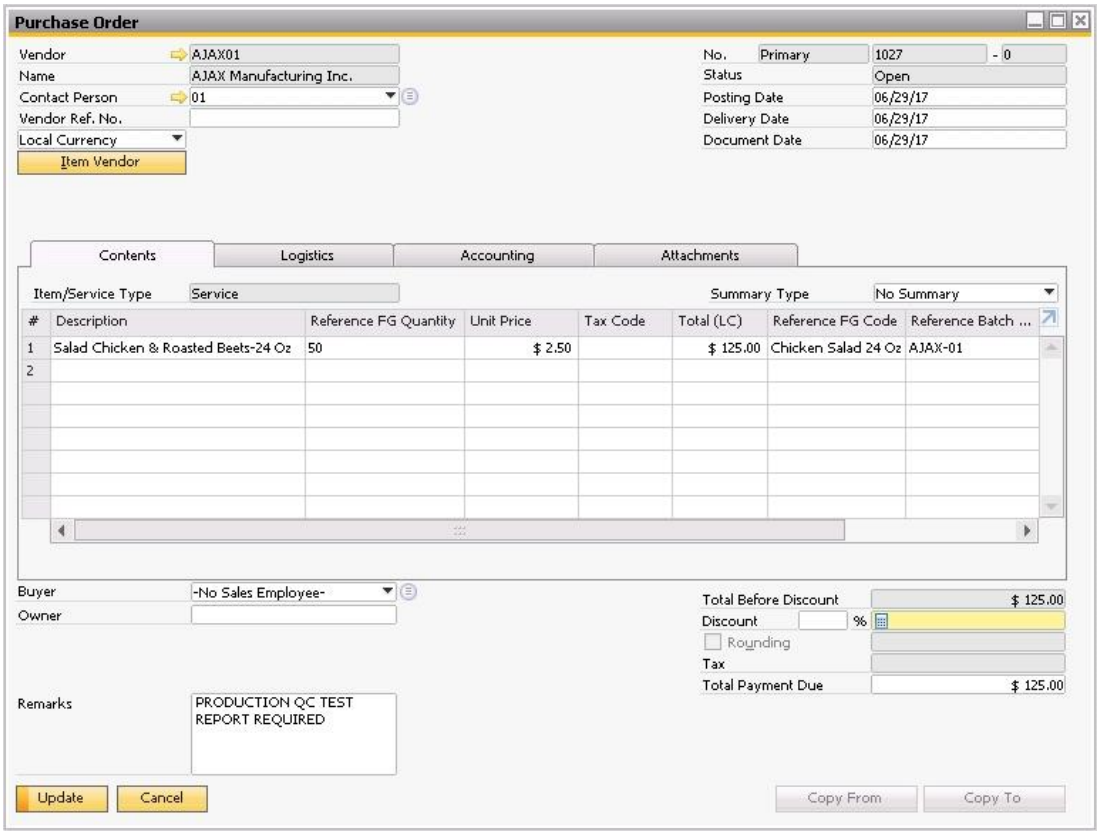
At the bottom of your screen in the system message area, the numbers of the service purchase order and the inventory transfer request tied to the batch will display. Write them down for future use.

Now from the context Menu, select "Release Batch" to release the created Batch. choose the Third Party Document Report option. The system will automatically generate the Service Purchase Order and Inventory Transfer Request for the third-party service.

Finally, click OK to close the batch entry screen.

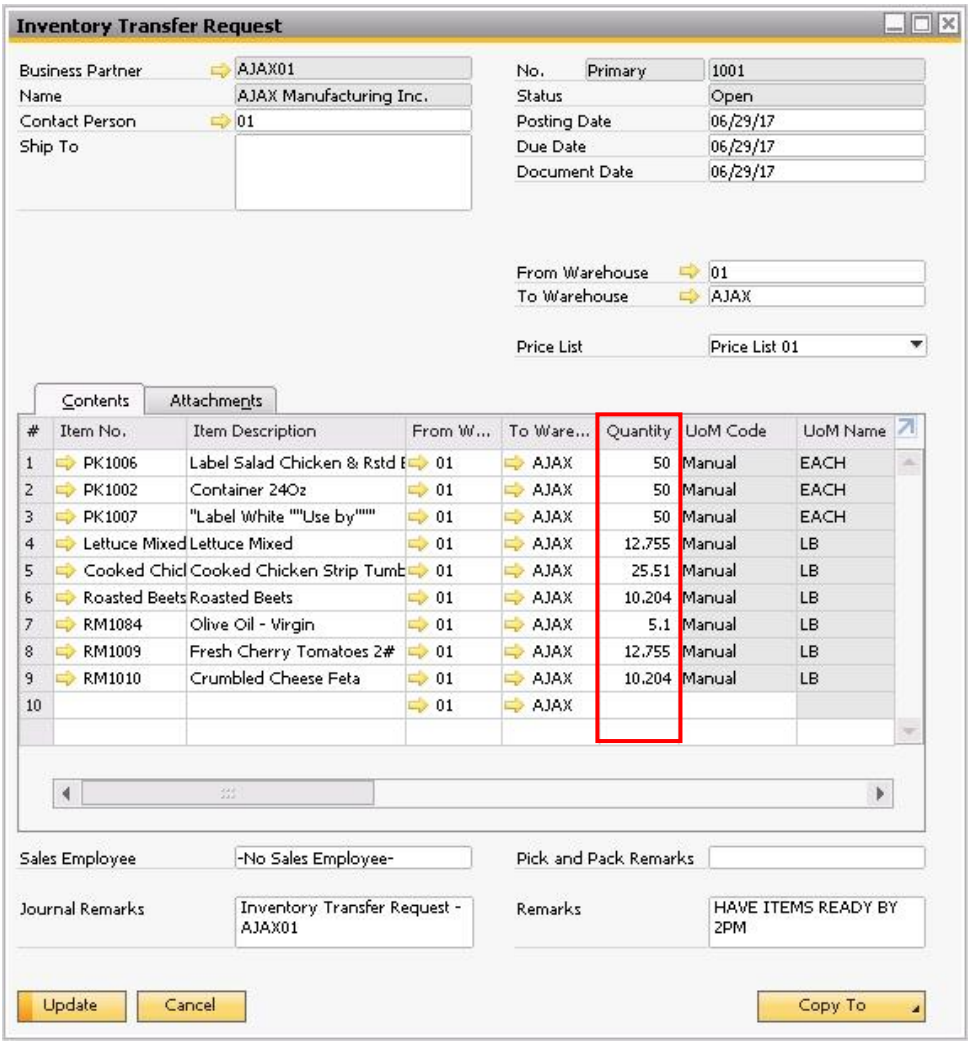
12.3 View/Edit Service Purchase Order

Go To: Purchasing – A/P → Purchase Order to view the service purchase order created when the outside-processing batch was saved. Observe that the production data from the batch, the service charge data from the BOM, and the outside-processing batch numbers are displayed. Make any edits needed to the PO, then click UPDATE to save your work or OK to close the screen.



12.4 View/Edit Inventory Transfer Request

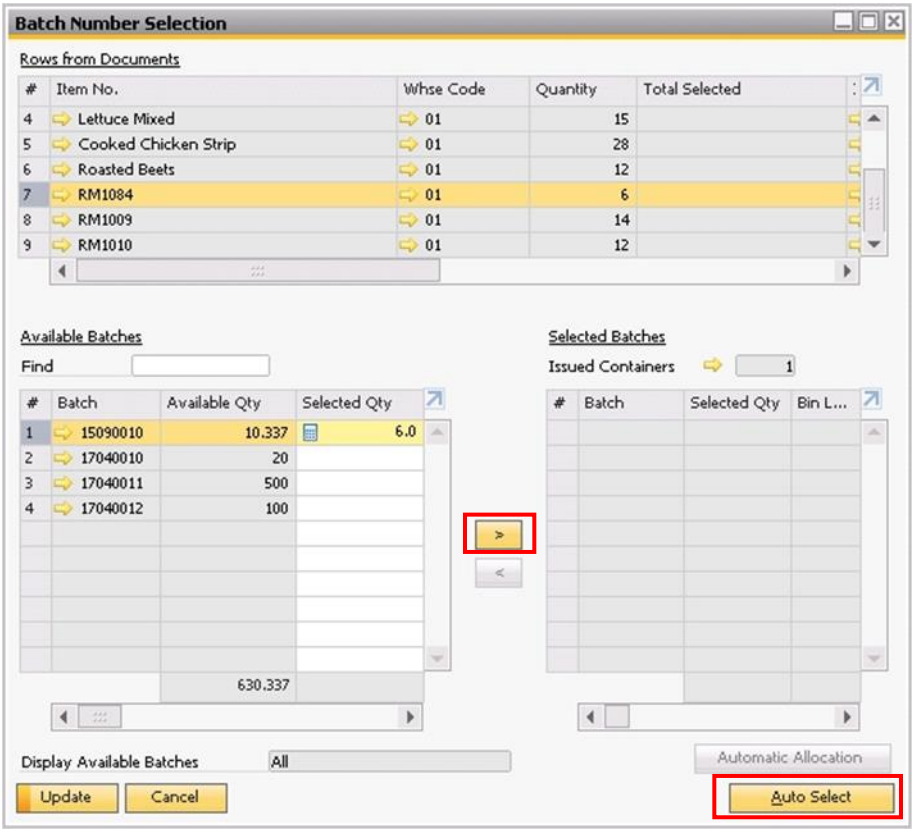
Go To: Inventory → Inventory Transactions → Inventory Transfer Request to view the draft inventory transfer request created when the outside-processing batch was saved. If necessary you can adjust the transfer quantities to reflect the package or carton quantities that you would ship to the contractor. This will also facilitate shipping some "extra" of each raw material and packaging item to account for any transit damage or losses at the contractor's facility.



When you have made necessary edits, click UPDATE to save your work, then click the "Copy To" button and select Inventory Transfer.

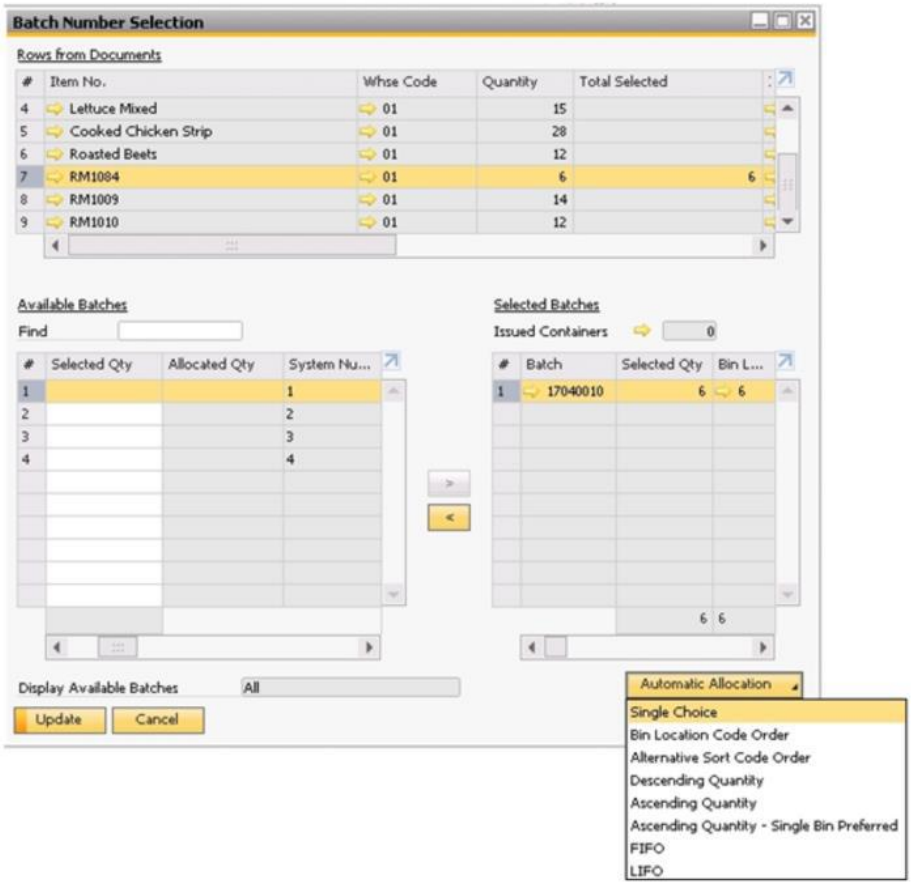
12.4.1 Select Material Lot Numbers to Transfer

In the window that appears, for each item you must choose one or more lot numbers to transfer to the contractor's warehouse. Remember SAP Business One refers to a "lot" as a "batch" which can be confusing! The top grid lists all the lot-controlled items required for production. As you highlight each row, the lower left grid shows all the lots available.



In this example, we need to select a quantity of 6 for item code RM1084. Based on the lot issue rules defined for the item at the *Item Master Details* screen, the system is suggesting we use lot number 15090010. To do so we would click the "auto select" button in the lower right corner of the screen. To over-ride the system suggestion, we would highlight the desired lot number, type in the selected quantity, then click the "greater than" button to process the selection. It is also possible to do a split issue, that is, issue from more than one lot. Repeat this process until you have addressed all the items in the top grid.

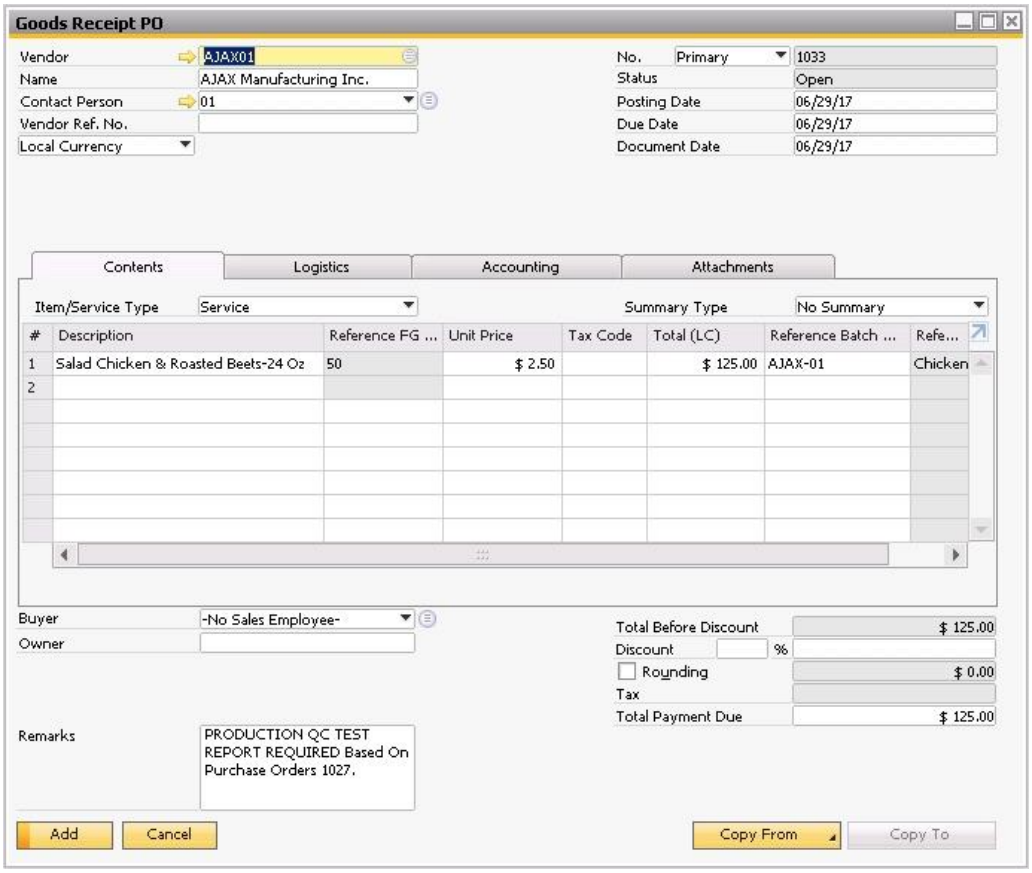
After you have selected all the lots to be transferred, you must determine the lot allocation method for each item. Highlight a row in the top grid and click the “Automatic Allocation” button. From the drop-down, select the desired method, then click the update button. When you have addressed all the items in the top grid, the OK button will be displayed on the Batch Number Selection screen. Click OK to close the screen, then click the ADD button on the Inventory Transfer screen. Answer “yes” to the warning message and the system will process the transfer.



To facilitate tight control over raw material lots it is critical that the contractor provides written evidence of the lots used in each batch. Unauthorized mixing of raw material lots in a batch must be avoided.

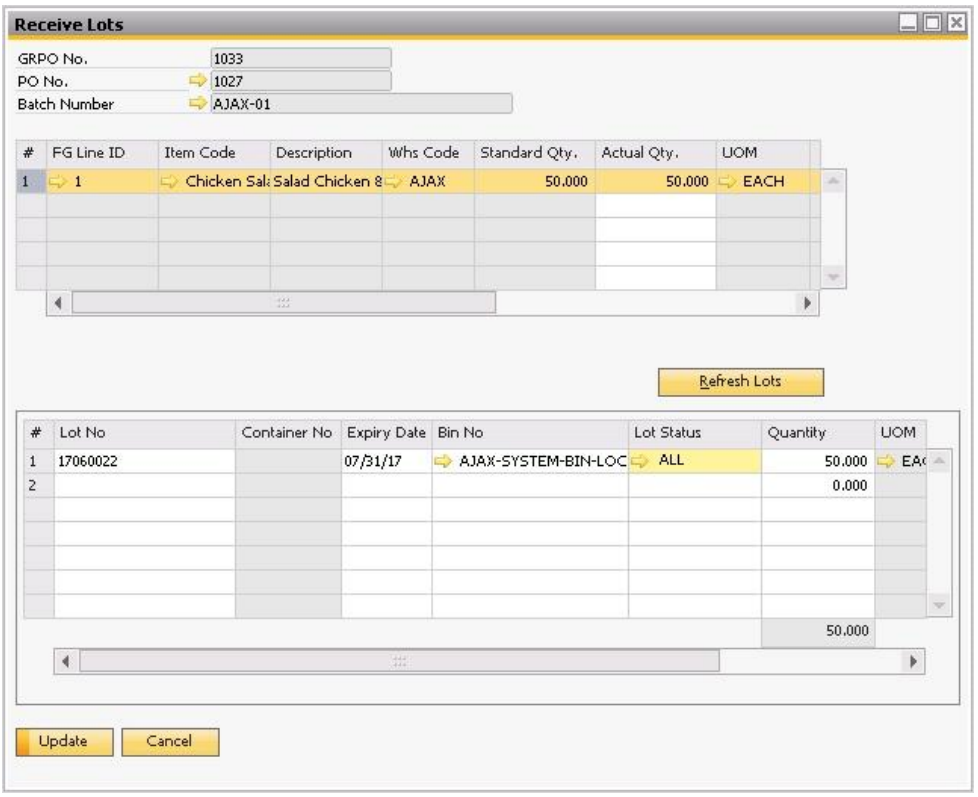
12.5 Create Goods Receipt PO

When production is completed at the sub-contractor's facility, we must complete some transactions in the system. The first of these is a Goods Receipt PO created from the service purchase order. **Go To: Purchasing – A/P → Purchase Order** to view the service purchase order tied to the outside-processing batch. At the bottom of the screen, click the "Copy To" button and select "G. Receipt PO" from the drop-down.



Make any edits needed to the GRPO, then click ADD to save your work. The Receive Lots screen will open, where you define the lot number data for the finished product.

12.5.1 Receive Finished Item Lots



In the upper grid we see a list of the items to be received from the contractor. In the lower grid, for each highlighted line the system will display a suggested lot number if you have defined a Batch Series for the item at the *Item Master Details* screen. You can over-ride the system suggestion. Enter an expiry date for the lot. If the lot to be received is suspect, change the lot status accordingly. You can split the lot, clearing a partial quantity for use, if needed. When you have finished editing the data, click ADD or UPDATE to save your work. Finally, click the ADD button on the GRPO screen to save that record.

12.6 Configuring and Mapping Service Charges in Third-Party Processing

This section explains the updated Third-Party Service Charge Integration within the Bill of Material (BOM) Entry screen in SAP Business One. The functionality supports the direct inclusion of labor costs in the cost calculation of finished goods (FG), ensuring accurate cost tracking and improved transparency.

Previously, labor costs were manually included in the Service Purchase Order (PO). With this update, when a production batch is closed, the system automatically calculates third-party service charges based on the posted and updated Service GRPO, posts the corresponding journal entry (JE), updates the FG unit cost, and clears the WIP account, transferring all related costs to finished goods.

The Special Prices for Business Partner (BP) feature allows users to map contractors to finished goods (BOM) and configure service charges using both Period Discounts (date-based) and Volume Discounts (quantity-based). This structure provides greater flexibility and control in managing third-party service pricing within production workflows.

12.7 Possible Scenarios for Service Charge Configuration in Third Party

1. **Period-Wise Service Charge Only**

   - If service charges are required based only on a date range, enter the details in the *Period Discount* screen.
   - Define the applicable date range in the *Valid From* and *Valid To* fields.

2. **Volume (Quantity)-Wise Service Charge Only**

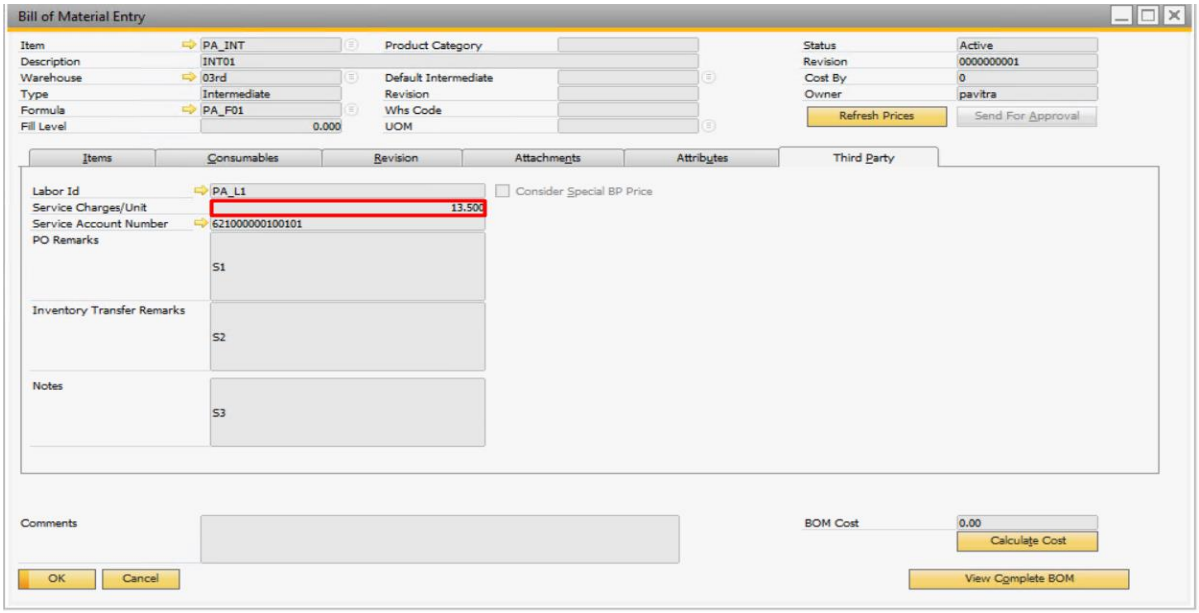
   - To apply service charges based on quantity slabs, first, enter a single line in the *Period Discount* screen with a long validity period (e.g., Valid To: 31.12.2099).
   - Double-click on the entry to open the *Volume Discount* screen.
   - Define service charges based on quantity slabs.
   - The system will always refer to the first period entry's linked Volume Discount Special Price.

3. **Period-Wise & Volume-Wise Service Charge Both Required**

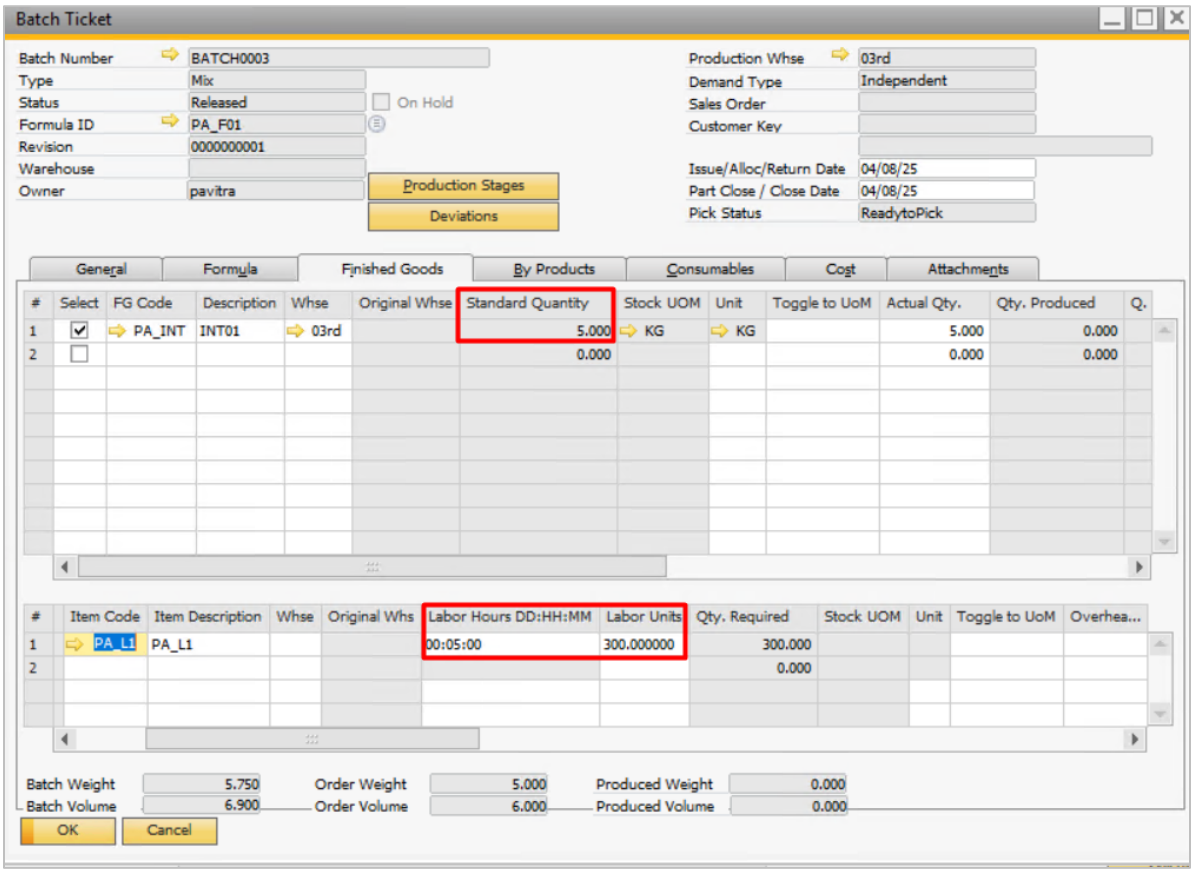
   - If both date-wise and quantity-wise service charges are needed, define the service charge in both the *Period Discount* and *Volume Discount* screens.
   - Ensure that quantity slabs are correctly mapped to the respective period slabs.
   - The system will apply the quantity-based service charge only within the selected period.
   - Proper configuration of date and quantity slabs ensures accurate service charge calculations.

12.7.1 Mapping labor cost as service charge in third party

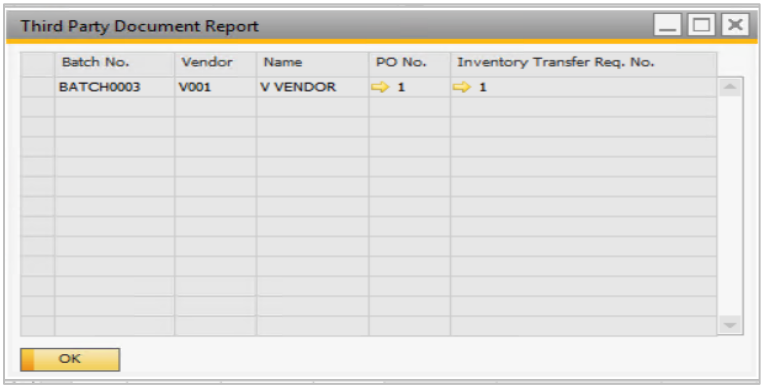
1. Bill of Material Entry: The process begins with defining what needs to be manufactured. The "Bill of Material Entry" screen for item "INTOL" outlines the necessary raw materials and, importantly, specifies the third-party processing cost (**Labor Cost: 13.5 $**) associated with purchase order "621000000100101." This cost is factored into the final BOM calculation for potential outsourcing.



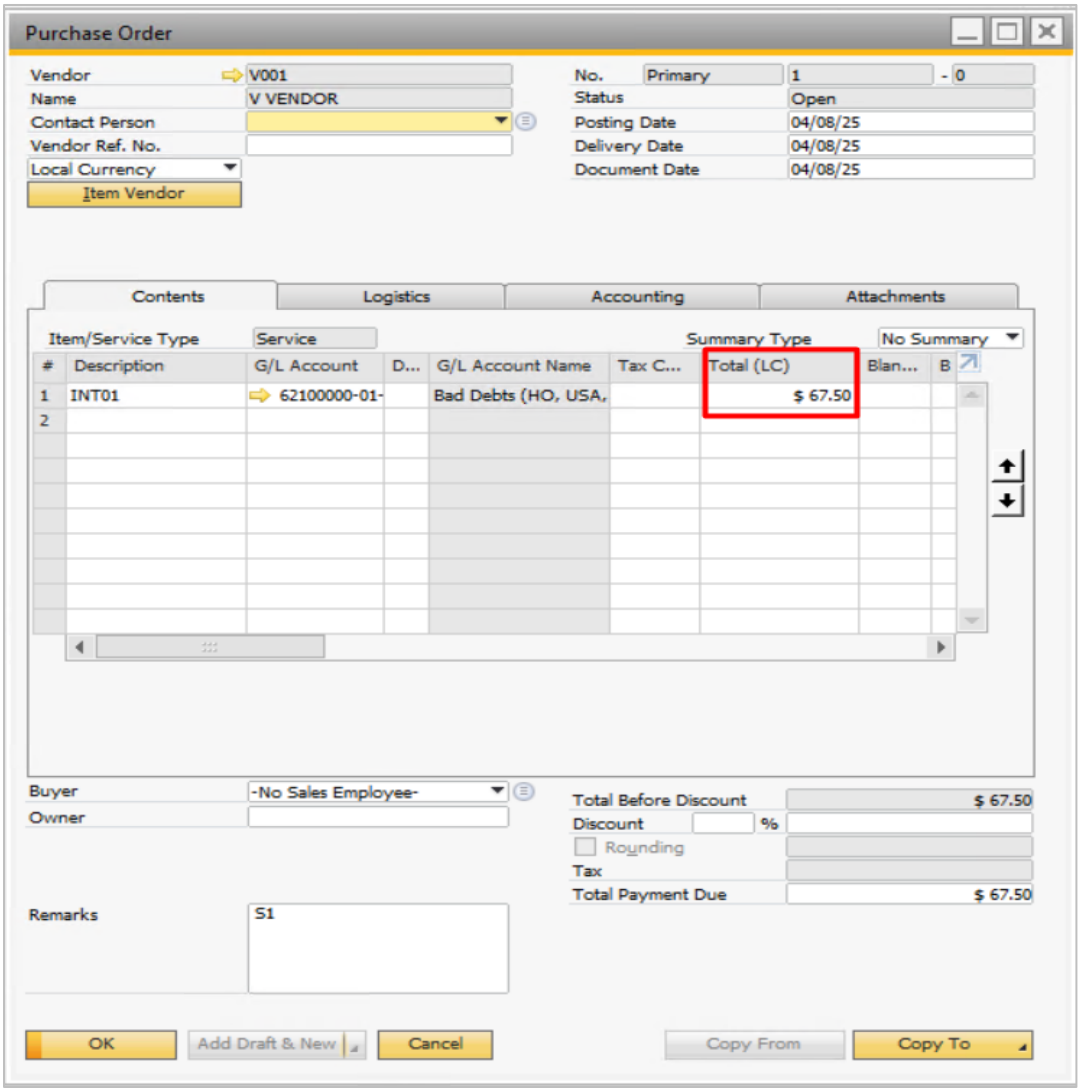
2. A production batch is created, as seen in the "Batch Ticket" screen for batch "BATCH0003" of item "PA_INT INT01." This stage details the **Standard Qty as 5 and Labor Hours as 5**, the planned labor ("PA_L1") and its estimated units and duration, and the intended warehouse ("03rd"). The batch is released and scheduled for material allocation and process completion around April 2025.



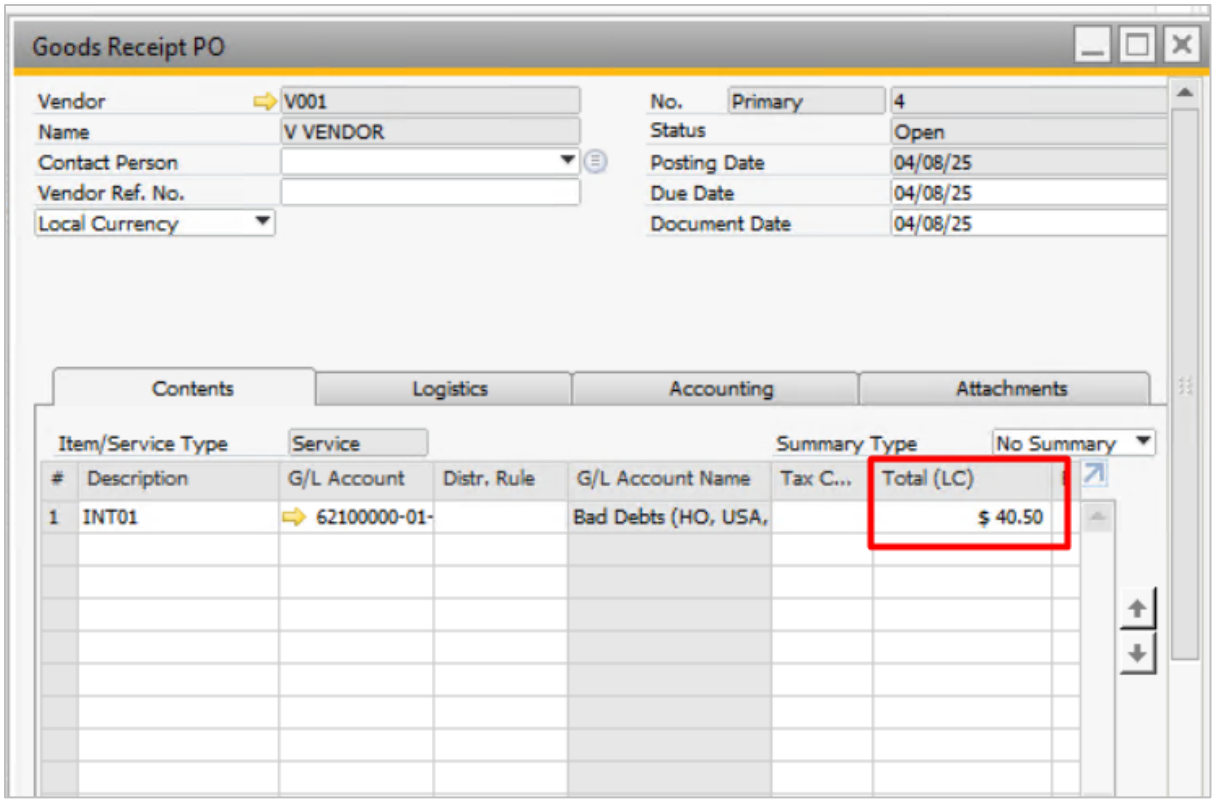
3. From the context menu, choose the Third Party Document Report option. The system will list the generated Service Purchase Order and Inventory Transfer Request for the third-party service.



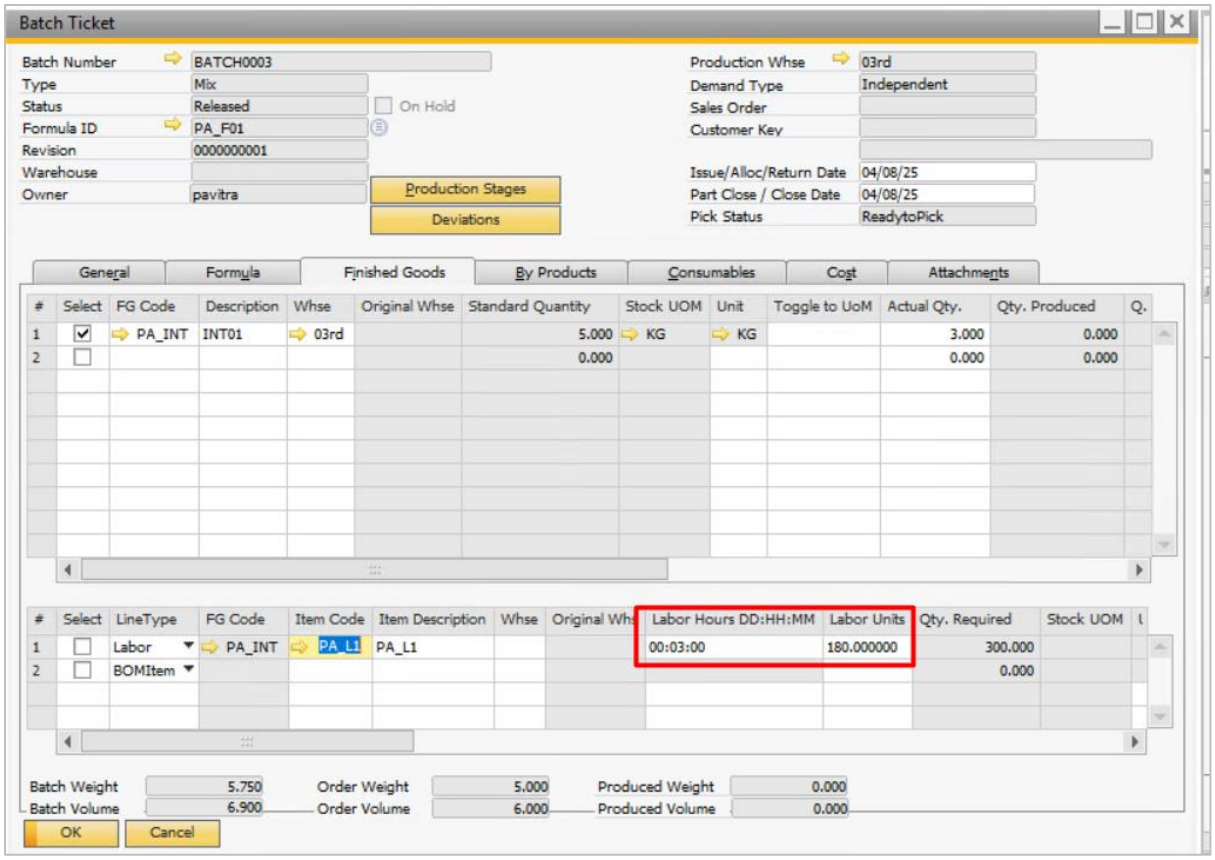
4. Below is Service PO screen created automatically at Batch release, that procure the manufacturing services for item "INT01" from the chosen third-party vendor, "V VENDOR" (PO No. 1). This Service PO, dated 04/08/25 and currently open, specifies the total cost of the outsourced service (**FG Standard Qty * Labor Cost => 5*13.5= 67.5**)



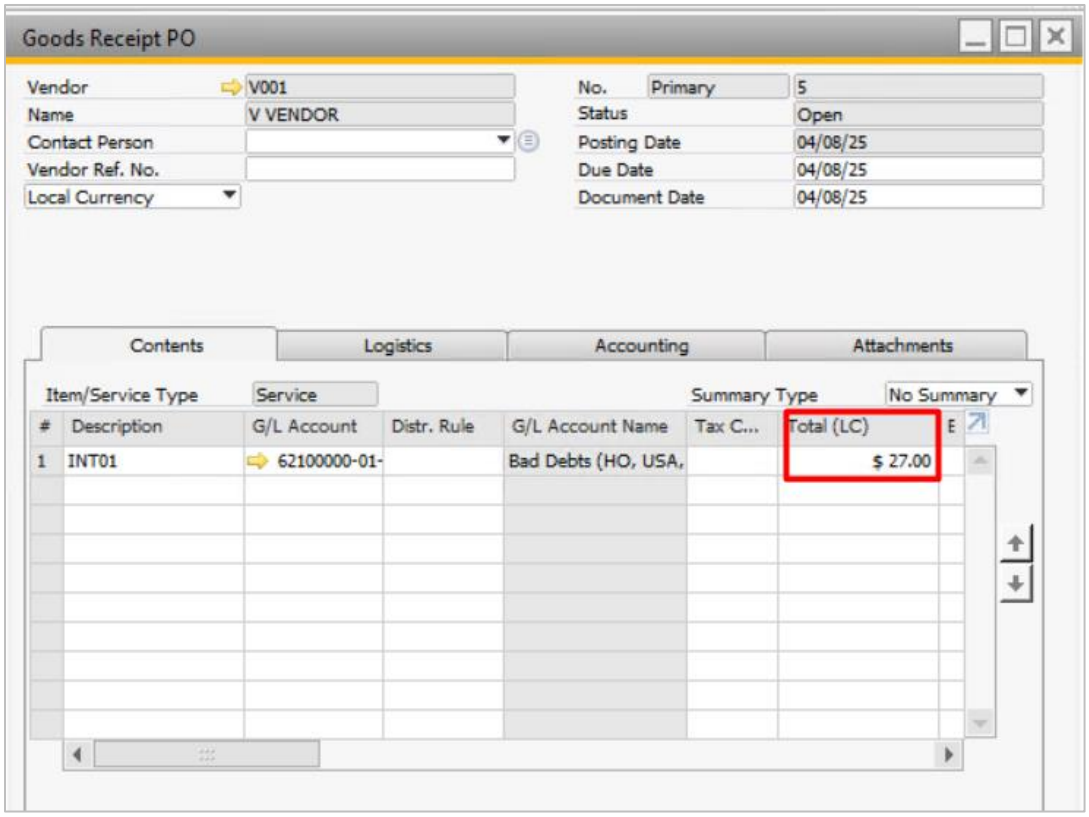
5. Receive the Outsourced Service (Goods Receipt PO): As the third-party completes their work, "Goods Receipt PO" screens (PO Nos. 4 posted on 04/08/25) confirm the receipt of 3 quantities (**First partial GRPO for 3 FG qty received 3 * 13.5 = 40.50 $**), manufacturing services from "V VENDOR" for item "INT01." These documents record the cost of the received services.



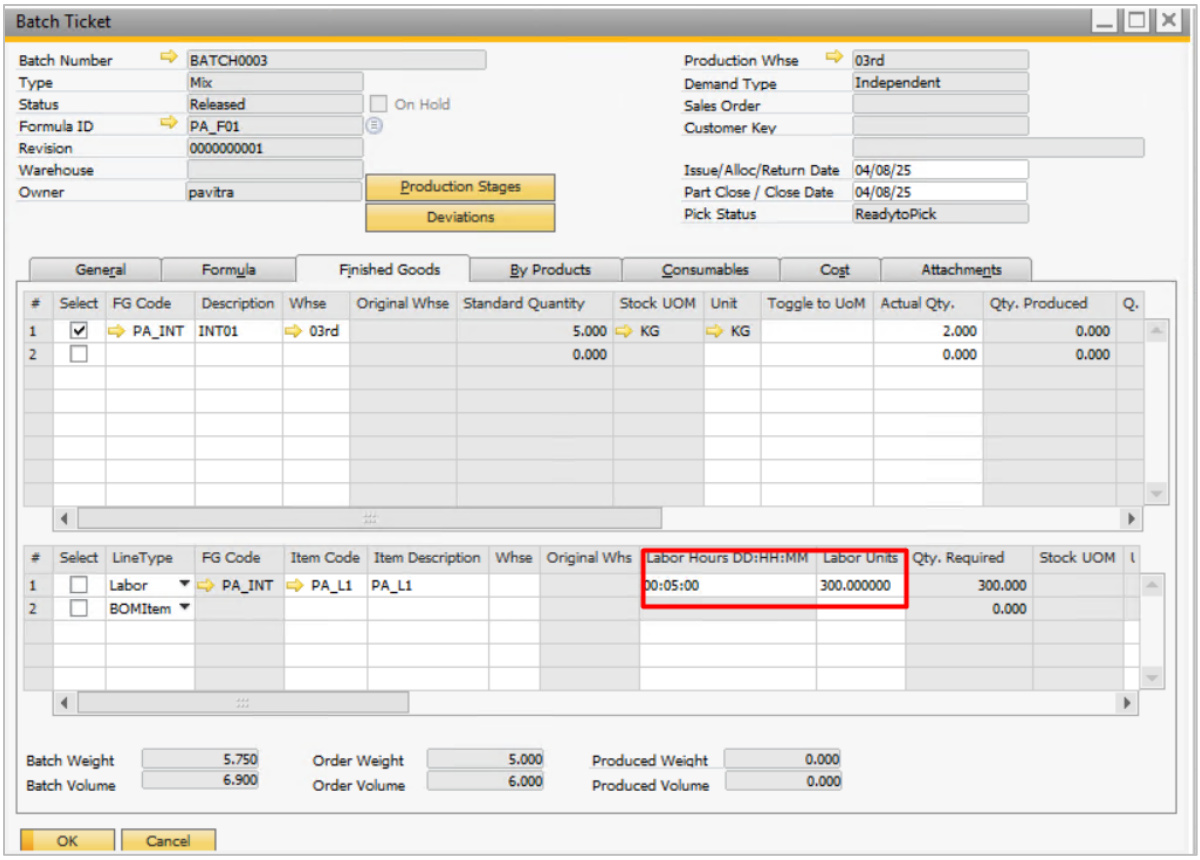
6. Update Planned Labor in Batch (Updated Batch Ticket): The "Batch Ticket" for batch "BATCH0003" is updated to reflect the planned labor of "PA_L1" requiring **180 labor units** over an estimated **3 hours**. This refined labor plan contributes to the batch weight and order weight calculations, with the batch remaining released and scheduled for material allocation and process completion around April 2025.



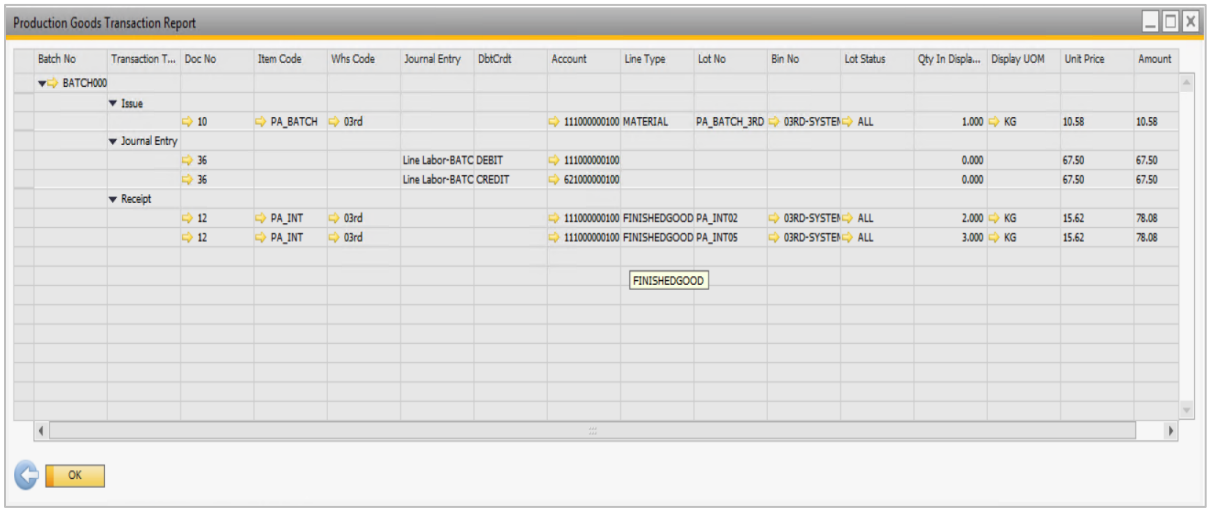
7. Receive the remaining Outsourced Service (Goods Receipt PO): Goods Receipt PO screen (PO Nos. 5 posted on 04/08/25) confirm the receipt of 2 quantities (**Second partial GRPO for 2 FG qty received 2 * 13.5 = 27 $**), manufacturing services from "V VENDOR" for item "INT01." These documents record the cost of the received services.



8. Update Planned Labor in Batch (Updated Batch Ticket): The "Batch Ticket" for batch "BATCH0003" is updated to reflect the planned labor of "PA_L1" requiring **300 labor units** over an estimated **5 hours**.



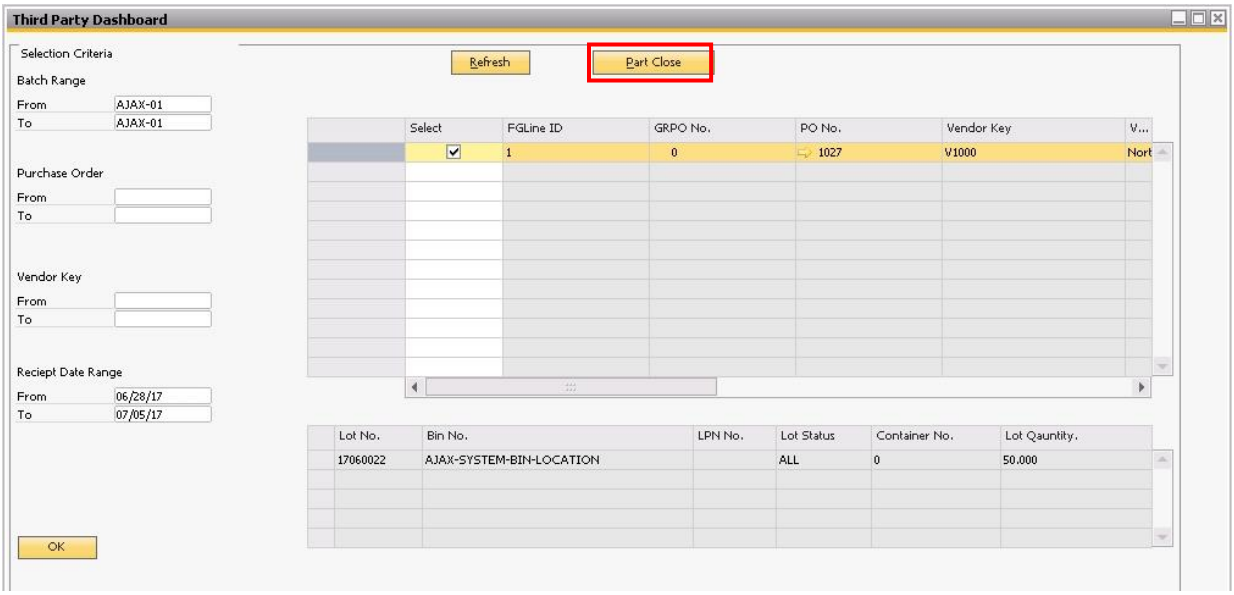
9. Finally full close the production batch. From the context menu, open the Production Goods Transaction Report for batch. The report will list down **labor line with 67.5 $** for service charge which will show effect in **finished goods received with 2 & 3 qty at part close**.



12.8 Third Party Dashboard

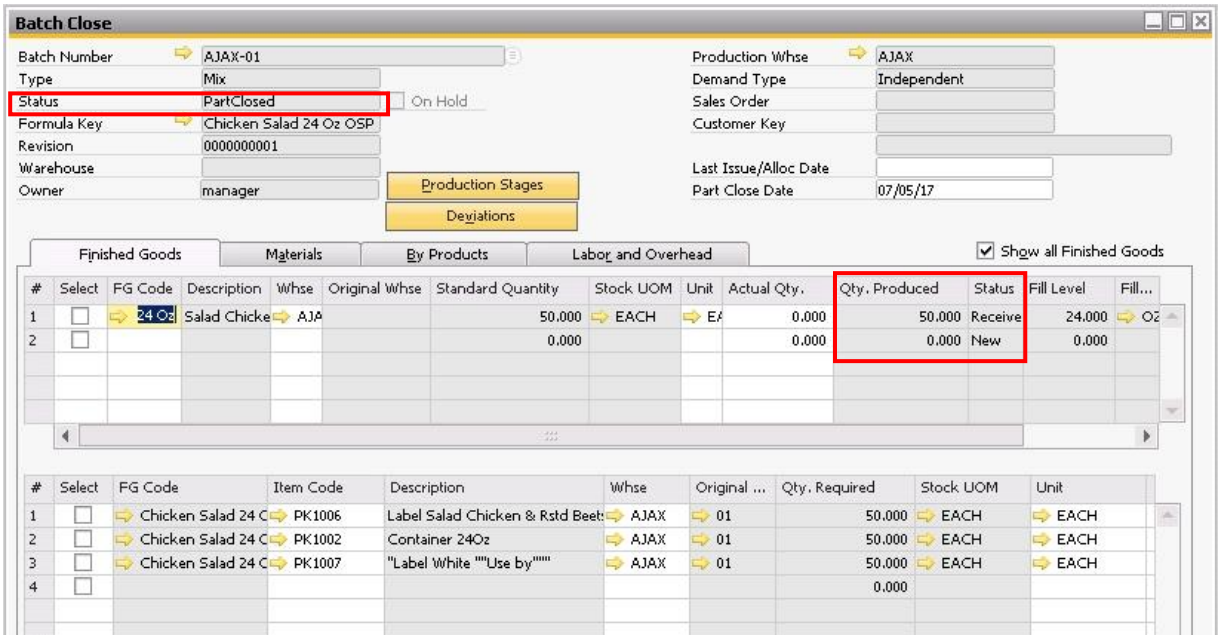
You can now access the outside-processing batch from the third party dashboard (see next page.) Enter the batch number or select from the lookup, then make sure the receipt date range includes the actual GRPO receipt date. Notice the lower grid displays the finished item lot number we accepted when receiving the GRPO tied to the service purchase order. When we click the "Part Close" button the batch will be removed from the dashboard.

Go To: Process Mfg. → Production Utilities → Third Party Dashboard



12.9 Material Issue to Outside-Processing Batch

On the batch close screen we see the status is now "part closed" and the finished goods tab shows we will receive 50 units of the chicken salad. We can modify this quantity as needed, as well as update the quantities of packaging items and raw materials used in production.

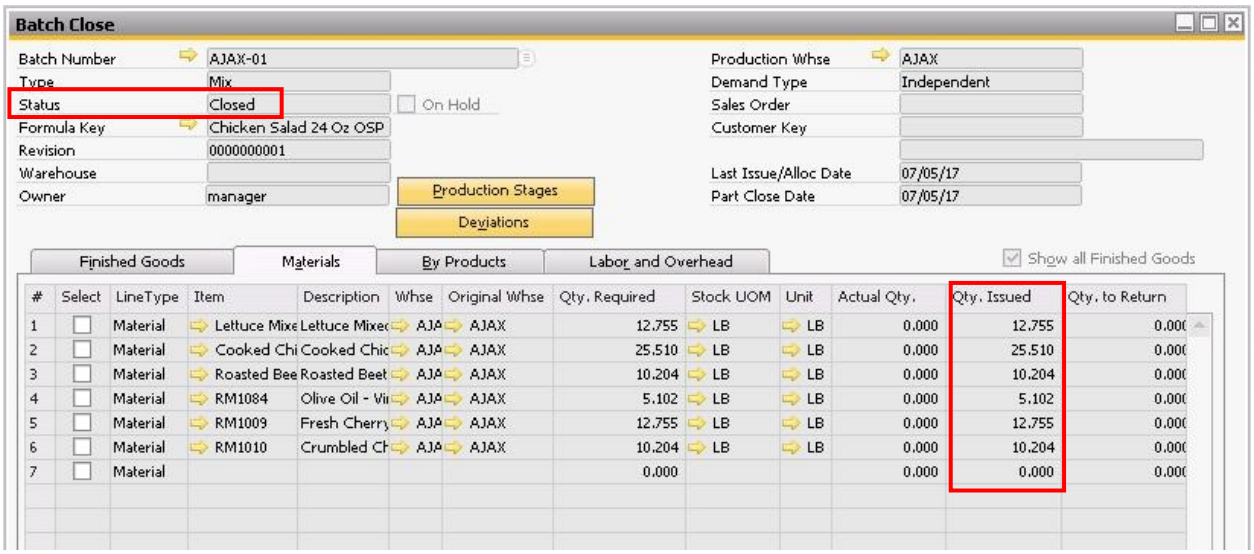


Right-click in the header area and choose “Issue Batch.” The Material Issue window appears, where we choose the lot number or numbers of each raw material and packaging item used during production.

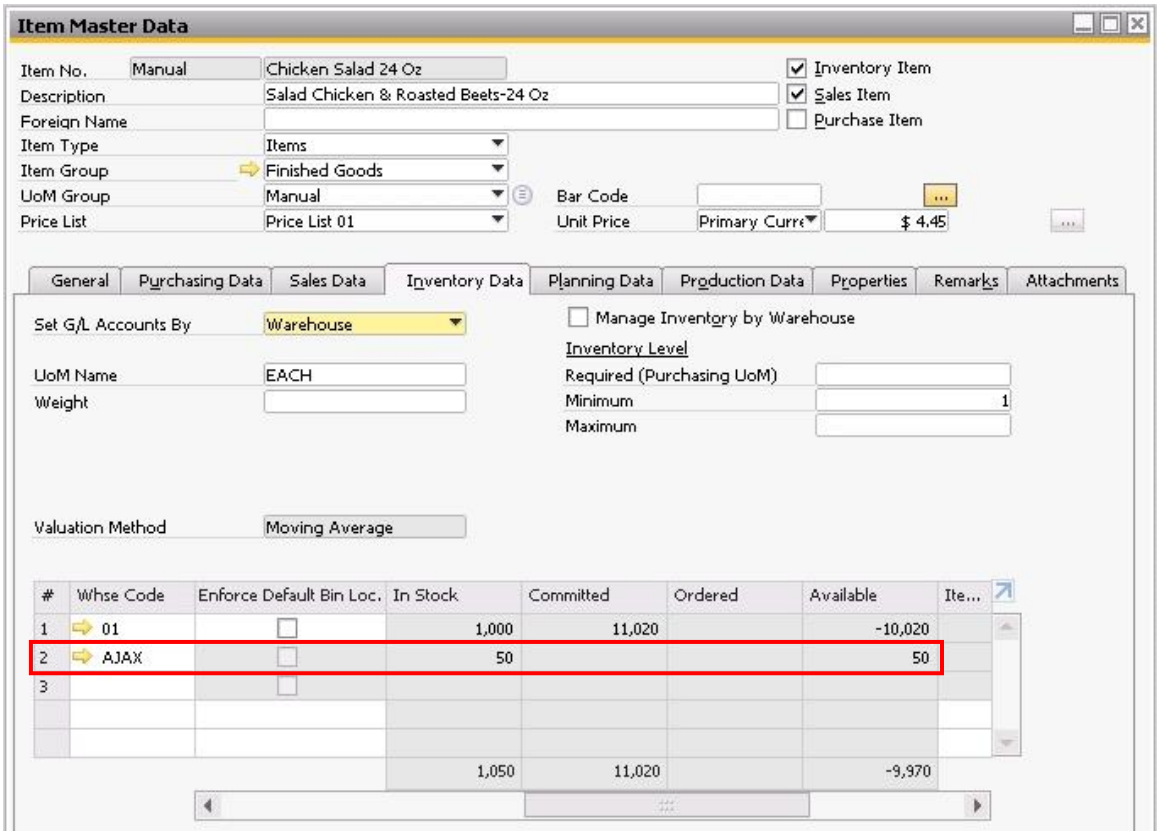
We can use the Auto Select function to have the system pick lot numbers based on the material issue rule defined at each item’s *Item Master Details* screen. Refer to the *BME-B1 18.2 Production User Guide* for details.

12.10 Batch Closed – Goods in Inventory

Following material issues, the last step is to mark the outside processing batch “closed” by right-clicking in the header and choosing “close batch.”



Observe that the finished items now appear in the contractor's warehouse. They can be transferred back to the main warehouse or shipped to customers directly from the contractor.



13 Adverse Event Reporting

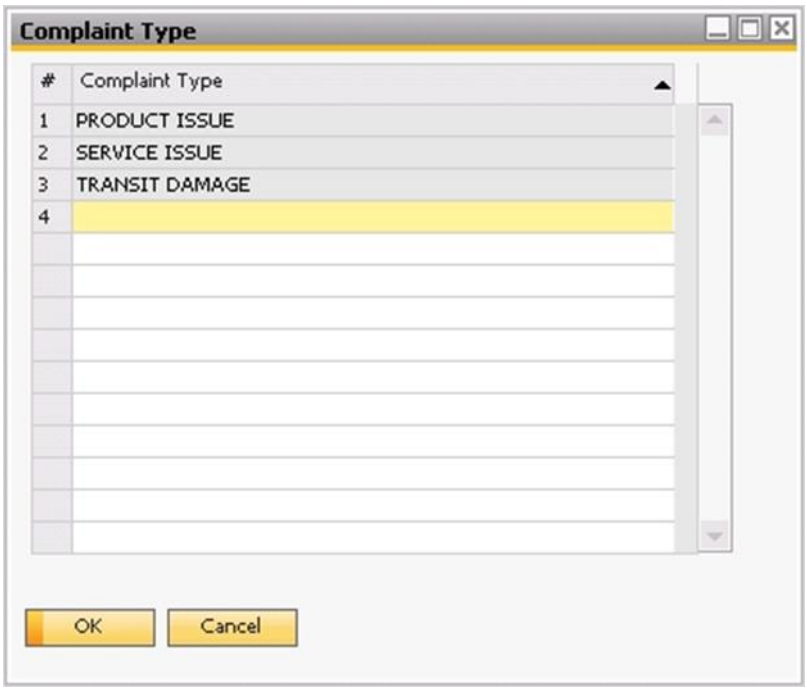
One of the salient and basic requirements of FDA is to record adverse events. Complaint management is a very important aspect in an organization and if it is relating to the manufacturing process, then it is often a bottleneck as may mean recalling production runs. Using BatchMaster ERP, you can efficiently enforce the process of complaint management through the system, ensuring that all complaints are handled properly from receipt to closure.

We will first address some prerequisites before covering the process of complaint entry.

13.1 Complaint Type

It is easy to handle complaints if you categorize them in logical groups. You can use the *Complaint Type* screen to define a complaint group, which you can use while recording a new complaint.

Go To: Administration → Setup → Service → Complaint Type

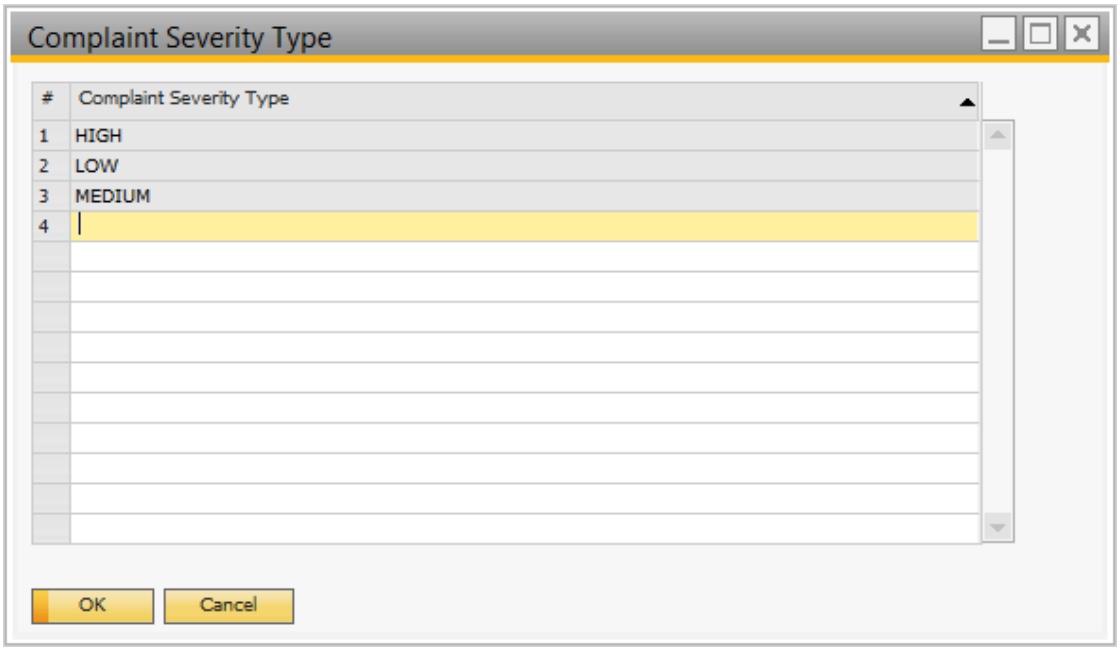

Complaint Type
#
Complaint Type
1
PRODUCT ISSUE
2
SERVICE ISSUE
3
TRANSIT DAMAGE
4
OK
Cancel

13.2 Complaint Severity Type

The degree of seriousness of a customer issue is another aspect of complaint management. Critical issues need to be resolved quickly; lesser complaints can be handled with less urgency. On the *Complaint Severity Type* screen, you can define the degree of severity of issues.

Go To: Administration → Setup → Service → Complaint Severity Type

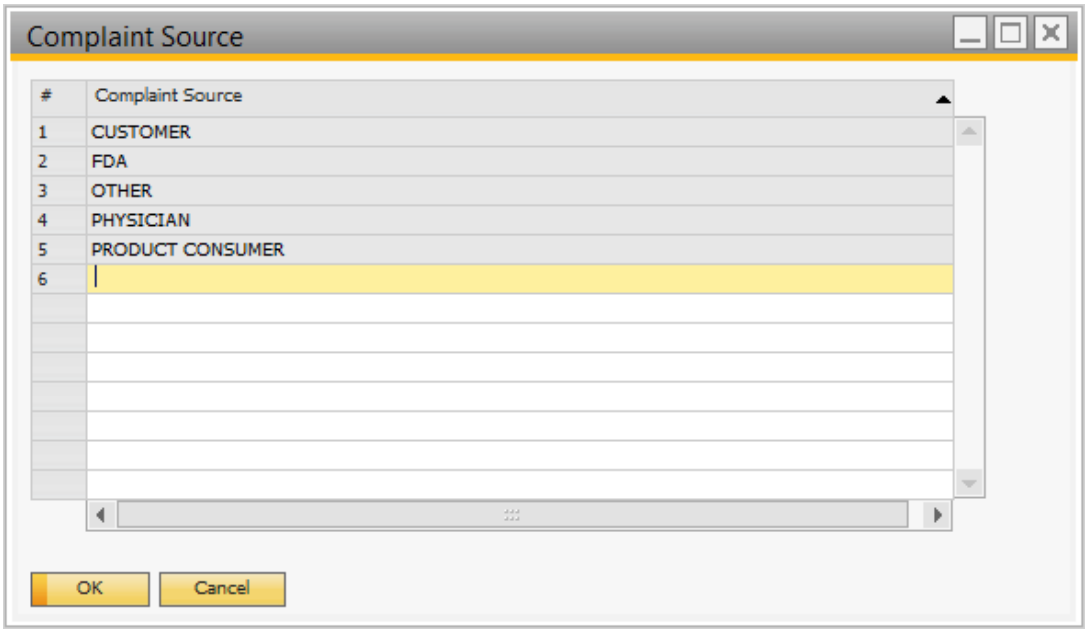
While recording a complaint, you can use the appropriate severity type.



13.3 Complaint Source

To meet regulatory compliances, you need to record the source of a complaint. Some examples of sources can be customer, FDA, and physician. You can use the *Complaint Source* screen to define possible sources.

Go To: Administration → Setup → Service → Complaint Source

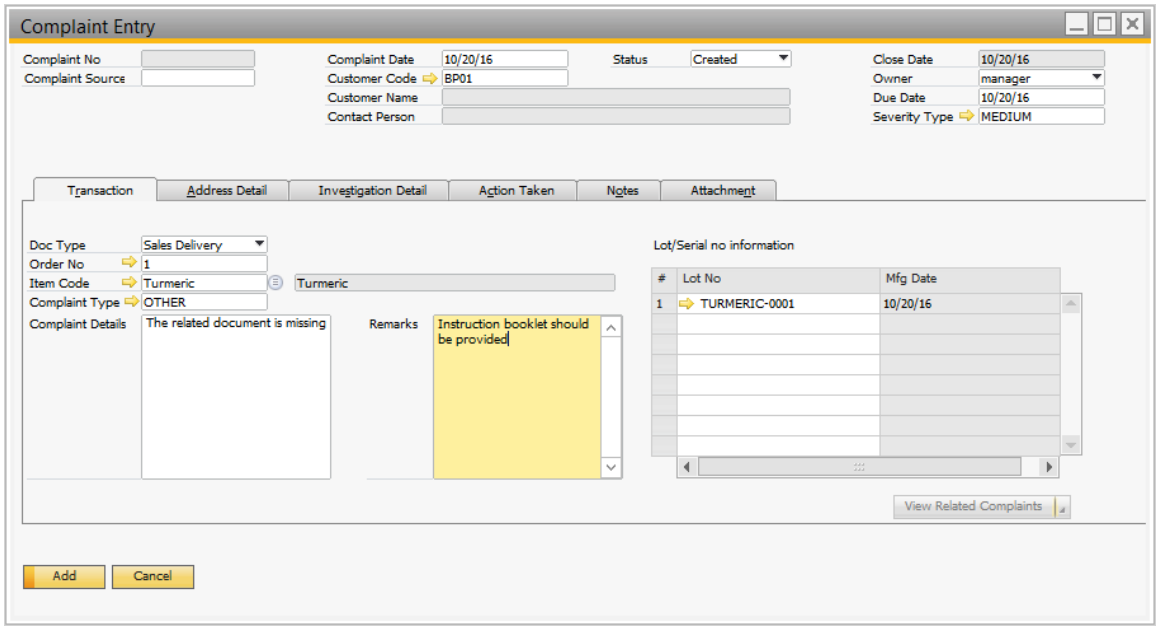


You can conveniently use this detail while recording a complaint using the *Complaint Entry* screen.

13.4 Complaint Entry

To implement appropriate corrective and preventive action plans for a customer complaint, a well-documented complaint record is expected needed. This record will help you manage the complaint until it is resolved, including root cause analysis and corrective and preventative actions.

Go To: Sales – A/R → Complaint Entry



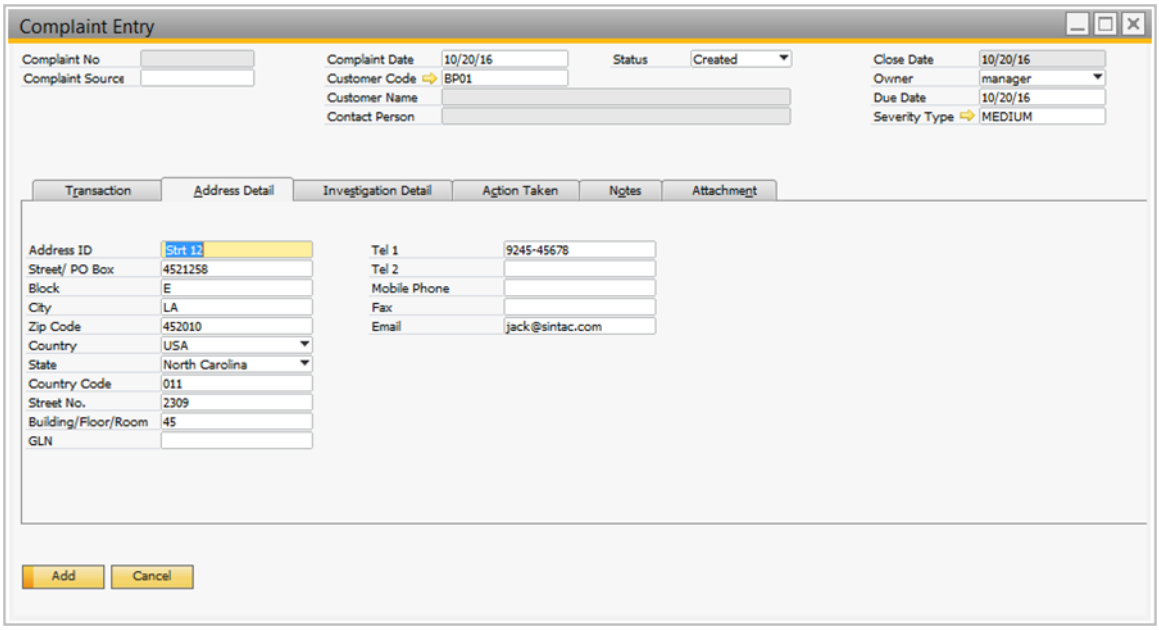
As soon as you receive a complaint, you can record it in the *Complaint Entry* screen, with all supporting information such as customer name and contact details, source of the complaint, and complaint date. To ensure traceability of an item, you can enter transactional details such as lot/serial number information. You can create an action plan to handle the complaint, assign actions to the concerned person, store investigation details of the complaint, and write any remark or note concerning the customer issue. Also, you get the flexibility to attach relevant documents to the complaint.

In the header section, you can enter basic details of the complaint, most importantly the complaint date, affected customer, complaint source and severity code.

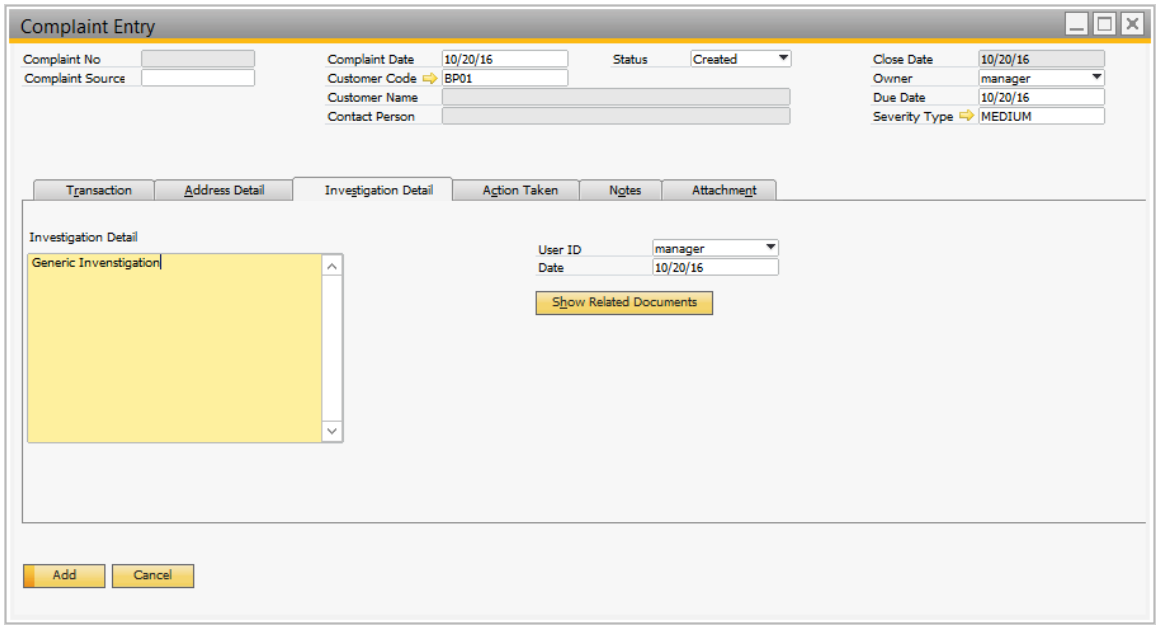
Use the *Transaction* tab to record more information:

- Document type: defaults as a sales order delivery but can be selected as “other”
- Order number: system will list delivery documents based on the customer code entered at the header. If document type “other” was chosen above, this is a free-form text field.
- Item code: the system will default the item code from the first line of the delivery. You can override this suggestion.

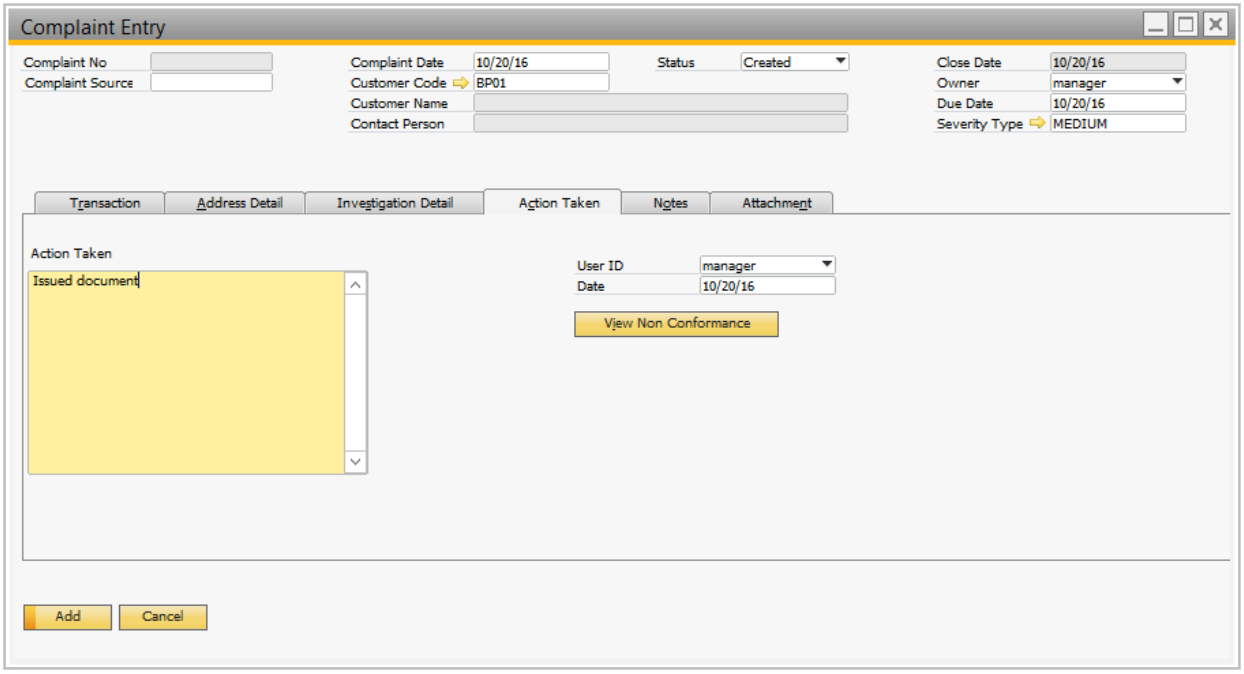
You can record the complete address and contact details of the complainant on the *Address* tab.



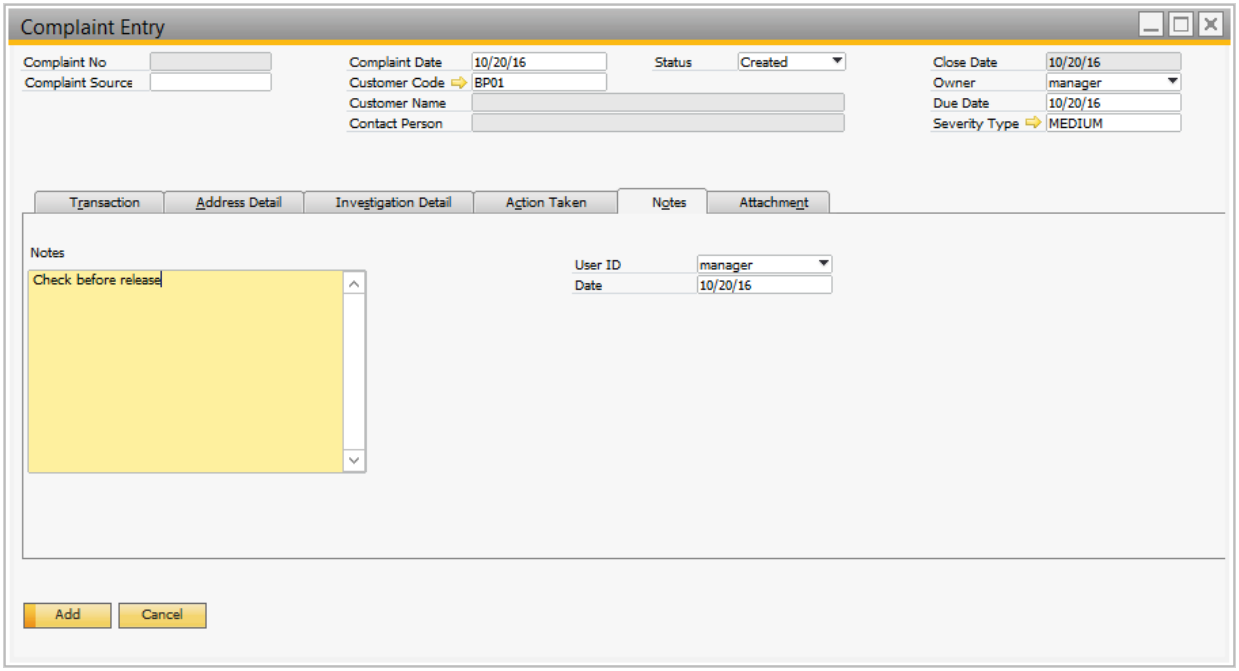
On the *Investigation* tab, you can enter information related to the investigation carried out on the product. You can also enter the user who performed the investigation and on what date.



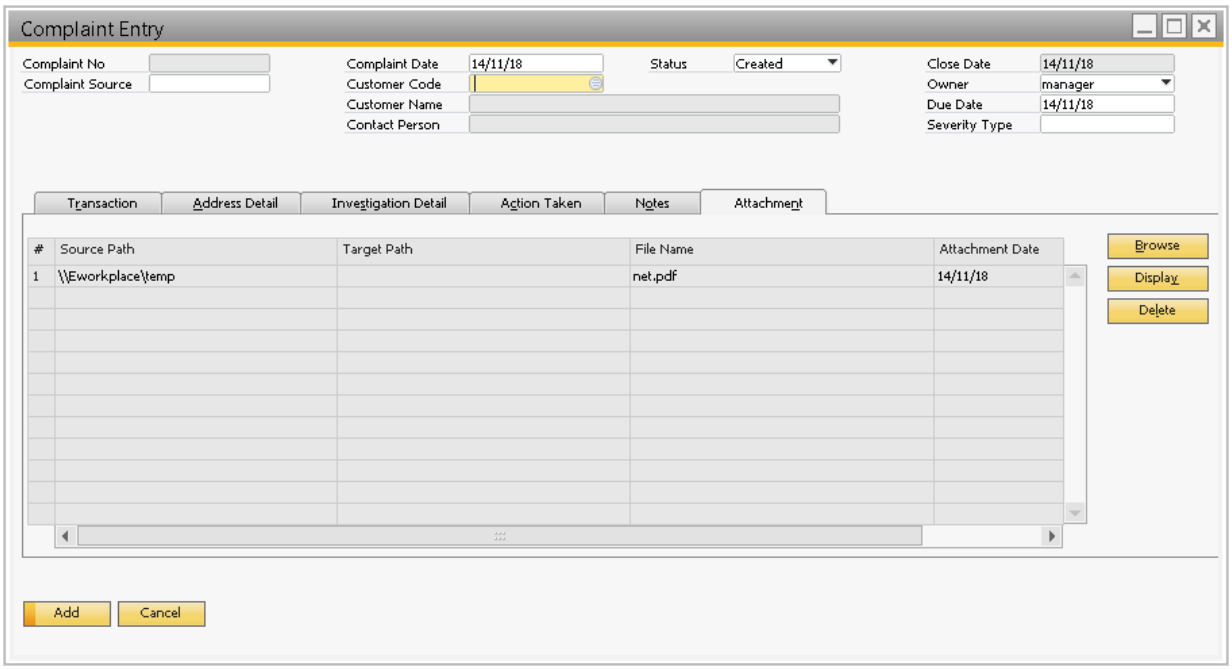
On the *Action taken* tab, you can record the actions that have been undertaken to resolve the complaint. Here, you can enter the follow-up activities and corrective actions that have been undertaken after the investigation. In addition, you can maintain information on preventive actions suggested by quality personnel.



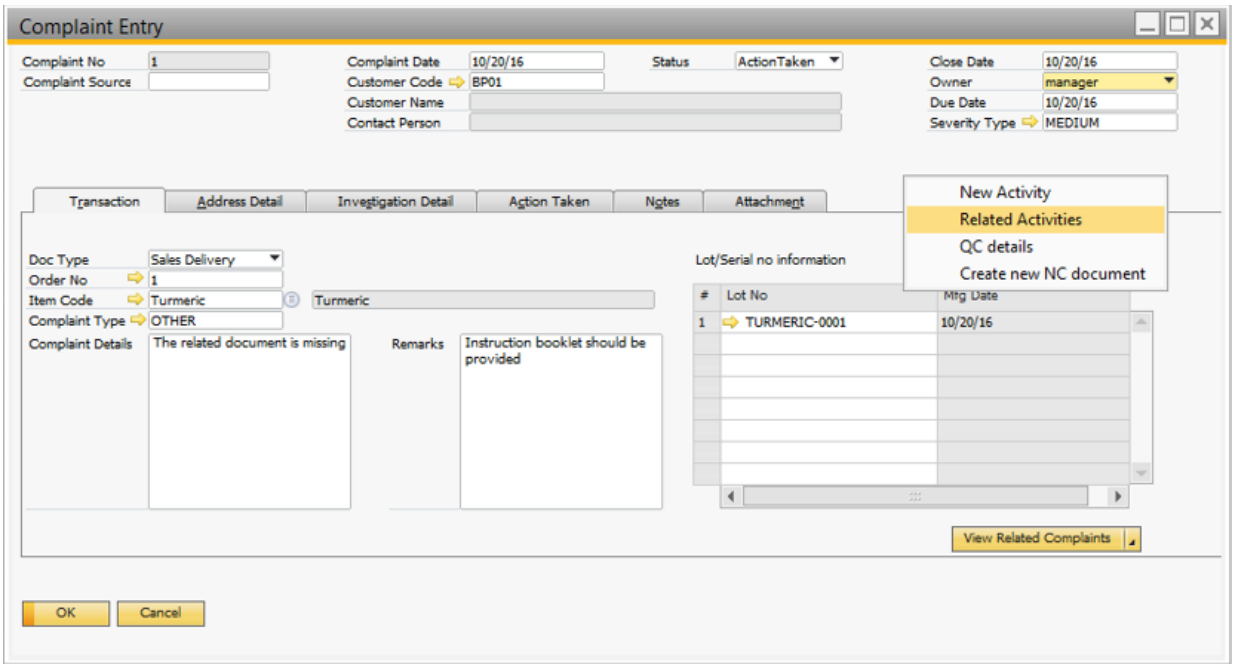
On the *Notes* tab, you can add any remark or comment related to the complaint.



On the *Attachment* tab, you can attach any supporting documents for reference. The path you browse here should lead to a network (shared) location.



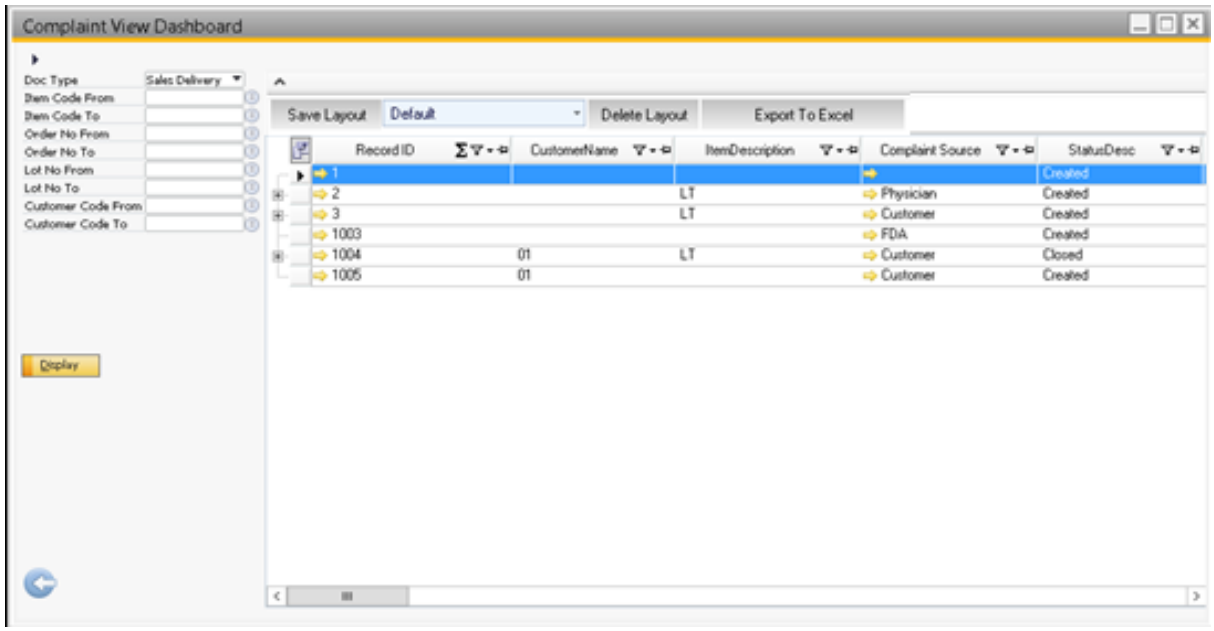
You can define a new activity or view related activities from the *GoTo* menu of the *Complaint Entry* screen. Also, you can view the QC details of the selected lot, and you can create a new non-conforming activity for the failed product.



13.5 Complaint View Dashboard

A well-recorded customer complaint is enough to understand the issue. This may not be sufficient to enhance processes, improve the customer experience, and avoid subjective decision making. The Complaint View Dashboard helps you handle these shortfalls.

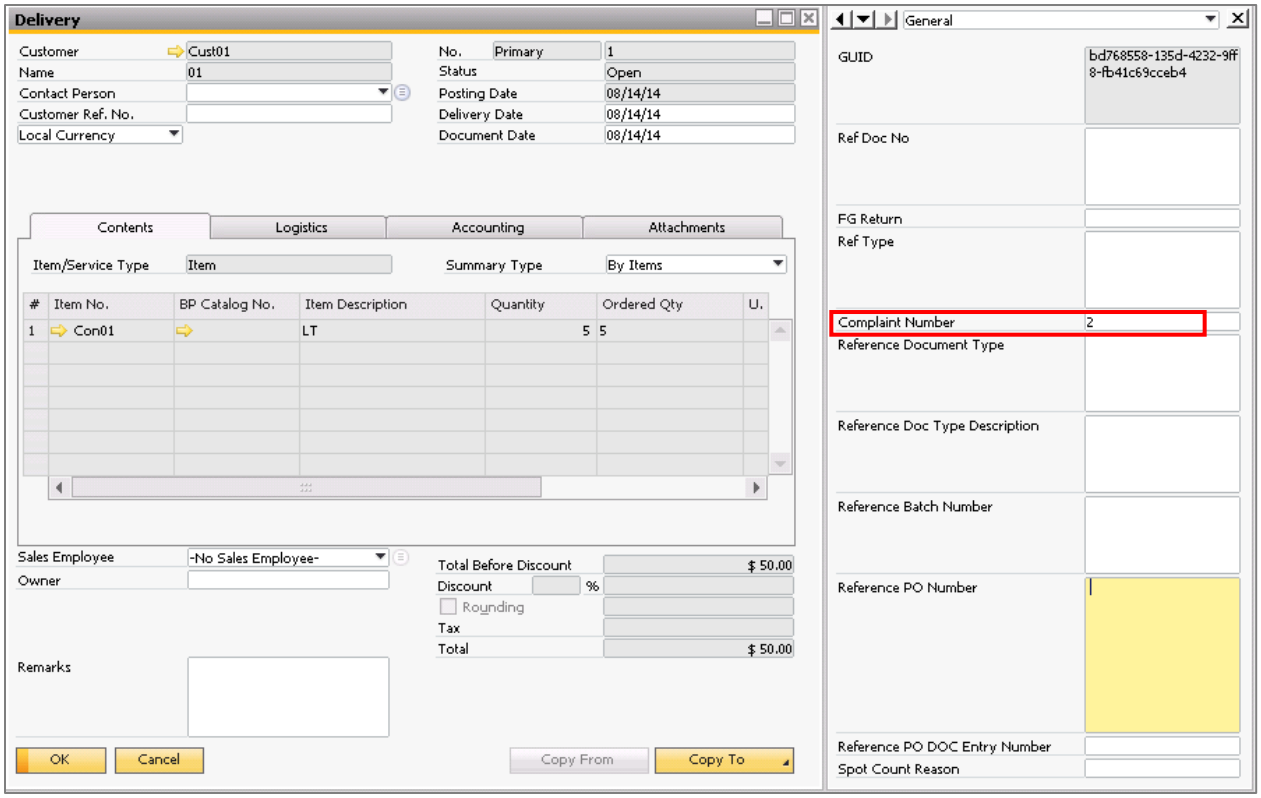
Using this dashboard, you can view and analyze complaints for sales delivery and other documents. The filter criteria on the dashboard helps you display just the required details, drawn from the *Complaint Entry* screen.



You can export the data to Excel sheet, if need be.

13.6 Sales Delivery Screen

The *Complaint Number* field is added in the *Sales Delivery* screen to store the complaint reference number created against the document. Press Ctrl+Shift+U to open the User-defined Fields window.



14 Nutra/Pharma-Specific Features

 *This section is applicable with a Nutraceutical Micro Vertical license only.*

As a Nutraceutical or Pharmaceutical manufacturer, you need to continually innovate new products to meet the current and future demands of customers. The Nutra features of the Laboratory module give you capabilities that can make your innovation faster, yet simpler and reliable by means of computerized calculations. This helps you produce a sample that accurately meets your customer requirements, so that you can supply the sample along with a price quotation to the customer.

14.1 Overview: Physical Property Analysis

The *Physical Property Analysis* screen is part of the standard Laboratory functionality. It helps you:

- Experiment with formulas
- Analyze the physical properties of formulas based on the physical properties of ingredients
- Experiment with the cost of the product based on ingredient cost changes

Please refer to the *BME-B1 18.2 Laboratory User Guide* for details.

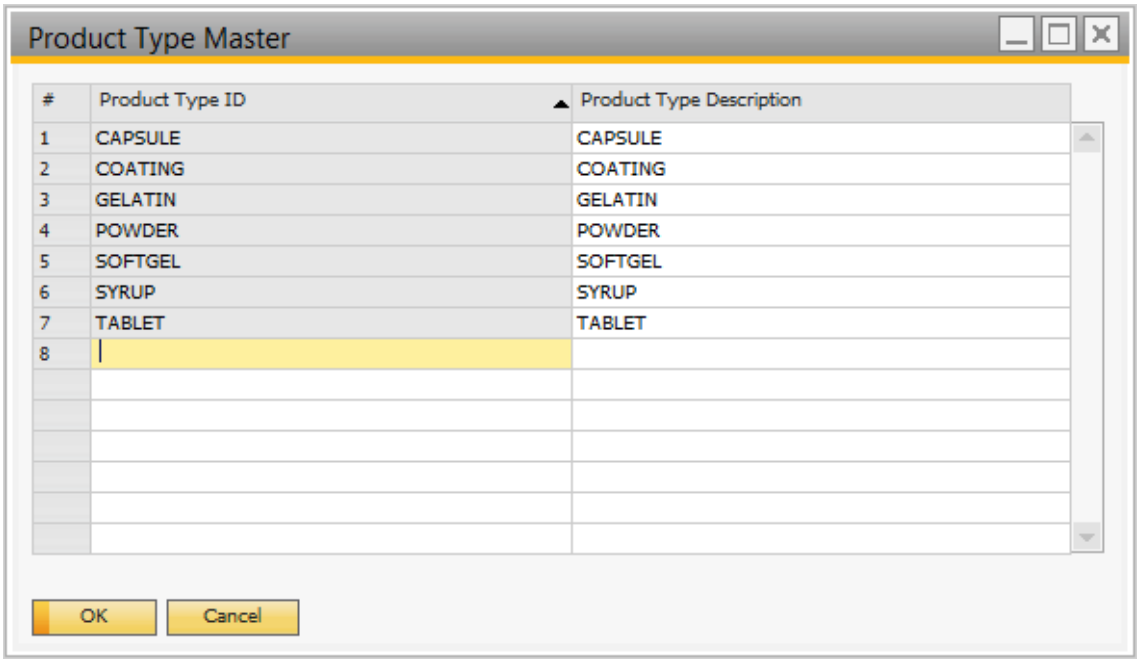
In addition to these basic functionalities, with the Nutraceutical license the following features are included and used in the *Physical Property Analysis* module:

- *Define Product types*
- *Define Soft-Gel types*
- *Define Capsule sizes*
- *Define Tablet shapes*
- *Define Tablet sizes*
- *Define Appearance colors*
- *Define Ribbon thickness*

14.2 Product Type Master

A product type can either refer to the dosage of your supplement or can indicate what product your formula is meant to produce. Some common product types are shown below.

Go To: Administration → Setup → Laboratory → Product Type Master



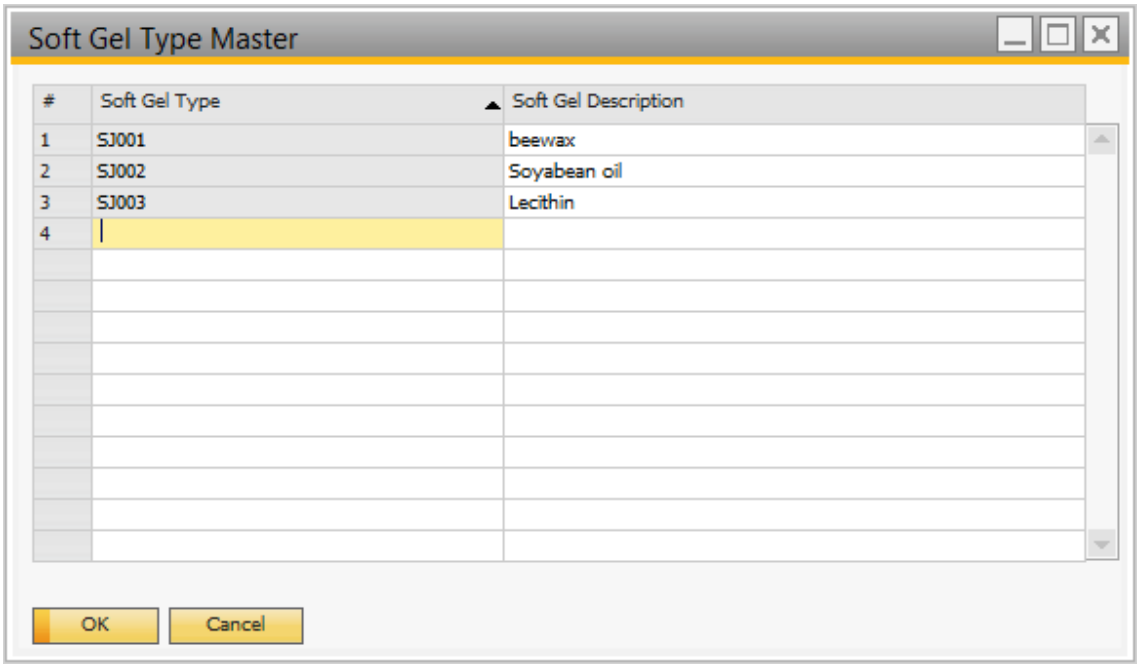
Enter a unique code for every product type in the *Product Type ID* field and a description for the same in the *Product Type Description* field. Click the *Update* button to save the new product type.

14.3 Soft Gel Type Master

Soft gel is the oil or lubricant that is used to provide a consistent texture to the product being manufactured. A homogeneous fill material plays a vital role to ensure the uniformity of each soft gel dose. Some of these filling materials include soybean oil, lecithin, bee's wax, oils and paste.

Use the *Soft Gel Type Master* screen to provide details of the soft gel being used.

Go To: Administration → Setup → Laboratory → Soft Gel Type Master



For every type of soft gel that you are adding, enter a unique code in the *soft Gel Type* field and a description for the same in the *Soft Gel Description* field. Click the *Update* button to save the data.

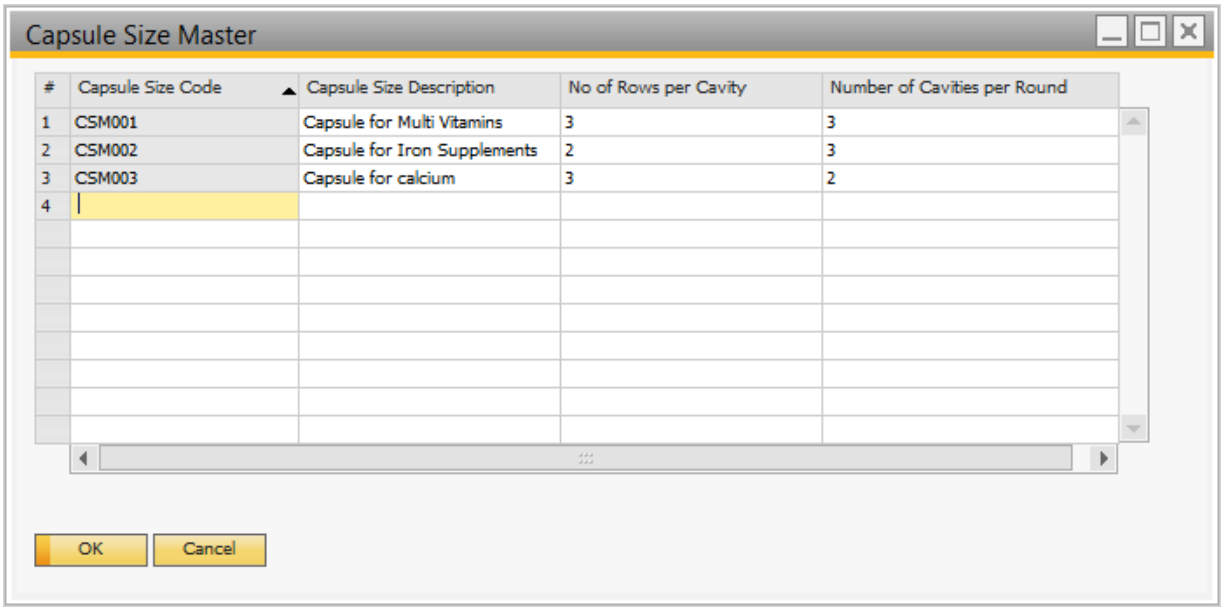
14.4 Capsule Size Master

You can use the *Capsule Size Master* to define the capsule sizes that you may use in your sample/product.

A capsule size is defined in terms of number of rows that contain cavities to hold ingredients and the number of cavities in each row.

To define a capsule size, open the *Capsule Size Master*:

Go To: Administration → Setup → Laboratory → Capsule Size Master

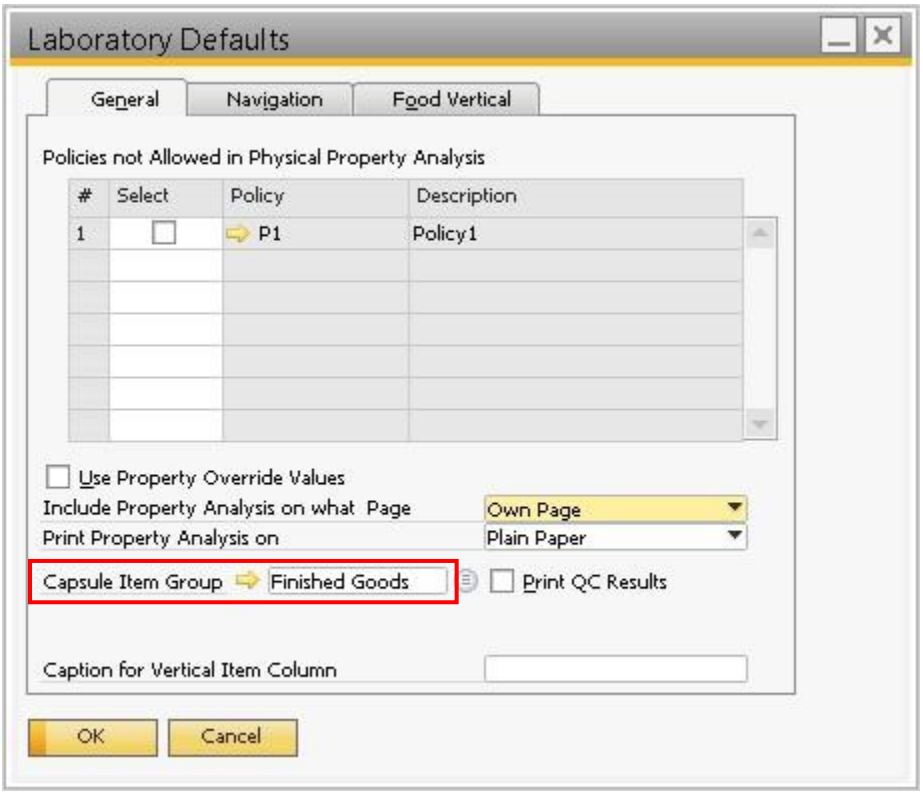


For every capsule size that you are defining, enter a unique code, a description for the code, number of rows and number of cavities in the respective fields.

Click the *Update* button to save the record.

14.4.1 Laboratory Defaults

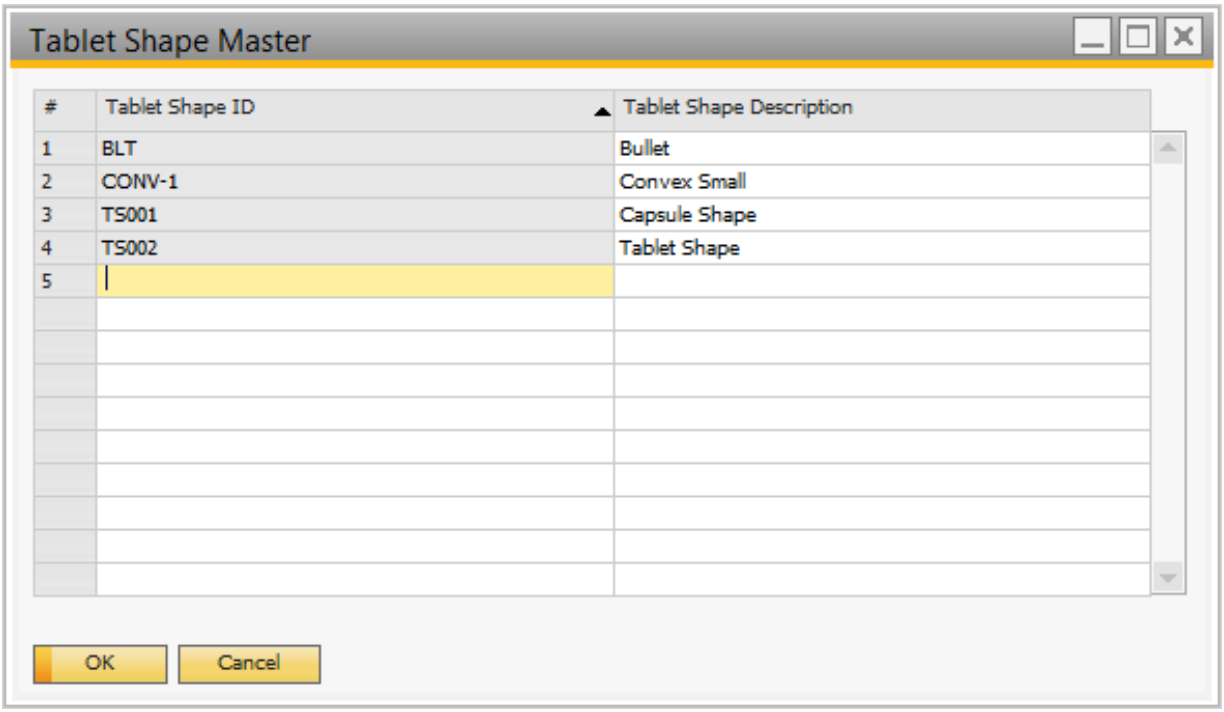
For a Capsule type of product, you can set the default Item Group whose item can be displayed in the Capsule Code lookup available at the *Physical Property Analysis* screen.



14.5 Tablet Shape Master

The *Tablet Shape Master* lets you define the shapes that you use for tablets. Later, during formulation at the *Physical Property Analysis* screen, you can select the desired shape for the tablet.

Go To: Administration → Setup → Laboratory → Tablet Shape Master

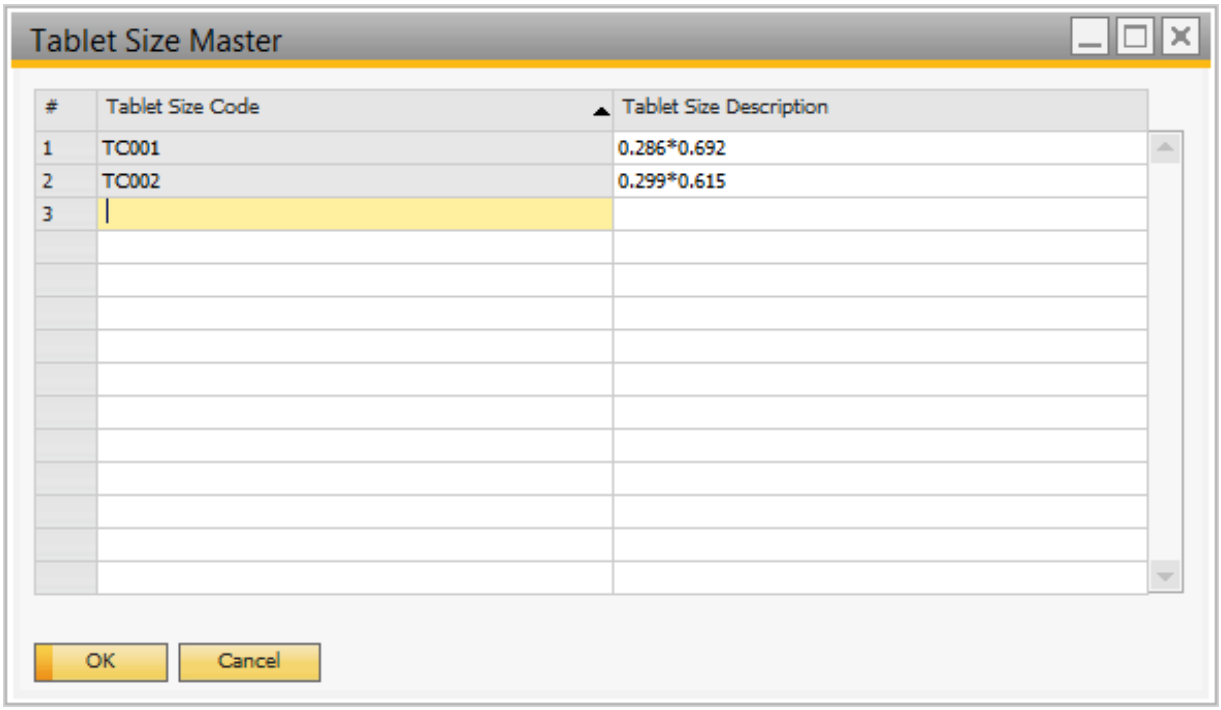


For every tablet shape that you are defining, enter a unique code and a description for the code in the respective fields. Click the *Update* button to save the record.

14.6 Tablet Size Master

You can define the dimensions or size of your tablet sample using the *Tablet Size Master*. Later, you can select the desired size for a tablet during its formulation in the *Physical Properties Analysis* screen.

Go To: Administration → Setup → Laboratory → Tablet Size Master

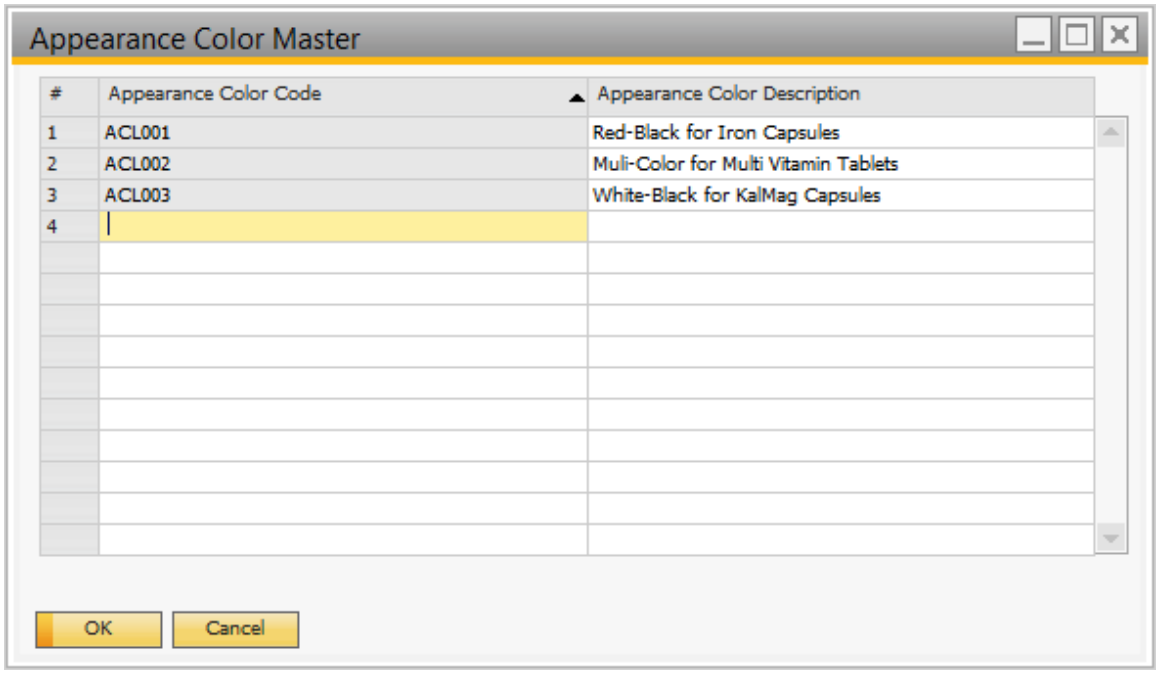


For every tablet size that you are defining, enter a unique code and the dimensions of the tablet in inches in the respective fields. Click the *Update* button to save the record.

14.7 Appearance Color Master

Use the *Appearance Color Type Master* to categorize the appearance of your nutraceutical products. Later, you can select the desired record for your sample during its formulation in the *Physical Properties Analysis* screen.

Go To: Administration → Setup → Laboratory → Appearance Color Master

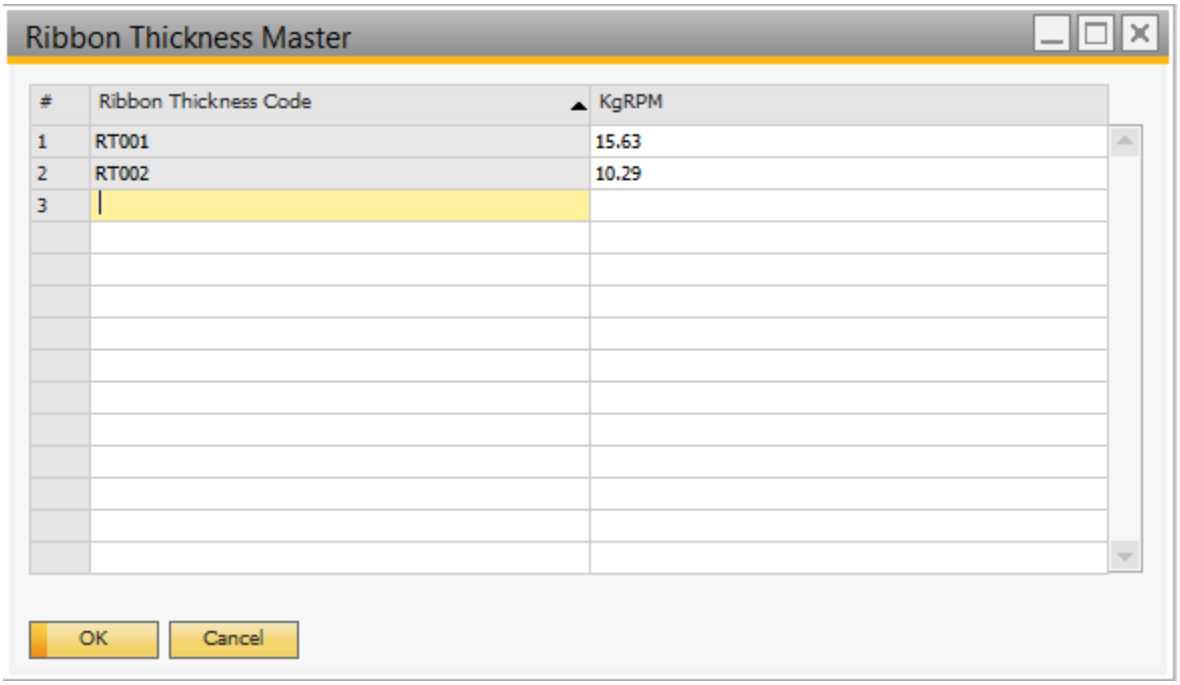


For every appearance record, enter a unique code and a description for the code, for better understanding. Click the *Update* button to save the record.

14.8 Ribbon Thickness Master

Use the *Ribbon Thickness* screen to define the thickness of soft gel ribbons. Later, you can select the desired record for your sample during its formulation in the *Physical Properties Analysis* screen.

Go To: Administration → Setup → Laboratory → Ribbon Thickness Master



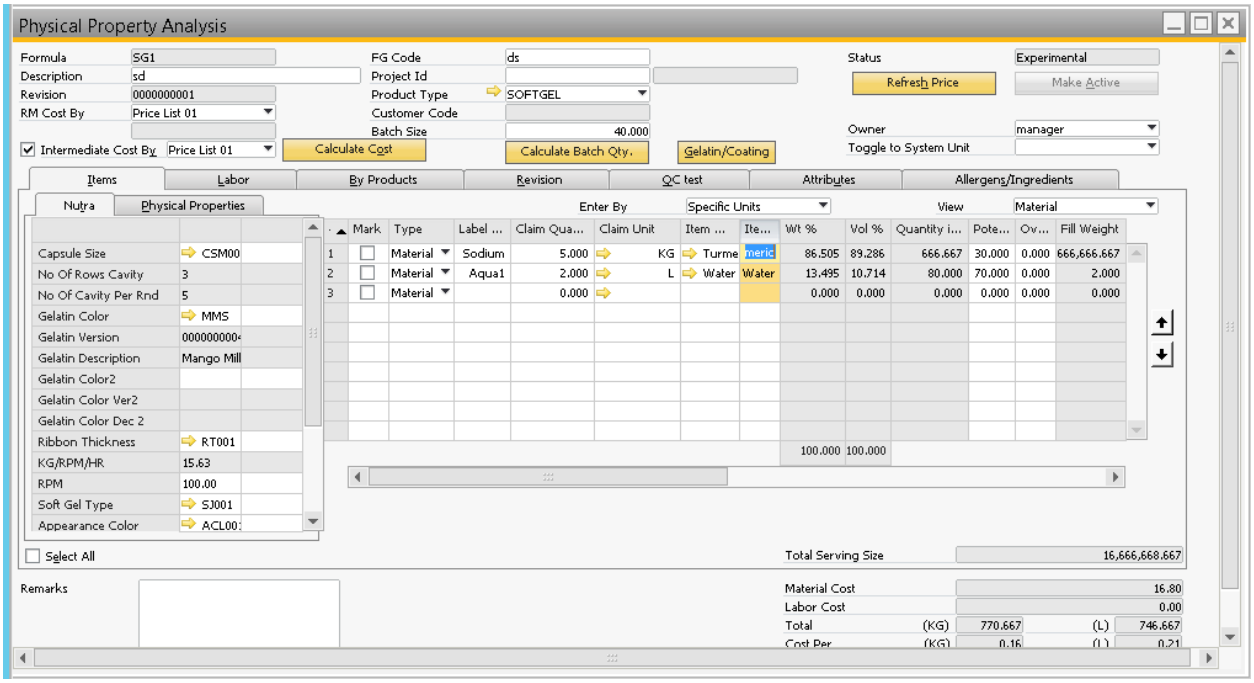
For every ribbon thickness record, enter a unique code and the ribbon thickness in RPM (Rotations Per Minute).

14.9 Physical Property Analysis Details

The *Physical Property Analysis* screen is equipped with special features discussed above that facilitate the development of sample formulas in a Nutraceutical or Pharmaceutical environment.

In order to make use of these sample-oriented features, you need to enter certain information on the *Physical Property Analysis* screen.

Go To: Laboratory → Physical Property Analysis



On the header, in the *Formula* field, select or enter the formula name. Next enter the item code of the finished good. When you are developing a formula for a sample for the first time, it is possible you have not added the finished good in the *Item Master*. You can define a temporary item key as the finished good item key. Once the quotation is approved by the customer, you can create the Item and BOM.

Next, select the product type of the sample that you will produce. Based on the *Product Type*, you may need to enter specifications on the Nutra tab.

The Nutra tab is disabled for the product types *Coating, Gelatin, Powder*, and *Syrup.*

In the *Customer Code* field, enter the customer for whom the product will be developed. This again helps you to associate a sample with the customer. You might have defined the formula for a specific number of capsules. In the *Batch Size* field, enter the number of capsules used in defining the formula.

Let us now move on to the *Items* tab. This tab contains fields that hold specific details about every ingredient of your sample formula. In the *Label Claim* and *Claim Quantity* fields, you provide the name and quantity of the item which will go into the supplement fact sheets. Also, enter *Potency* and *Overage* for every ingredient.

Potency is the percentage of active ingredient present in the item.

Overage is the excess quantity of the drug/ingredient that needs to be added to compensate for storage loss.

BatchMaster ERP automatically calculates the fill weight and batch quantity for every ingredient.

Fill weight is the quantity of the formula or drug that is filled into the product.

Batch quantity is the quantity of the formula used to produce the batch.

Fill weight = Claim Qty* [1+(overage/100)]*(100/potency)

Batch Quantity = Fill Weight (calculated above) * Multiplying Factor

The Multiplying Factor varies for different product types.

- For Capsule, Soft Gel, and Tablet, the multiplying factor is the same as the Batch Size.
- For Powder, the multiplying factor is Batch Size/Serving Quantity.

14.9.1 Soft Gelatin Capsules

If you have selected the *Product Type* of your sample as *Soft Gel* in the header section, you can view the fields pertaining to soft gels on the Nutra tab.

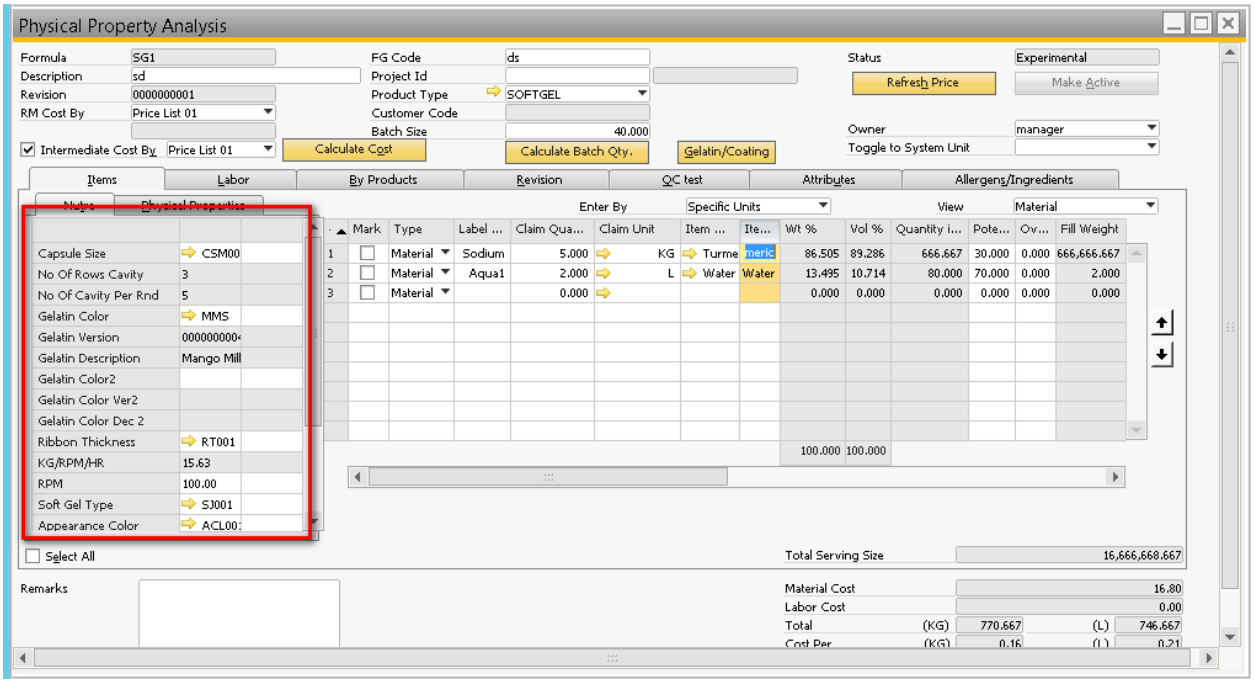
To develop a formula for a soft gel capsule, you need to work on the following prerequisites:

a. Use the *Item Master Data* and *Item Master Details screens* to create a gelatin item.

b. Use the same name or naming convention to prepare an intermediate BOM and make the BOM Active.

c. Prepare a formula for the gelatin item with the product type as *Gelatin*.

d. Make the formula Active. You may have to send it for approval, if approval procedure has been implemented for formulation.



Switch to the Nutra tab. First, you need to select the desired *Capsule Size*. The lookup in this field displays all the capsule sizes that you have defined. Once you have selected the capsule size, then the fields *No of Rows Cavity* and *No of Cavities per Round* are populated accordingly. Next, you need to select the desired formula for *Gelatin Color.* This is the formula that will be used to prepare the gelatin ribbon, used in making the capsule.

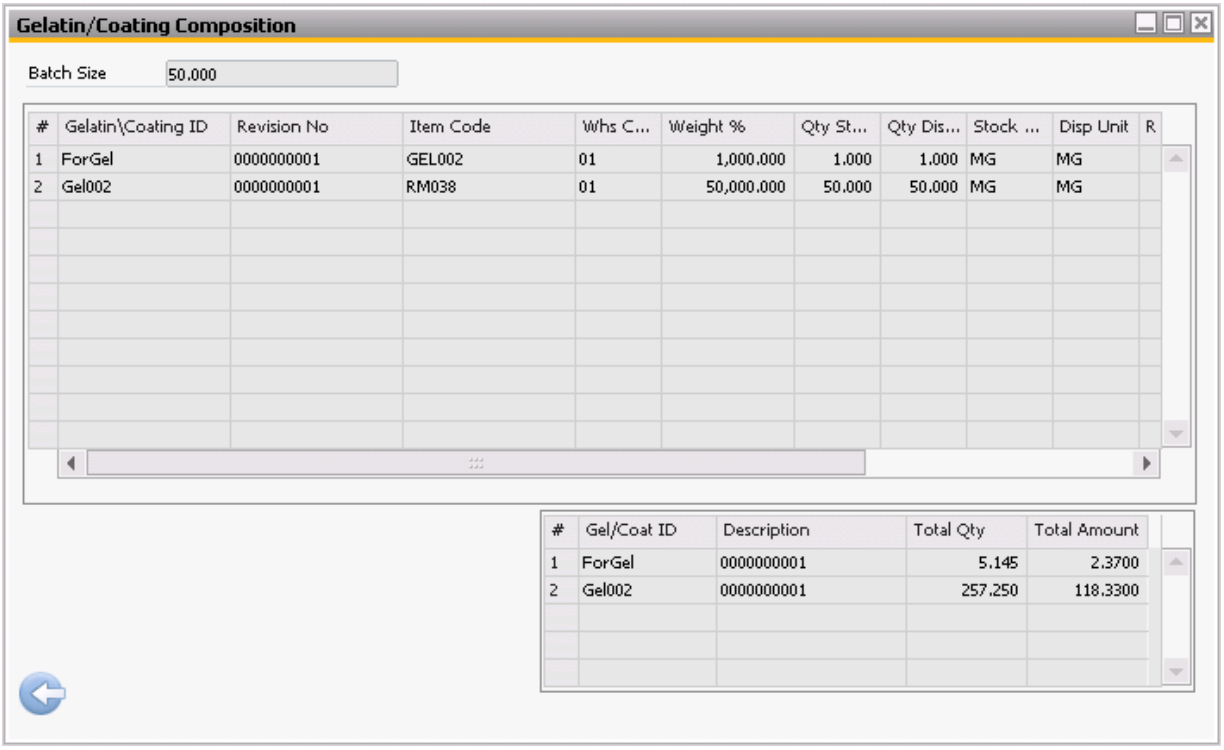
The lookups in the *Gelatin Color* field will display only those formulas whose *Product Type* is Gelatin.

Now, you need to select the *Ribbon Thickness* of gelatin that should be used in making the soft gel capsule. Once you have selected the ribbon thickness, the value of the field *KG/RPM/Hr* is populated automatically. Enter the speed of the roller dye in the *RPM* field.

Select the desired *Soft Gel Type* such as "paste and oil." Next, select the desired color for the soft gel capsule in the *Appearance Color* field. Enter the tolerance limit for fill weight (in percentage) in the *Control%* field.

Enter the average weight for 10 gel capsules. Enter the yield of gelatin formula in percentage. If the soft gel capsule is bi-colored, then enter the formula for the second gelatin color in the *Gelatin Color2* field.

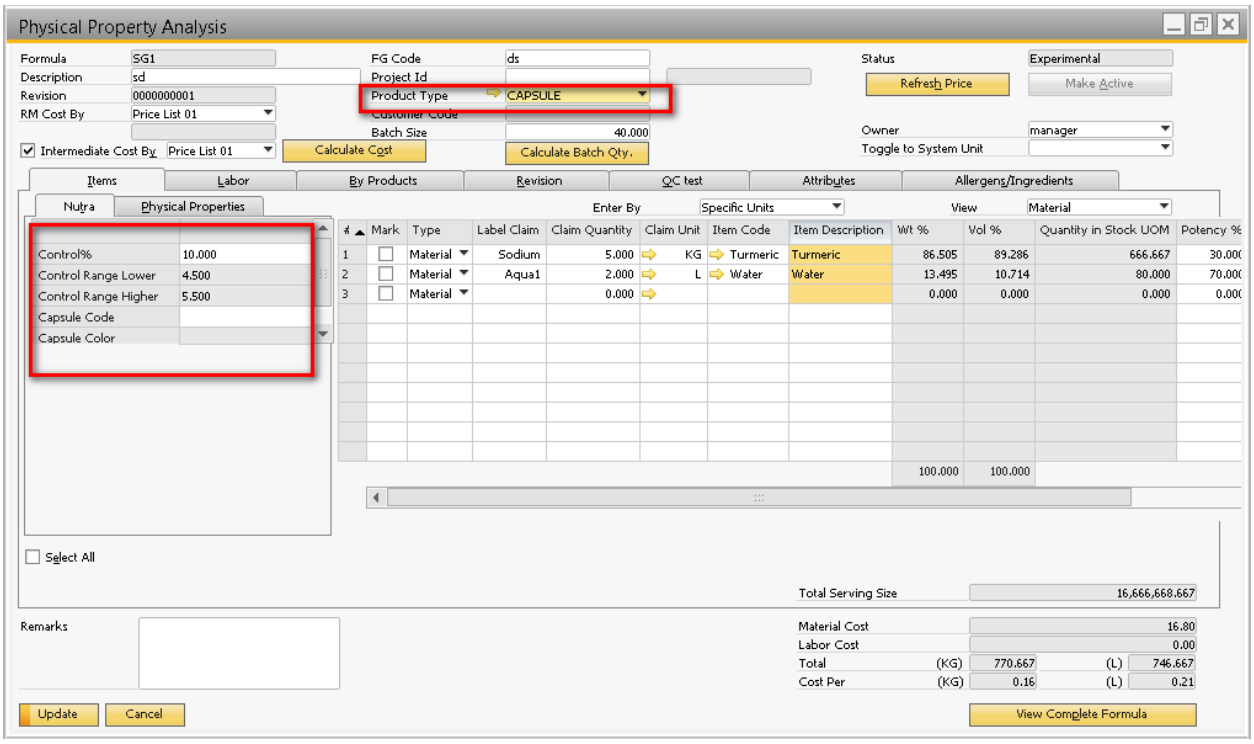
Click the *Gelatin/Coating* button on the header to view information on the gelatin formula used.



Here, you can view the details of the gelatin formulas that you have selected in the *Gelatin color*, and *Gelation Color 2* fields.

14.9.2 Capsules

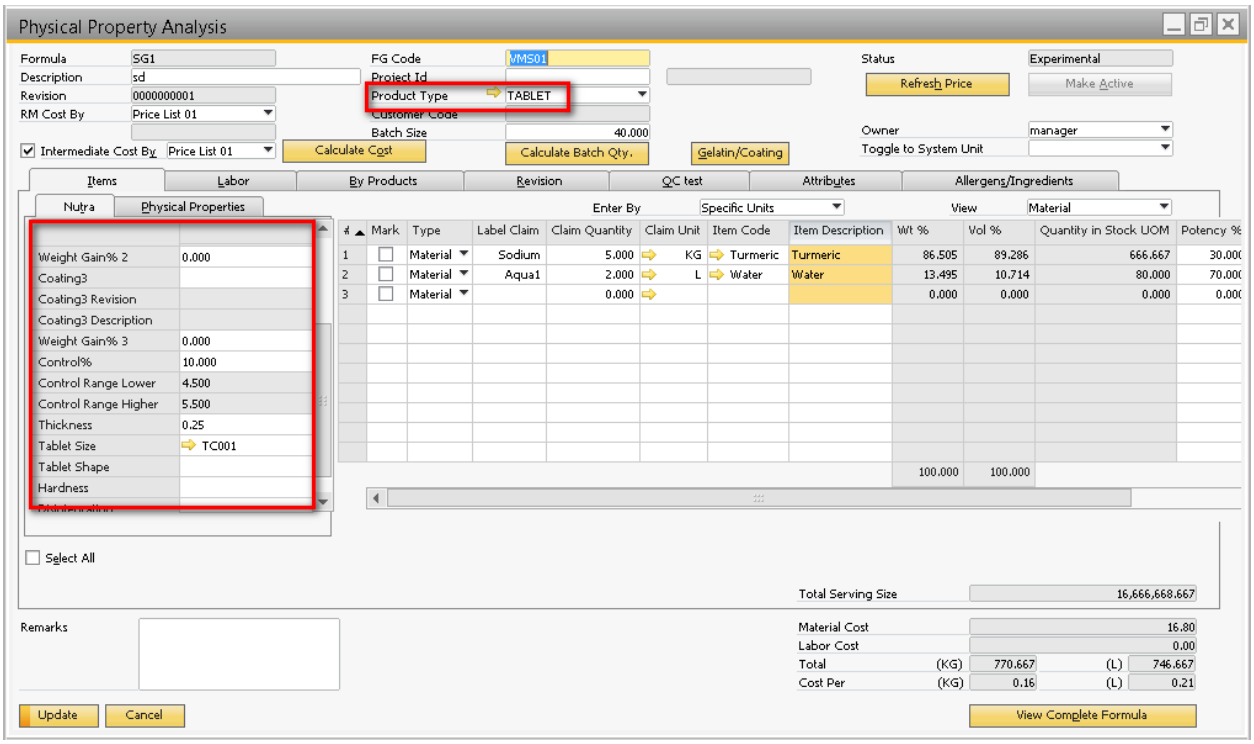
Just like Soft Gels, this product type has its own specifications. If you have selected the *Product Type* of your sample as *Capsule* in the header section, then these specifications will appear on the *Physical Property Analysis* screen.



You need to enter the item code of the hard gelatin capsule, in the *Cap Code* field. A Capsule is a purchased item so the search feature in this field will display items associated with the Item Group selected here. You can see that the *Capsule Color* field displays the description of the capsule code selected. It is drawn from the *Item Description* field of the *Item Master Details screen.* Enter the weight of the empty capsule. Then, enter the tolerance limit for fill weight, in percentage, in the *Control%* field.

14.9.3 Tablets

Like soft gels and hard gels, the specifications of tablets appear on the *Physical Property Analysis* screen, if you have chosen *Tablet* as the *Product Type* for your sample.



First, you need to enter the *Thickness* of the tablet. Next, select the *Tablet Size*. The lookup in this field will display all records from the *Tablet Size Master screen.* After tablet size, you need to select the desired *Tablet Shape*. The lookup in this field will display all records from the *Tablet Shape Master screen.*

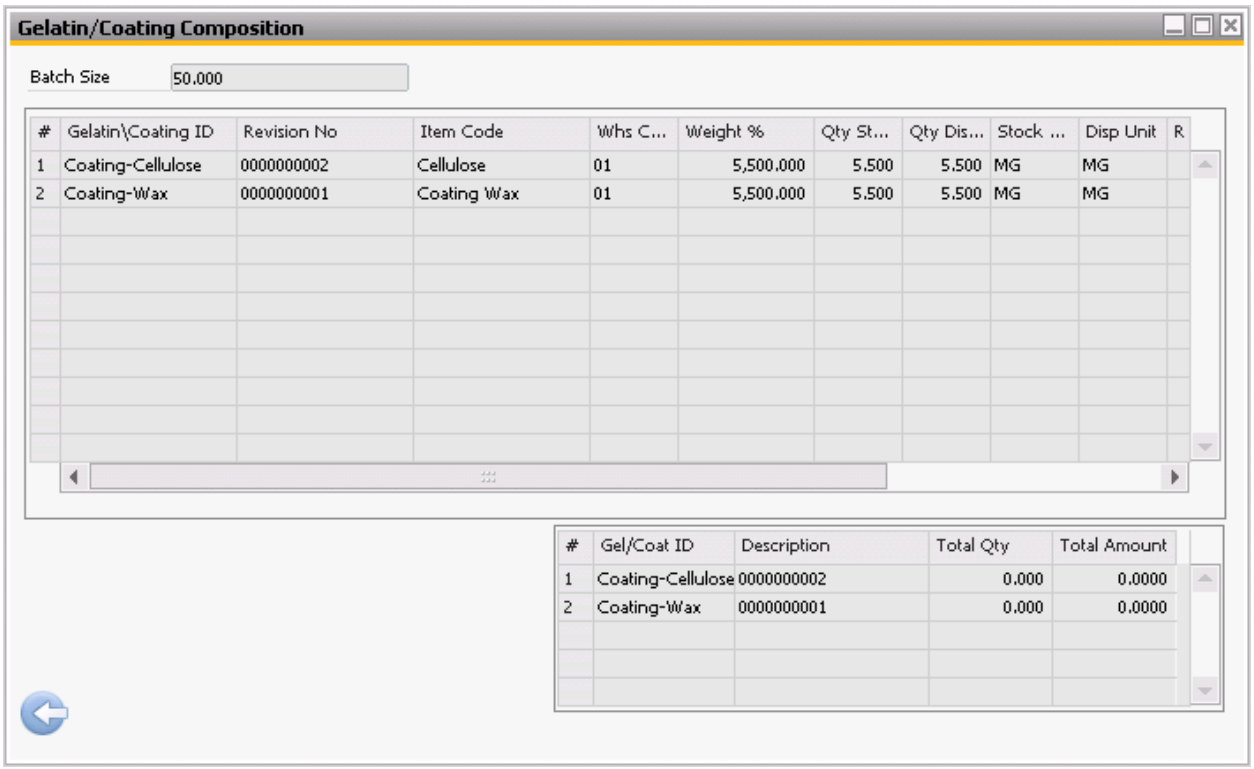
Let us now move on to coating formulas. A tablet may need to be coated multiple times and each time with a different formula. Enter the coating formulas, one by one, in the *Coating1*, *Coating2*, and *Coating3* fields.

The lookups in the Coating fields will display only those formulas whose *Product Type* is Coating.

Once you have specified the formulas for coatings, enter the percentage of weight gained in each of these coatings, in the *Weight Gain%1, Weight Gain%2*, and *Weight Gain%3* fields.

Next, enter the *Hardness* of the tablet. Hardness is the property of a material to hold all its constituents intact. Also, in the *Disintegration* field, enter the time taken by the tablet to disintegrate and release medicine. Then, enter the tolerance limit for fill weight (in percentage) in the *Control%* field.

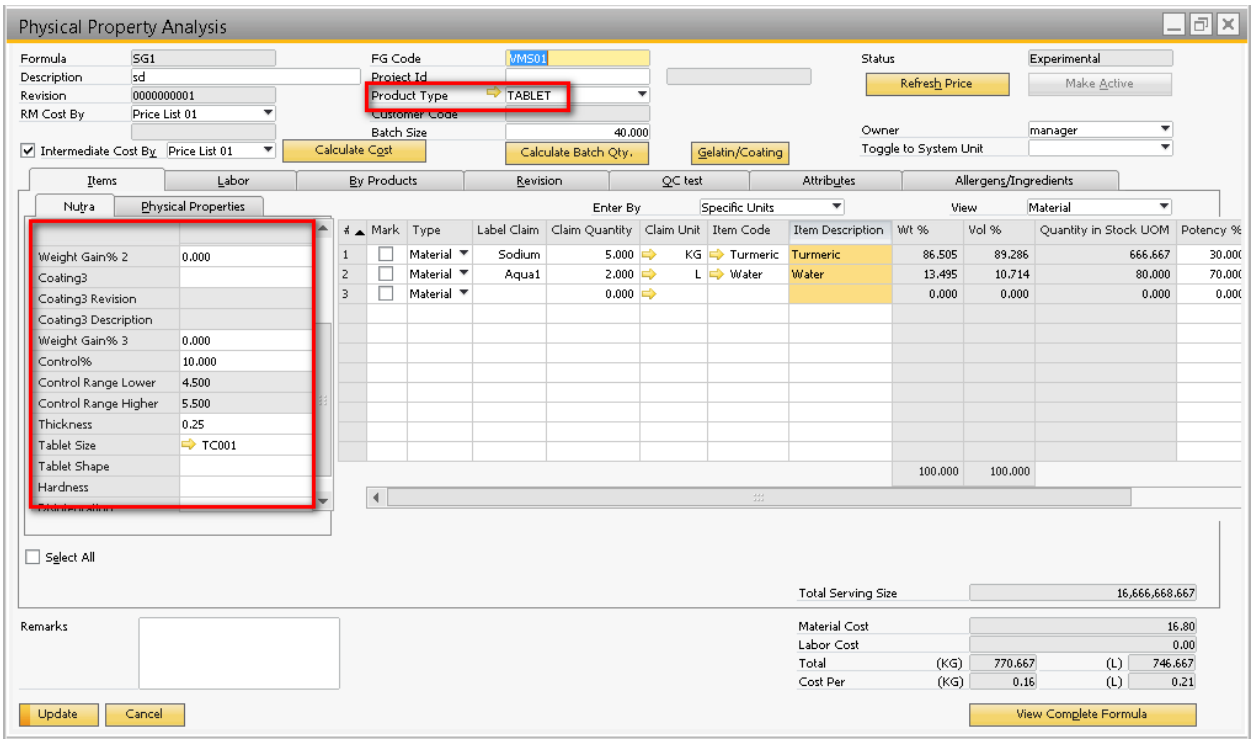
Click the *Gelatin/Coating* button in the header area to view the coating information of tablets.



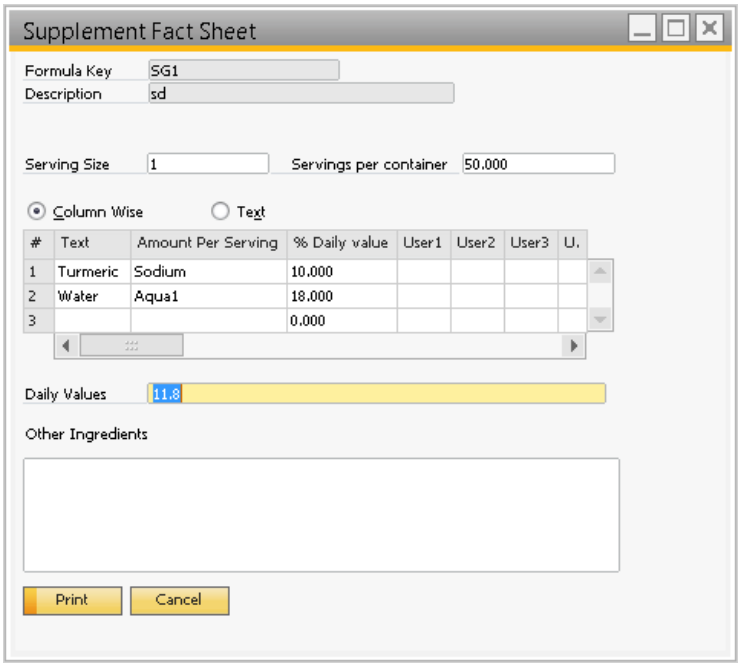
Here you can view the details associated with the coating formulas that you've selected in the *Coating 1, Coating 2*, and *Coating 3* fields.

14.9.4 Supplement Fact Sheet

You can generate a supplement fact sheet right from the *Physical Property Analysis* screen. To do so, right-click anywhere on the screen and select the *Supplement Fact Sheet* option.



You can use the *Supplement Fact Sheet* screen to obtain formula-specific item-wise details, such as the nutrition value of ingredients, serving size, and servings per container.



You can view the formula key of the sample in the header of the screen. Enter the *Serving Size* of the supplement/product. Then, enter an estimated number of servings available in each container of the product/formula, in the *Servings Per Container* field.

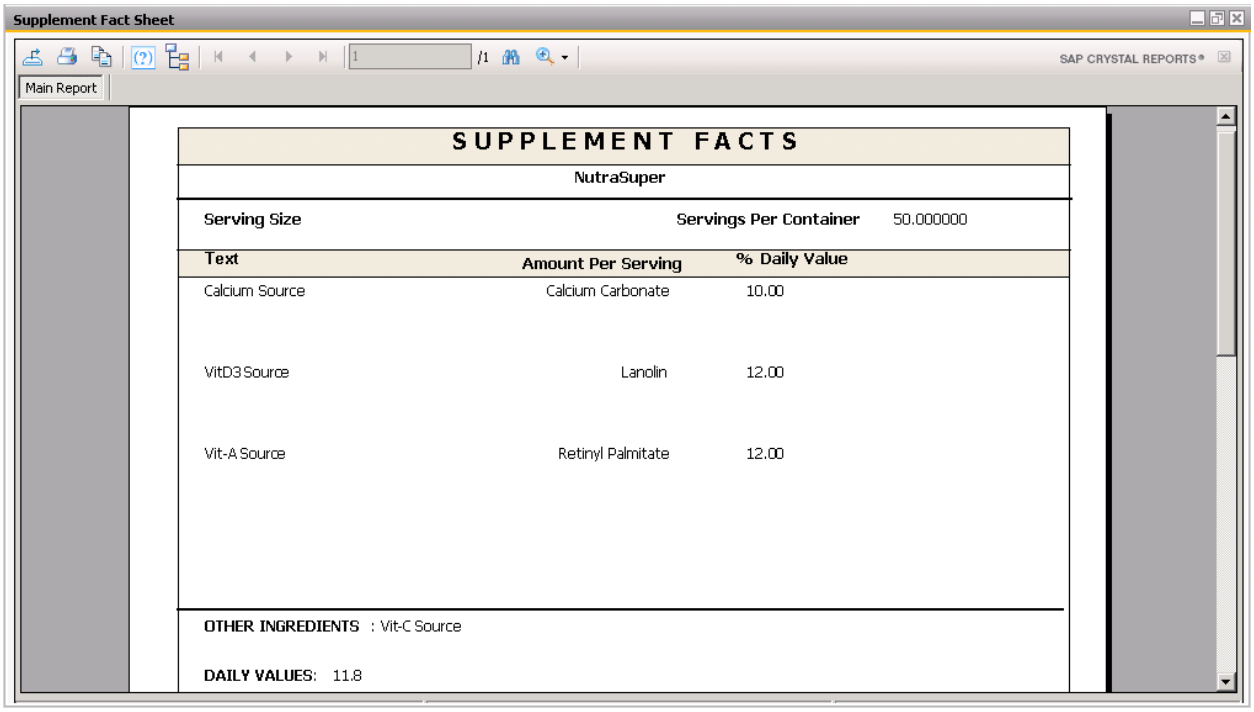
Serving Size is the quantity of the formula to be consumed in one serving.

Next, you need to select the desired option*: Column Wise* or *Text*, to choose whether you would like to display the information in multiple columns of a table/grid or in a read-only paragraph format. **The grid displays only those ingredients for which the label information is maintained in the *Physical Property Analysis screen, Items tab, grid.***

For every ingredient in the grid, you need to enter the quantity of the ingredient to be consumed in each serving, in the *Amount Per Serving* field and the percentage of ingredient quantity to be consumed in each serving, in the *%Daily Value* field.

Enter the quantity of the formula/product to be consumed in each serving, in the *Daily Values* field. In the *Other Ingredients* field, you can view those ingredients for which no value has been specified in the *Label Claim* field of the *Physical Property Analysis screen.*

Once you have specified the above details in the *Supplement Fact Sheet* screen, click the *Print* button to generate the Supplement Fact Sheet.



15 Supplement Fact Sheet

Supplements are products intended to complement the diet, containing such ingredients as vitamins, minerals, herbs. In Nutraceutical industries, for compliance with regulatory requirements, you need to print a supplement fact sheet to exhibit the contents of supplements in a specified formula or finished good.

BatchMaster Enterprise lets you print a supplement fact sheet including details such as name and quantity of ingredients present in the product that have daily dietary requirement values, serving size, and servings per container. In sequence, it lists nutrients like total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron, if present in measurable amounts. Following the listing of dietary ingredients, it also displays other dietary ingredients that do not have daily values.

15.1 Key Terms

Serving Size: One serving of a dietary supplement equals the maximum appropriate or recommended amount listed for consumption per dose. Say, serving size would be 2 tablets if directions on the label suggested an intake of 1-2 tablets daily.

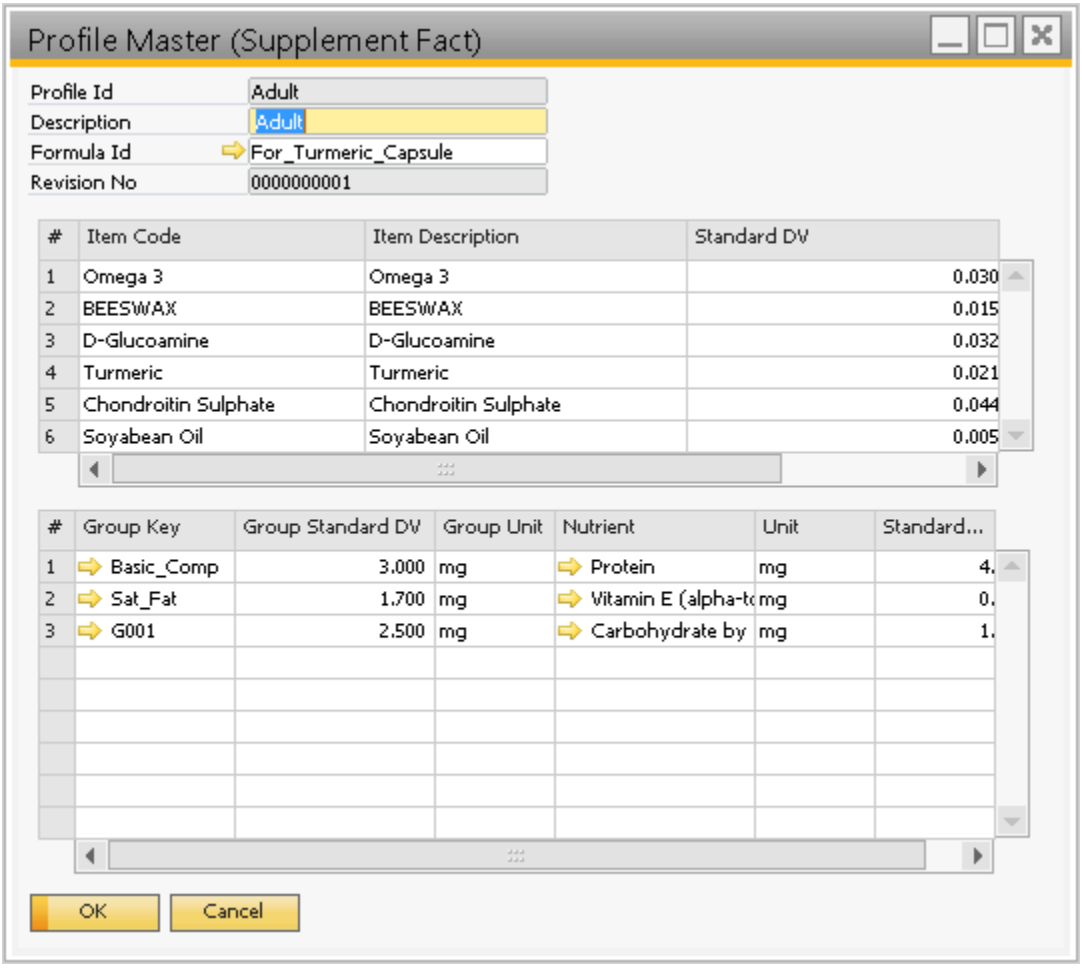
Serving per container: Provides the number of Servings in the container.

%DV: Percentage of daily reference value of dietary ingredients consumed per serving of a formula/product.

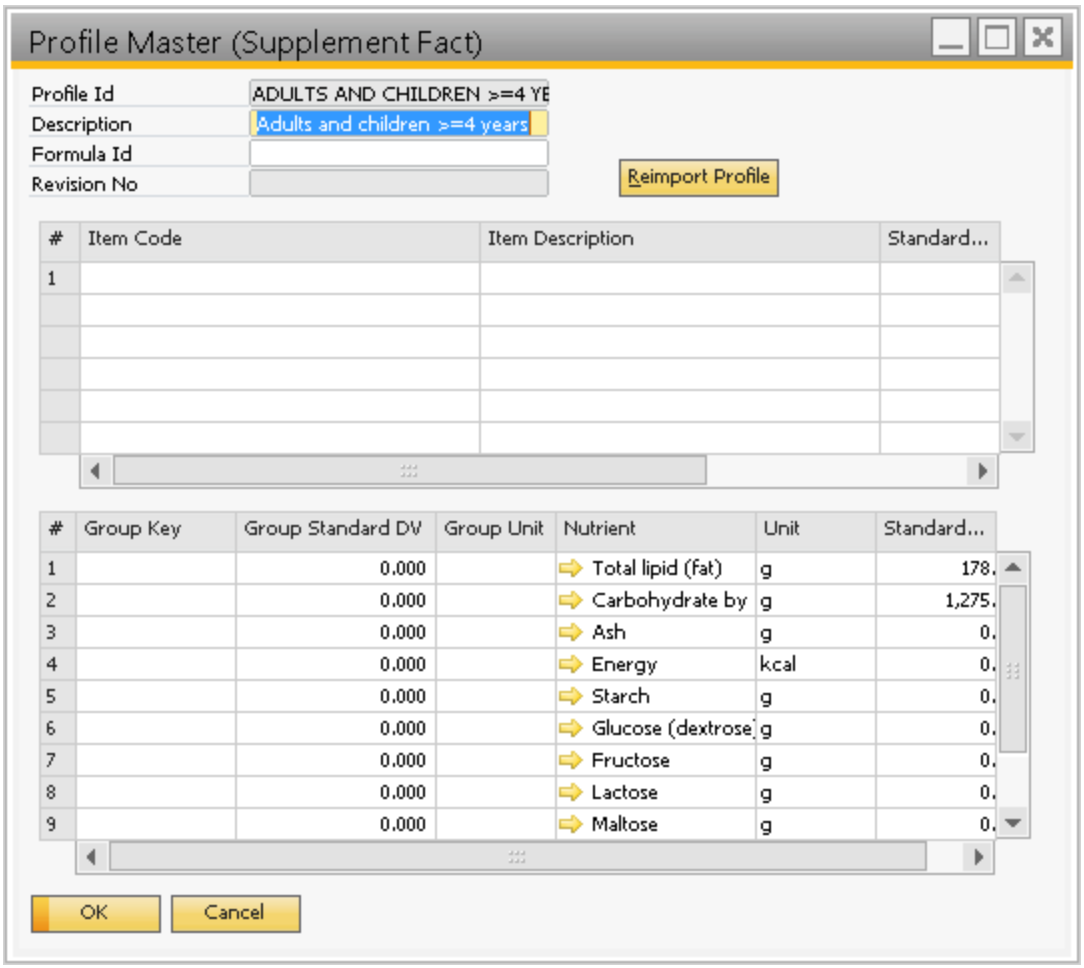
= (Calculated label claim Value at Print supplement fact sheet * 100) / Standard Value of selected Profile for the property (as Maintained at Profile Master)

15.2 Profile Master

Using the *Profile Master* screen you can define various profiles such as adult, child, for which supplement fact sheets need to be generated. On the screen you can select the finished good formula and specify the nutritional value of its constituents.



If you have imported the standard profiles for the supplement fact sheet from the *Formula Defaults* screen then for the imported profiles the *Profile Master* screen displays the *Reimport Profile* button.



15.2.1 Maintaining the Profile Master

1. Enter a unique identification key of the profile and its description in the *Profile ID* and *Description* fields respectively.

2. Using the *Formula* Lookup select the formula for which the profile is required to be maintained.

3. In the upper grid, the formula ingredients for which label claim value are specified on the *Physical Property Analysis* screen are auto-populated. If required, modify the standard daily values.

4. To add more items, click the *Add line* button. This will insert a blank line in the grid. Obtain the required item and specify the Standard Daily values.

5. To delete any existing line in the grid, select it and click the *Delete Line* button.

6. In the lower grid, nutrients/nutrient group, for which *Use in Supplement Fact* checkbox is checked on the *Material Property Master* Screen, are displayed.

7. Specify their standard daily values and unit in the respective fields.

   The Group Standard DV value should be unique for the same Group Key.

8. Use the *Add line/Delete Line* button to add or delete the required item/nutrient.

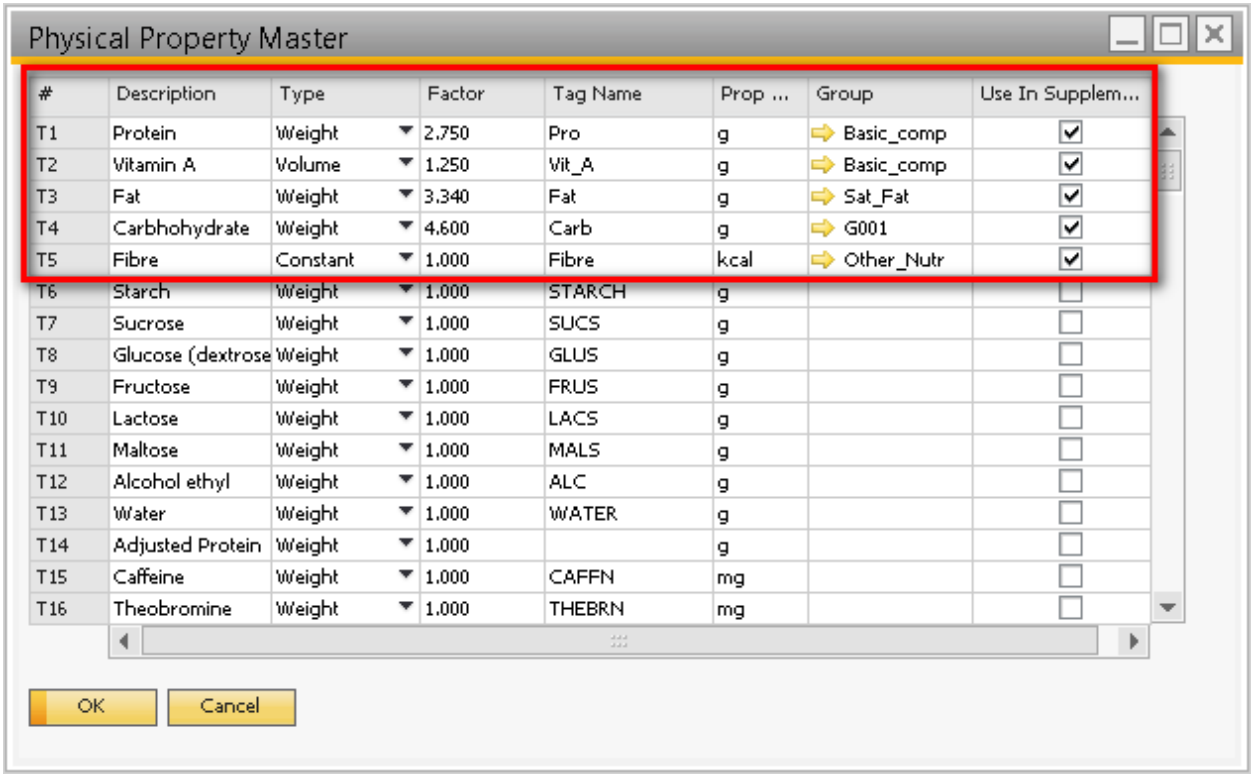
9. For the Profile you have imported from the *Formula Defaults* the *Reimport* button gets displayed. Clicking on it will overwrite the values specified on the screen with the standard data values.

10. Click the *Save* button to save the record.

15.3 Material Property Master

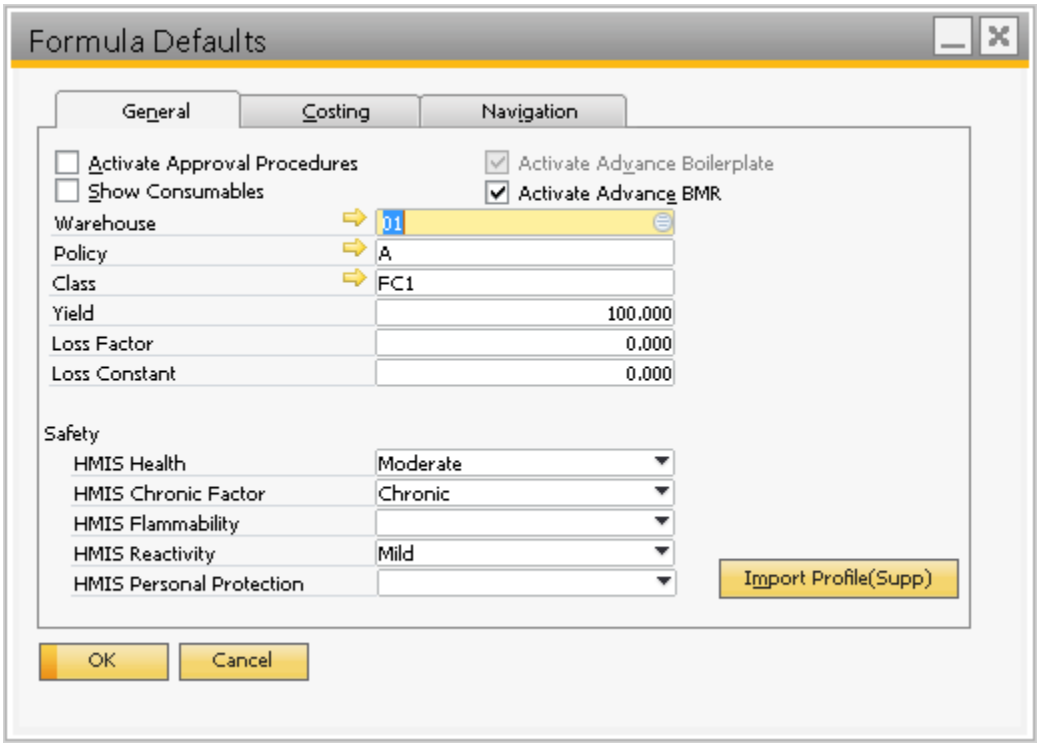
On the *Material Property Master* screen, *Use in supplement Fact* checkbox lets you specify that the respective property can be printed on a Supplementary Fact Sheet.

Go To: Laboratory → Physical Property Master



15.4 Formula Defaults

You can import the standard Profile on *Supplement Fact sheet* by using the *Import Profile* button. The imported profiles will be copied as the default profiles on the *Profile Master* screen.



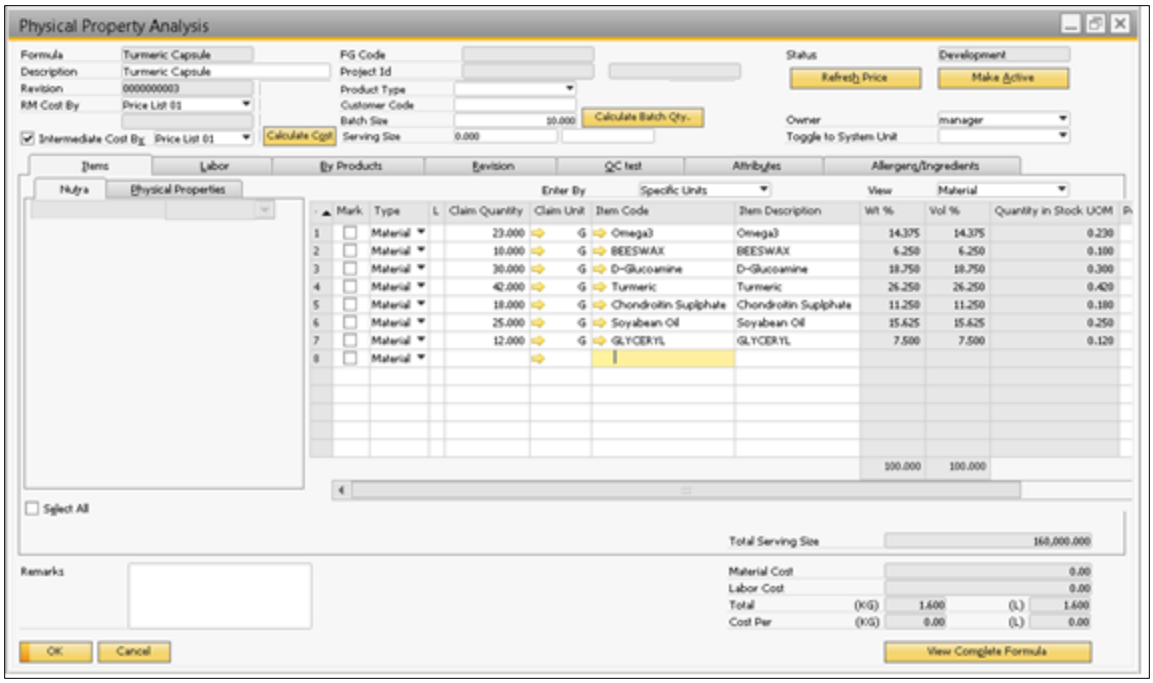
15.5 Printing Supplement Fact Sheet

The nutrition label of a dietary supplement is the Supplement Fact Sheet. You can print a Supplement Fact Sheet in 5 distinct formats, each contributing specific details.

The *Physical Property Analysis* screen has a special function button to launch a Supplement Fact Sheet for the formula. The steps for printing a Supplement Fact Sheet are as follows:

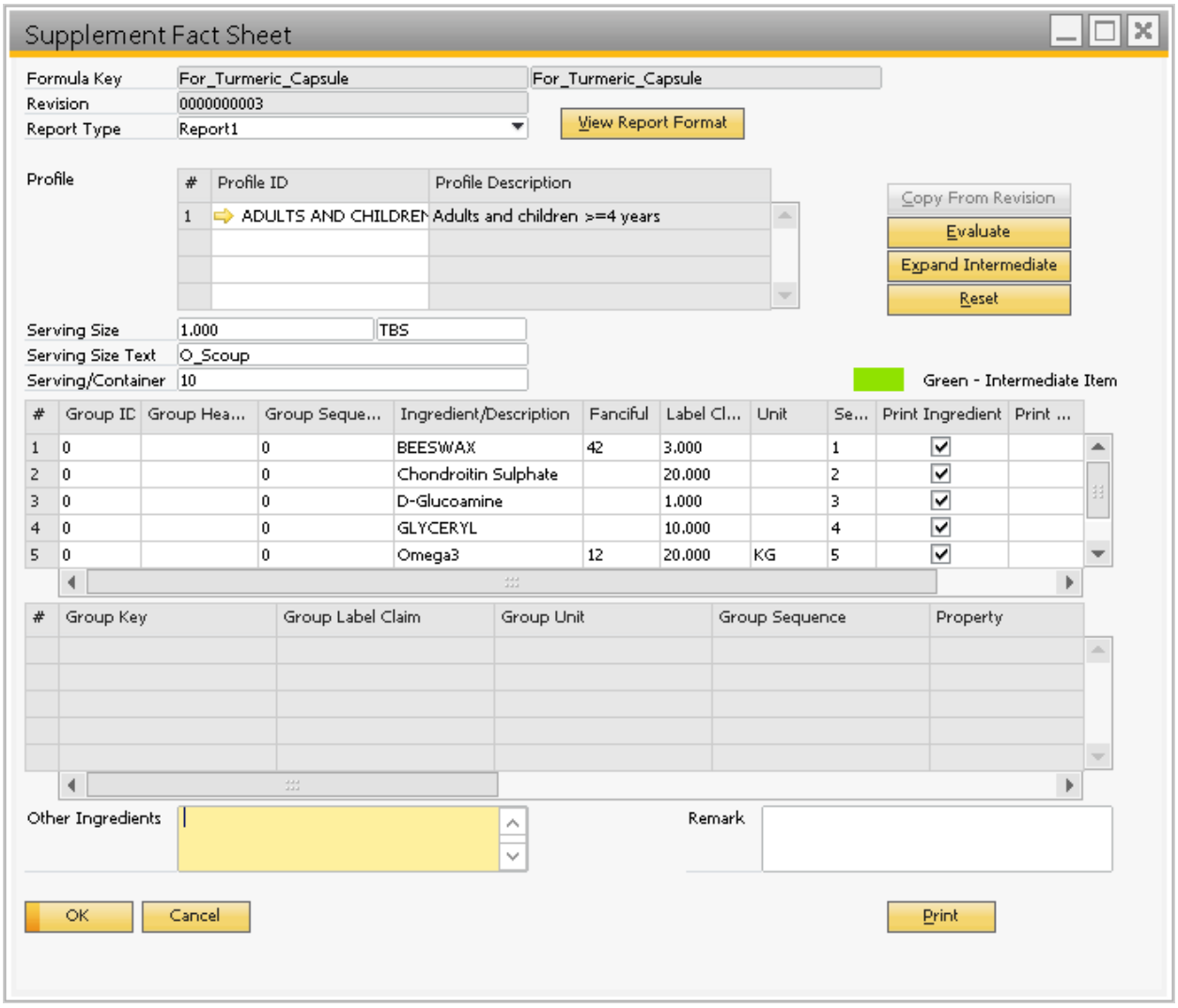
Go To: Laboratory → Physical Property Analysis.

1. Open the *Physical Property Analysis* screen.
2. Select the Formula Key of the finished good item for which a supplement fact sheet needs to be printed.



3. Right click on the screen and choose the *Supplement Fact Sheet* option from the pop-up list.

4. The *Supplement Fact Sheet* screen appears as below.



5. Using the *Report Type* dropdown, select the report you wish to print, from the 5 standard formats you can choose from. You can use the *View Report Format* button to see the layout of the selected report.

6. Select the required *Profile*. You can add *n* number of profiles here. Each profile added will be a new column in the report.

7. Specify the recommended amount of dietary supplement in the *Serving Size* field and select its measuring unit using the lookup button. If you have specified the Serving Size value and units at the Physical Property Analysis screen then those values will be copied here in the respective fields.

8. Use the *Serving Size Text* field to enter details related to serving size. Note that the text you specify in this field will overwrite the Serving Size value on the report.

9. Enter the quantity of servings in a container in the *Servings Per container* field.

10. Click the *Evaluate* button.

11. The upper grid displays the formula material items for which a label claim value is specified on the *Physical Property Analysis* screen, while in the lower grid the nutrition properties and groups, for which the *Use in Supplement* checkbox is checked on the Material Property Master screen, are displayed.

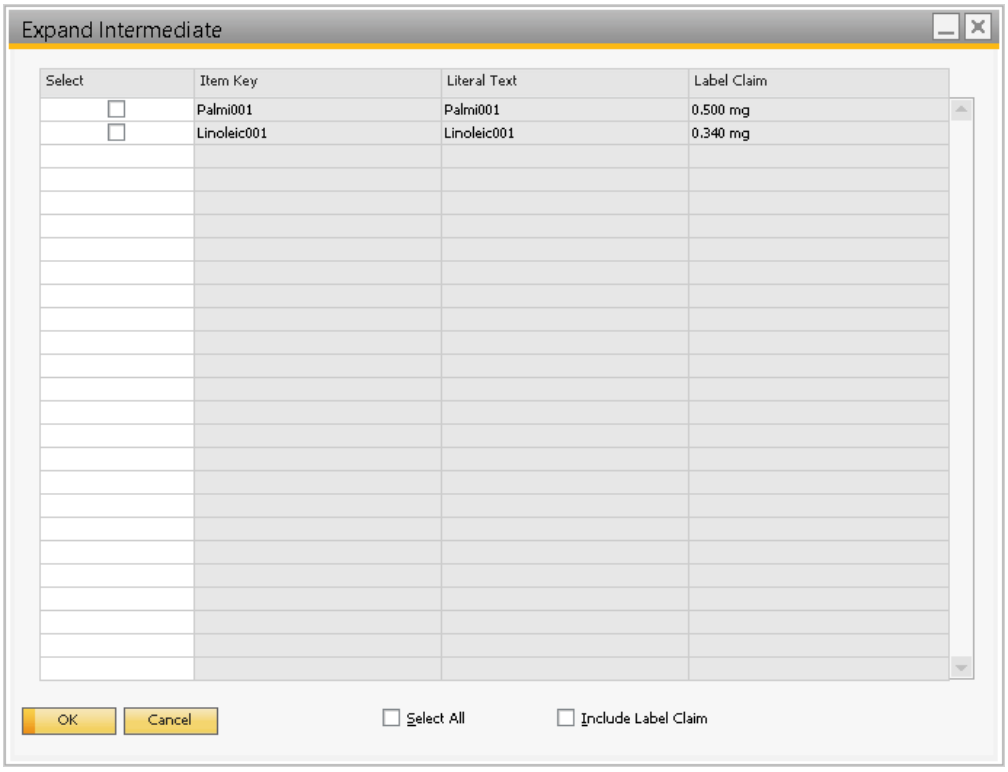
12. In the *Group Sequence* field enter the printing order of item and nutrition properties. It signifies the order in which they will be printed on the report. Note that, irrespective of the Group sequence number you specified for an item, the system will always print all nutrient property preceding items.

13. Specify the Group Heading with respect to the Group ID. The title you specify here will be displayed as the section head on the report.

14. The *Text* field is defaulted with the name/description of an ingredient. If required, you can modify it. Every time you modify the text, it will be added in the master list and can be reused further via the respective field lookup.

15. To print the report for any other revision of the formula, click on the *Copy from Revision* button. This will open the formula lookup window from where you can select the required version.

16. You can click on the *Expand intermediate* button to see intermediate details of the selected item. For the item, if the BOM has already been released, then on clicking this button the *Expand Intermediate* screen pops up. From this screen you can choose the items required to be displayed on the report. Also, the *Include Label Claim* checkbox is available to print the Label claim on the report.



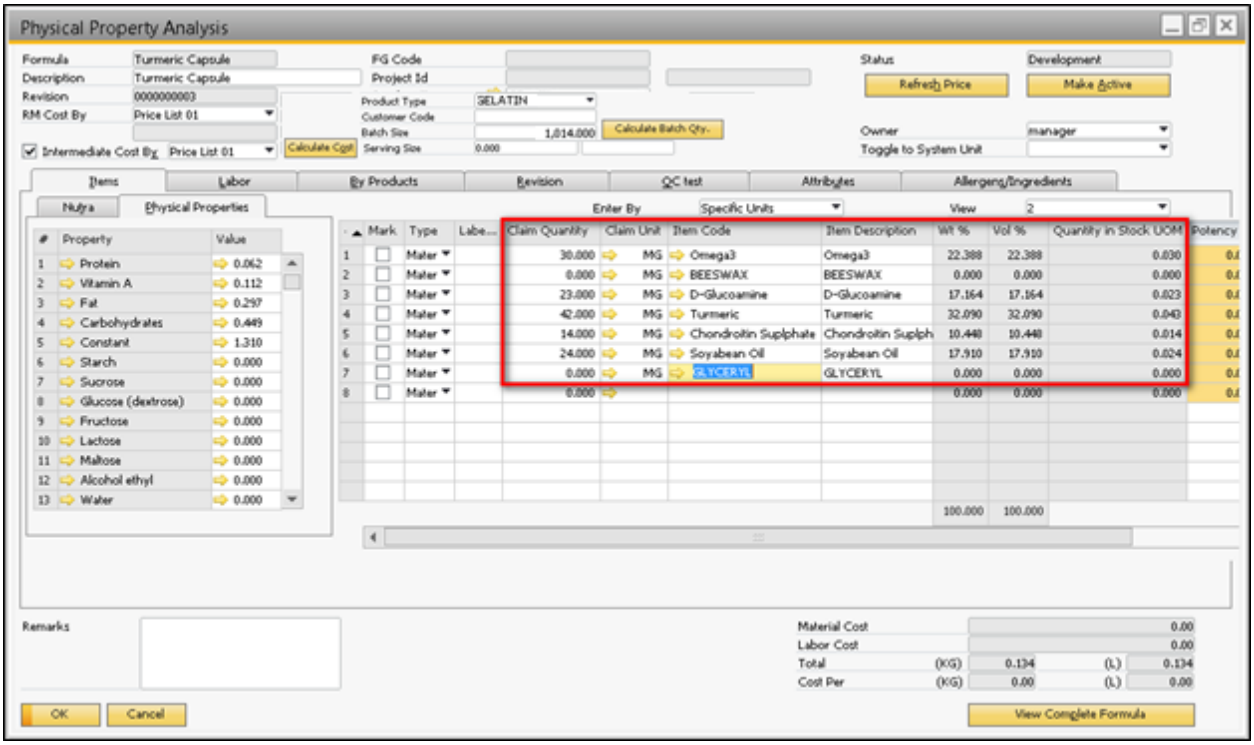
17. You can use the *Reset* button to refresh the screen with the actual property values, mentioned at the Physical *Property Analysis* Screen.
18. You can check the *Hide Column* checkbox to hide the % DV value of a specific dietary ingredient from the report.
19. Use the *Total Column* checkbox to display a *Property Group* total for the selected nutrient and property. The value obtained will be indented to the right.
20. In the *Other Ingredients* field, the material lines for which a label claim value is not specified on the *Physical Property Analysis* screen are displayed. If required, you can specify more items in this field.
21. In the *Remark* field you can add any note or comment specific to the report. The text you specify here will be printed at the end of the report.
22. Click the *Print* button to print the *Supplement Fact Sheet* report.

15.5.1 Understanding the Supplement Fact sheet with an example.

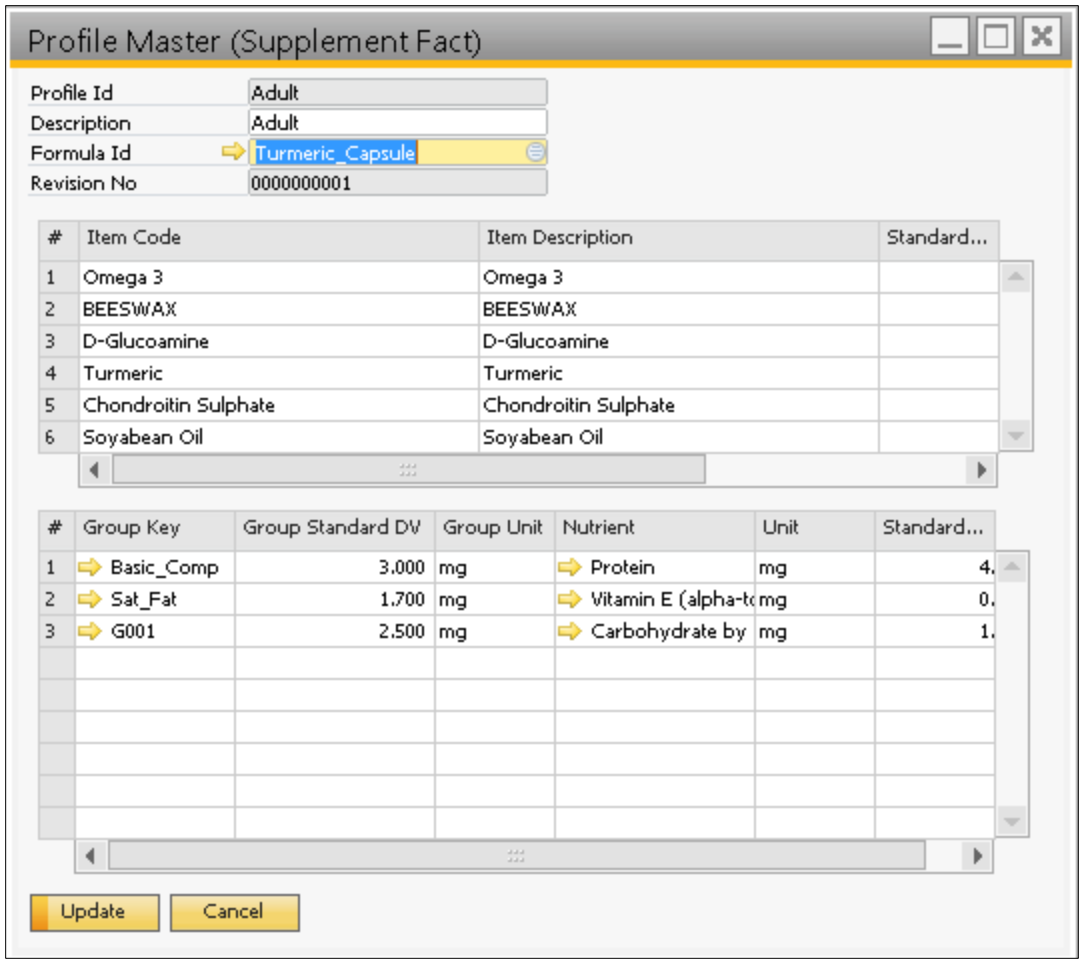
Recall the Formula on the *Physical Property Analysis* screen and specify the Label Claim value of formula items.

Items for which you don't enter the label claim value will not be retrieved in the grid of *Print Supplement Fact Sheet* and will be printed as an *Other Ingredients* item on the report.

Say, for our finished good formula key 'Turmeric Capsule', we have specified label claim values for the item keys *Omega 3, D-glucoamine, Turmeric, Chondroitin Sulphate, Soyabean Oil* but left it blank for item keys *Bees Wax* & *Glyceryl*.



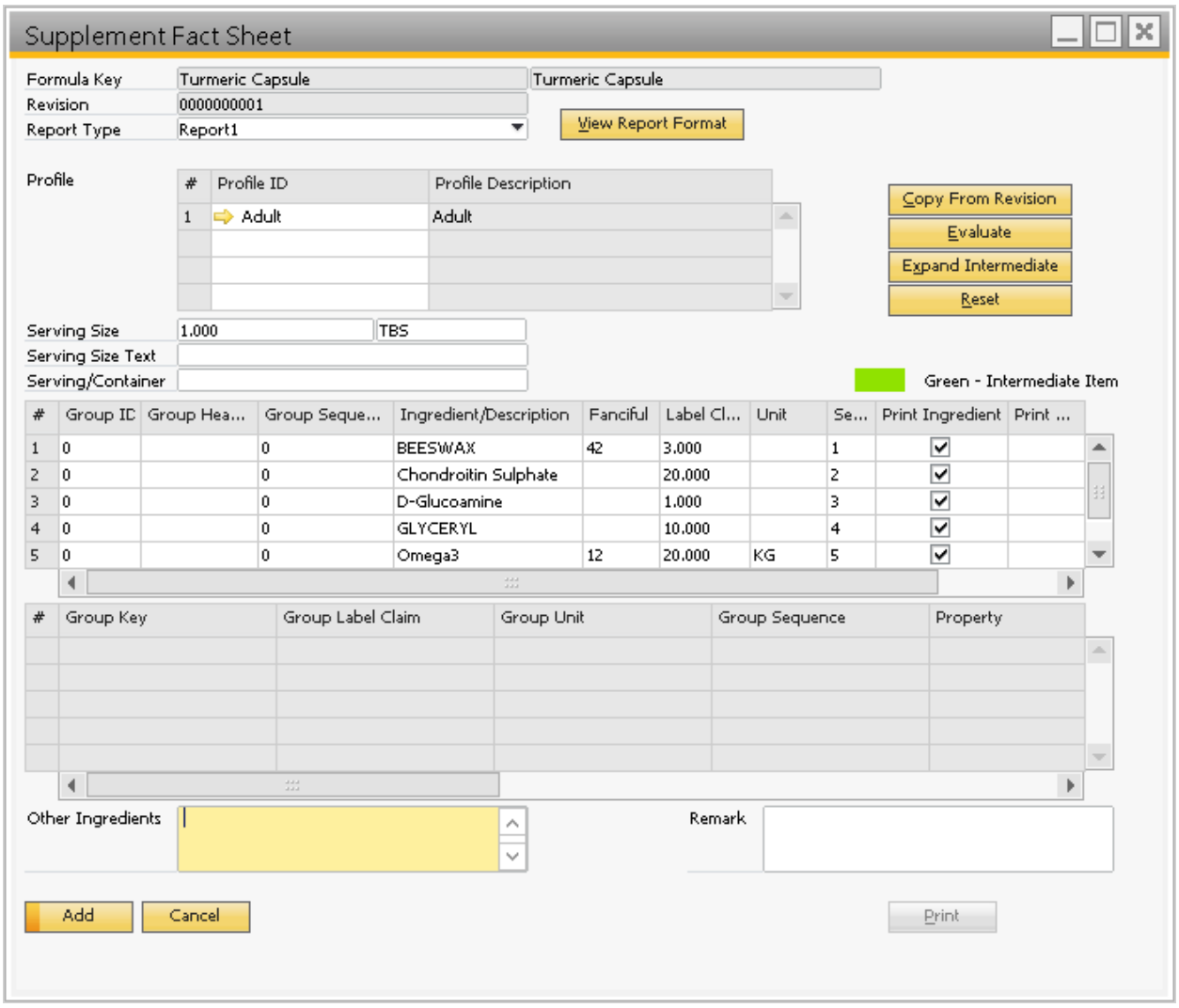
As the dietary value of ingredients is always printed in the context of age group, let's define a profile 'Adult001'. On the *Profile Master (Supplement Fact)* screen, as soon as we select the formula, the formula ingredients for which label claim values are specified are auto-populated in the upper grid. In the lower grid nutrients/nutrient groups for which the *Use in Supplement Fact* checkbox is marked are displayed.



You can add or delete a required item/nutrient using the *Add Row/Delete Row* option, available on right click. If required, modify the standard DV values and save the record.

Now open the *Physical Property Analysis* screen and select the required formula. Click the *Print Supplement Fact Sheet* button on the toolbar.

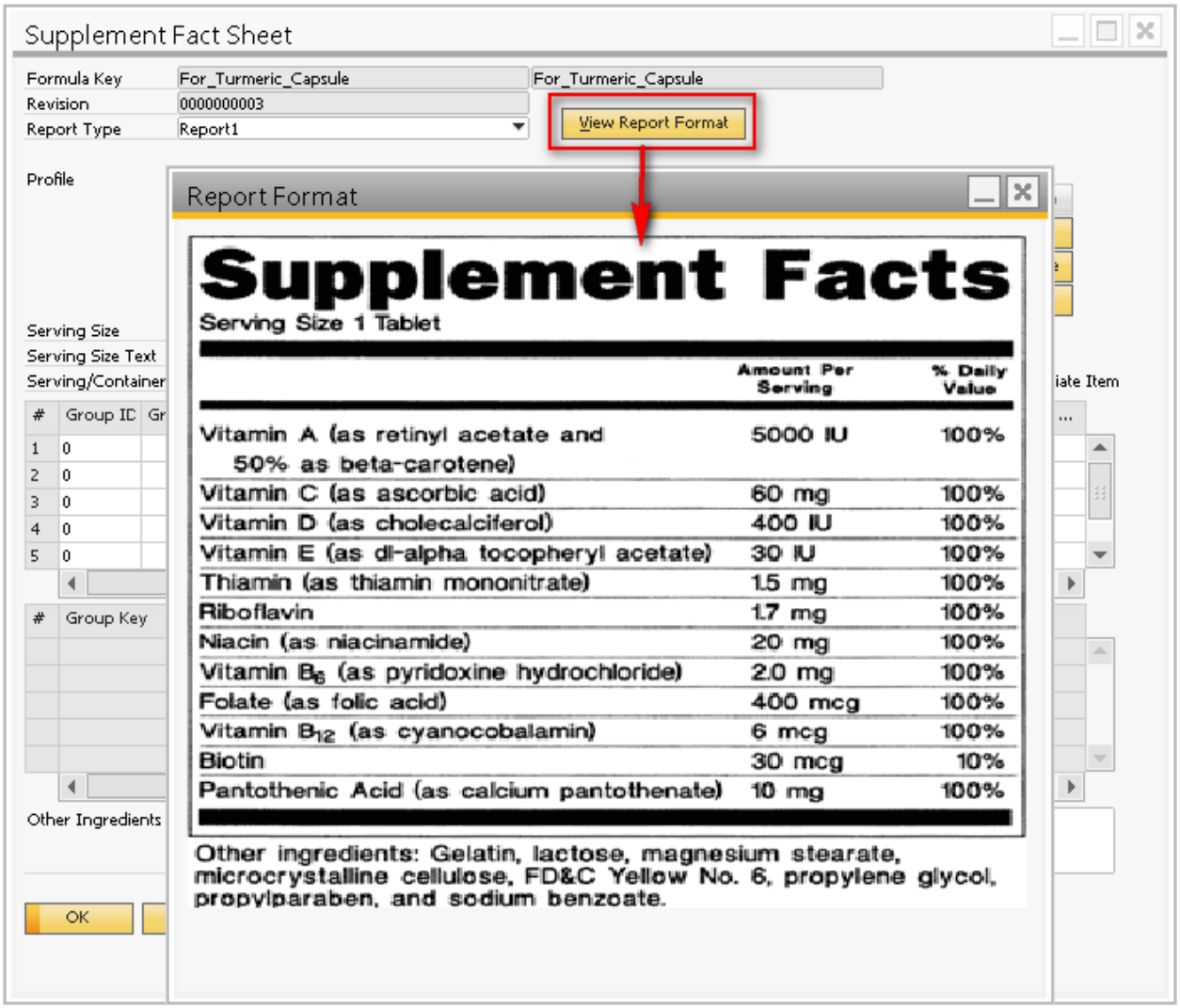
The *Print Supplement Fact Sheet* screen appears.



The screen is defaulted with the selected revision of the formula. If you wish to use any other revision of the formula, click the *Copy From Revision* button. It will pop up a window from where you can select the desired revision.

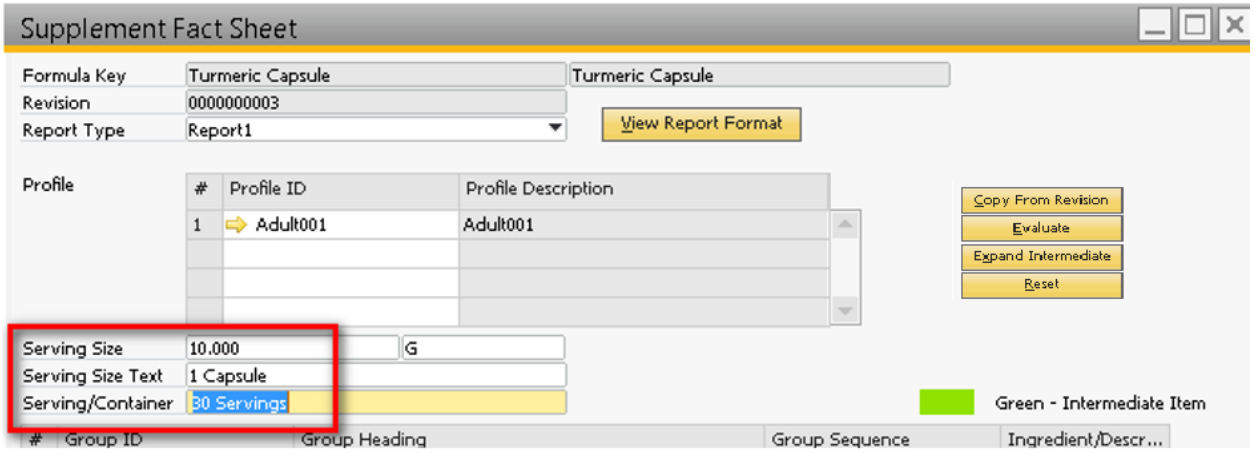
On the *Supplement Fact* screen, the *Report Type* option is available to choose the format in which the report is required to be printed. The report can be printed in 5 distinct formats.

You can preview the selected report format using the *View Report format* button.

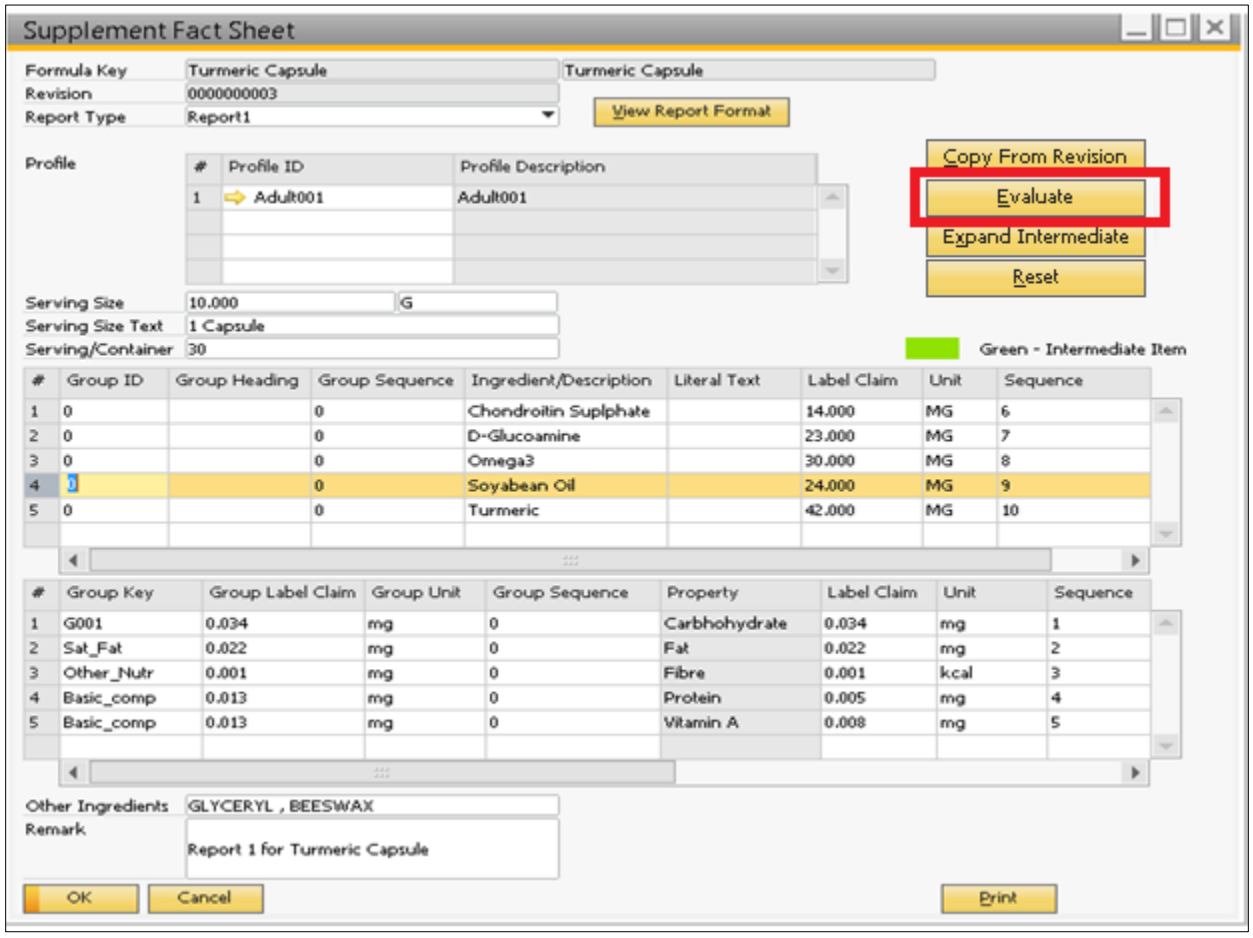


In the profile grid, add the profile for which the report needs to be printed. You can add multiple profiles in the grid.

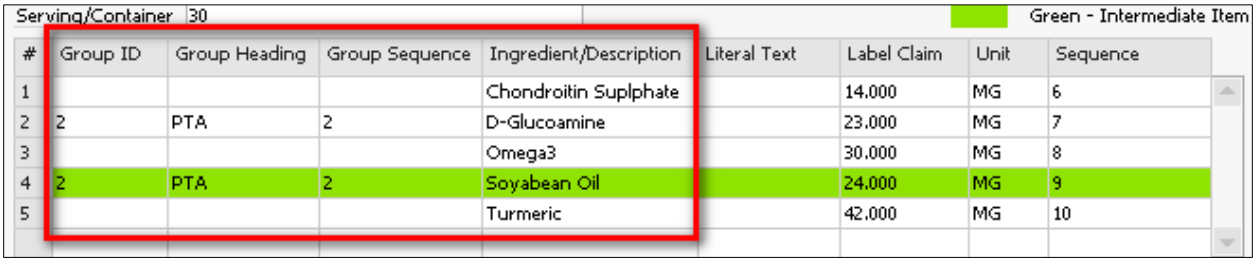
Enter the required value in *Serving Size*, *Serving Size Text* and *Serving /Container* fields.



Click the *Evaluate* button. On the basis of the Serving size specified, the system will calculate the label claim amount of nutrients. The label claim value of the Ingredient item is obtained from the *Physical Property Analysis* screen.



In the *Group heading* field, you can specify the title of the group. The *Group ID*, *Group Heading* and *Group Sequence* of the items you are grouping should be identical. Say in the screen below, we grouped items *D-Glucoamine*, *Soyabean oil* under 'PTA' group. Their *Group ID*, *Group Heading* and *Group Sequence* are same.


Serving/Container 30 — Green - Intermediate Item

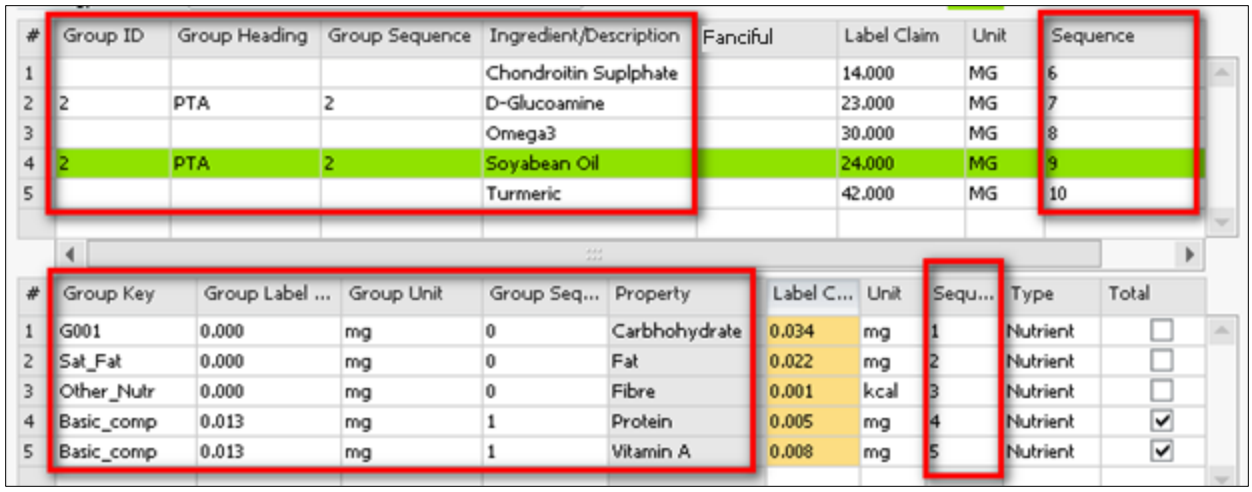
#	Group ID	Group Heading	Group Sequence	Ingredient/Description	Literal Text	Label Claim	Unit	Sequence
1				Chondroitin Suplphate		14.000	MG	6
2	2	PTA	2	D-Glucoamine		23.000	MG	7
3				Omega3		30.000	MG	8
4	2	PTA	2	Soyabean Oil		24.000	MG	9
5				Turmeric		42.000	MG	10

Similarly, in the lower grid we can group the nutrient properties. In the screen below we grouped Nutrient properties *Protein* and *Vitamin A* under the '*Basic_comp'* group. Their *Group key* and *Group sequence* are similar.

#	Group Key	Group Label ...	Group Unit	Group Seq...	Property	Label C...	Unit	Sequ...	Type	Total
1	G001	0.000	mg	0	Carbhohydrate	0.034	mg	1	Nutrient	☐
2	Sat_Fat	0.000	mg	0	Fat	0.022	mg	2	Nutrient	☐
3	Other_Nutr	0.000	mg	0	Fibre	0.001	kcal	3	Nutrient	☐
4	Basic_comp	0.013	mg	1	Protein	0.005	mg	4	Nutrient	☑
5	Basic_comp	0.013	mg	1	Vitamin A	0.008	mg	5	Nutrient	☑

The *Group Sequence* field signifies the printing order of items and nutrient groups on the report. On the report, Nutrient properties are always printed before item properties. The system defaults the sequence of nutrients and items such that the nutrient sequence is preceded by the item.

If grouping is implemented on Nutrients properties, the system will print Group-wise nutrient properties after item properties. If grouping is performed on nutrient as well as item, the printing sequence will be Nutrient property, Item property, Nutrient group and lastly Item group.



#	Group ID	Group Heading	Group Sequence	Ingredient/Description	Fanciful	Label Claim	Unit	Sequence
1				Chondroitin Suplphate		14.000	MG	6
2	2	PTA	2	D-Glucoamine		23.000	MG	7
3				Omega3		30.000	MG	8
4	2	PTA	2	Soyabean Oil		24.000	MG	9
5				Turmeric		42.000	MG	10

#	Group Key	Group Label ...	Group Unit	Group Seq...	Property	Label C...	Unit	Sequ...	Type	Total
1	G001	0.000	mg	0	Carbhohydrate	0.034	mg	1	Nutrient	☐
2	Sat_Fat	0.000	mg	0	Fat	0.022	mg	2	Nutrient	☐
3	Other_Nutr	0.000	mg	0	Fibre	0.001	kcal	3	Nutrient	☐
4	Basic_comp	0.013	mg	1	Protein	0.005	mg	4	Nutrient	☑
5	Basic_comp	0.013	mg	1	Vitamin A	0.008	mg	5	Nutrient	☑

In the example above, items *Soyabean Oil* and *D-Glucoamine* are grouped under 'PTA' group, while the nutrient properties 'Protein' and 'Vitamin A' are grouped under 'Basic_Comp' Group. The supplement fact sheet report is therefore printed as below.

Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30

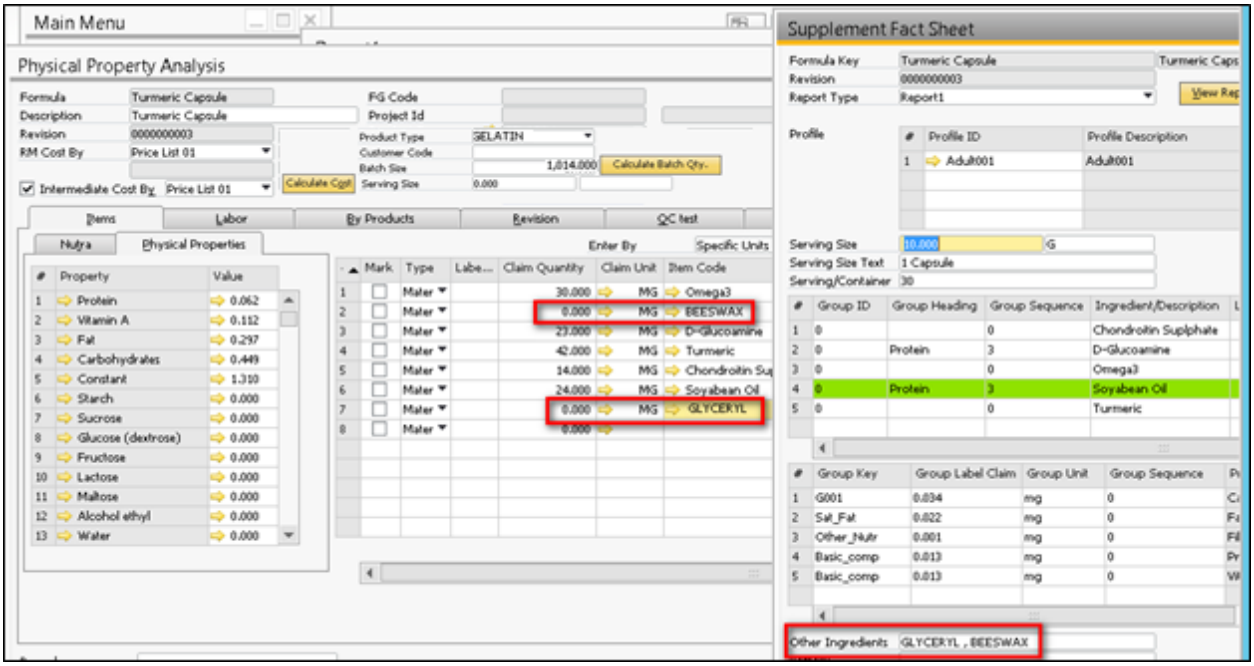
	Amount Per Serving	Ad800 1
Carbhohydrate	**0.03 mg**	**3%**
Fat	**0.02 mg**	**4%**
Fibre	**0.00 kcal**	**†**
Chondroitin Suplphate	**14.00 MG**	**17%**
Omega3	**30.00 MG**	**79%**
Turmeric	**42.00 MG**	**86%**
Basic_comp	**0.01 mg**	**†**
Protein	**0.00 mg**	**1%**
Vitamin A	**0.01 mg**	**2%**
PTA	**47 MG**	**†**
D-Glucoamine		
Soyabean Oil		

† Daily Value not established

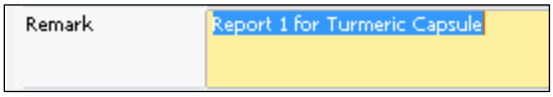
Other Ingredients: GLYCERYL, BEESWAX

Report 1 for Turmeric Capsule

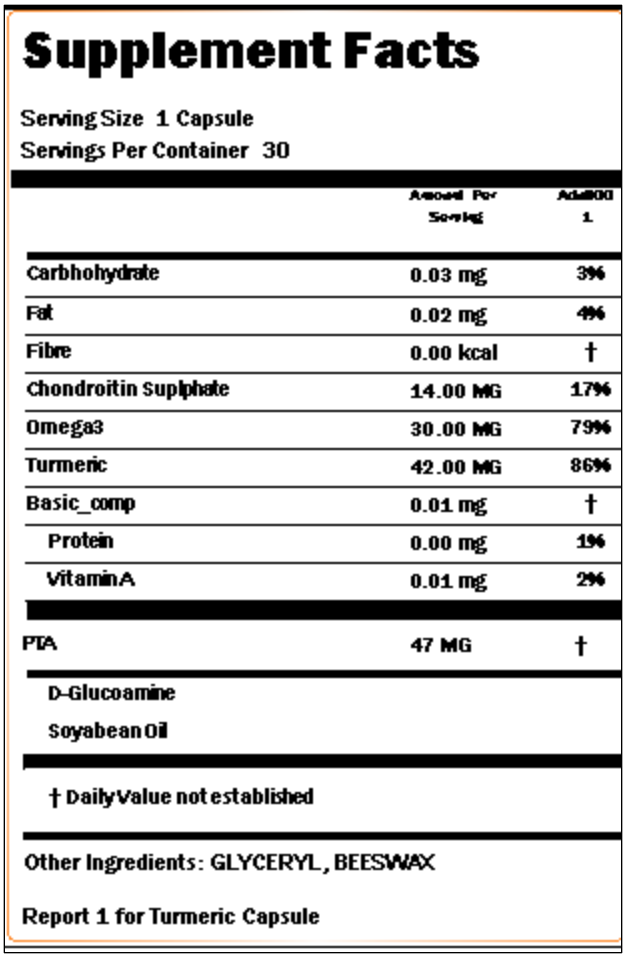
In the *Other Ingredients* field, any item whose label claim value is not specified on the *Physical Property Analysis* screen, is displayed. If required, you can specify more items in the field.



In the *Remark* field, enter any note or comment. The text you specify here will be printed at the end of the report. In this field, to obtain basic effects of the font like Bold, Italic, you can paste the desired formatted text from Microsoft Word.



Click the *Print* button to print the desired report.



Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30

	Amount Per Serving	Ada800 1
Carbhohydrate	0.03 mg	3%
Fat	0.02 mg	4%
Fibre	0.00 kcal	†
Chondroitin Suplphate	14.00 MG	17%
Omega3	30.00 MG	79%
Turmeric	42.00 MG	86%
Basic_comp	0.01 mg	†
Protein	0.00 mg	1%
Vitamin A	0.01 mg	2%
PIA	47 MG	†

D-Glucoamine
Soyabean Oil

† Daily Value not established

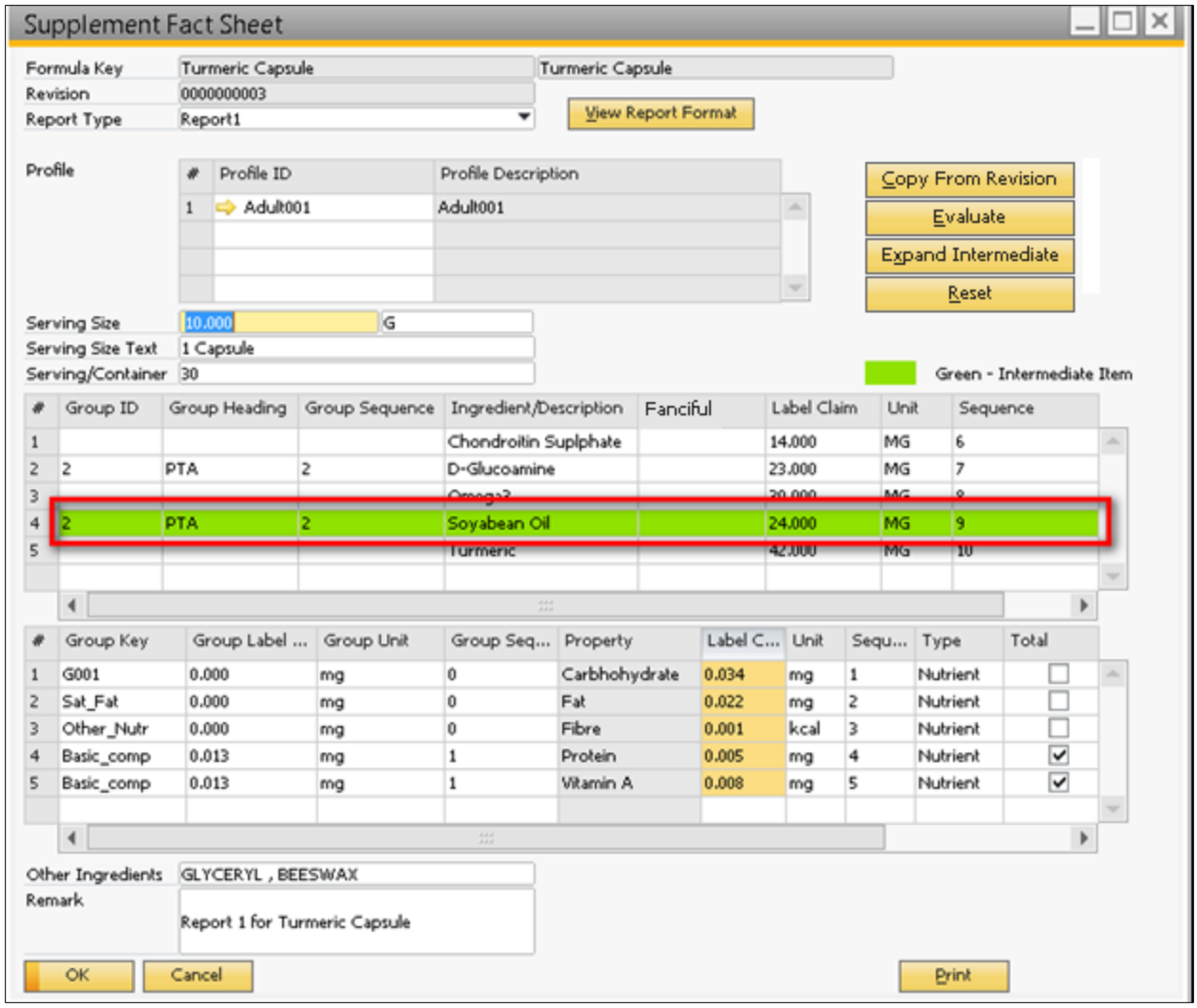
Other Ingredients: GLYCERYL, BEESWAX

Report 1 for Turmeric Capsule

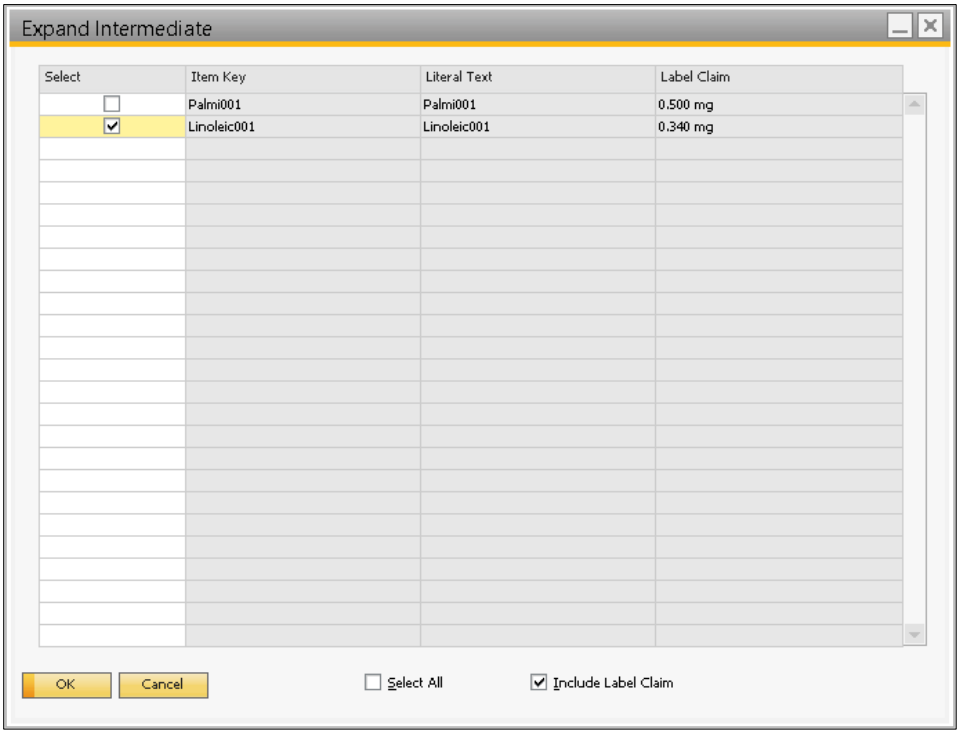
As we didn't specify the *Label claim* value for formula ingredients *GLYCERYL, BEESWAX*, they are displaying in the *Other Ingredients* section.

Use the *Expand intermediate* button to obtain details of any intermediate of the selected item for which a BOM is already released.

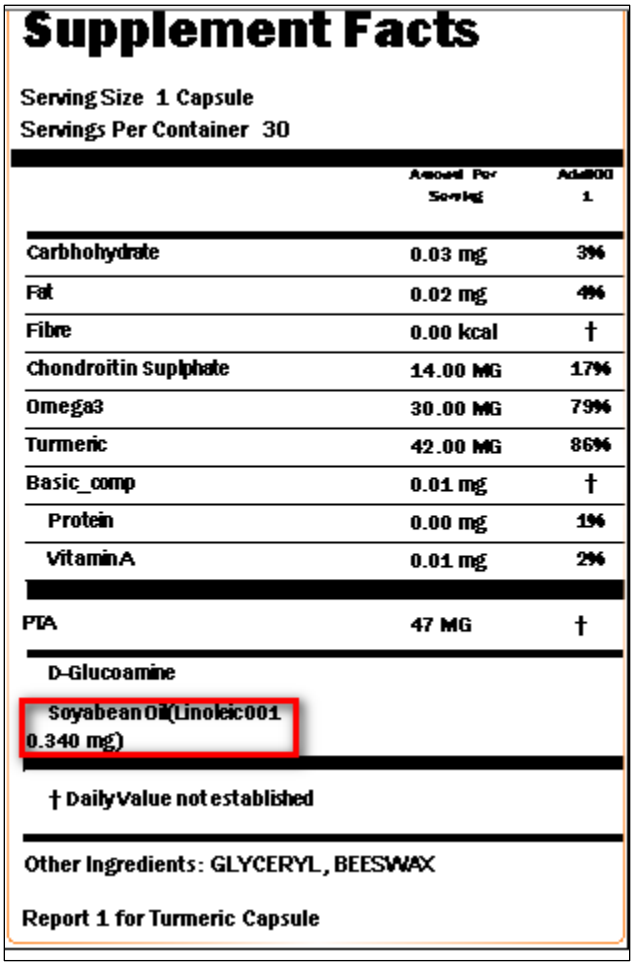
An Intermediate Item will be displayed highlighted in Green.


Supplement Fact Sheet
Formula Key
Turmeric Capsule
Turmeric Capsule
Revision
0000000003
Report Type
Report1
View Report Format
Profile
Profile ID Profile Description
1 Adult001 Adult001
Copy From Revision
Evaluate
Expand Intermediate
Reset
Serving Size
10.000
G
Serving Size Text
1 Capsule
Serving/Container
30
Green - Intermediate Item
Group ID Group Heading Group Sequence Ingredient/Description Fanciful Label Claim Unit Sequence
1 Chondroitin Suplphate 14.000 MG 6
2 2 PTA 2 D-Glucoamine 23.000 MG 7
3 Omega3 20.000 MG 8
4 2 PTA 2 Soyabean Oil 24.000 MG 9
5 Turmeric 42.000 MG 10
Group Key Group Label ... Group Unit Group Seq... Property Label C... Unit Sequ... Type Total
1 G001 0.000 mg 0 Carbhohydrate 0.034 mg 1 Nutrient
2 Sat_Fat 0.000 mg 0 Fat 0.022 mg 2 Nutrient
3 Other_Nutr 0.000 mg 0 Fibre 0.001 kcal 3 Nutrient
4 Basic_comp 0.013 mg 1 Protein 0.005 mg 4 Nutrient
5 Basic_comp 0.013 mg 1 Vitamin A 0.008 mg 5 Nutrient
Other Ingredients
GLYCERYL , BEESWAX
Remark
Report 1 for Turmeric Capsule
OK
Cancel
Print

On the *Expand Intermediate* screen, you can select the items you wish to include on the report. Also, select the *Include Label Claim* checkbox to print their label claim value.



The item added is printed on the report with the intermediate item.



Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30

	Amount Per Serving	Add000 1
Carbhohydrate	0.03 mg	3%
Fat	0.02 mg	4%
Fibre	0.00 kcal	†
Chondroitin Suplphate	14.00 MG	17%
Omega3	30.00 MG	79%
Turmeric	42.00 MG	86%
Basic_comp	0.01 mg	†
Protein	0.00 mg	1%
VitaminA	0.01 mg	2%
PDA	47 MG	†
D-Glucoamine		
Soyabean Oil(Linoleic001 0.340 mg)		

† Daily Value not established

Other Ingredients: GLYCERYL, BEESWAX

Report 1 for Turmeric Capsule

15.5.1.1 Calculations

Let's have a look at the entered values.

On the *Print Supplement Fact Sheet* screen, the label claim values specified for dietary nutrients are:

Item /Nutrition Group /Nutrition Property	Label Claim	Label claim unit
Omega3	30	MG
D-Glucoamine	23	MG
Chondroitin Sulphate	14	MG
Soyabean Oil	24	MG
Turmeric	42	MG
Carbohydrate	0.034	MG
Fat	0.022	MG
Fibre	0.001	MG
Protein	0.005	MG
Vitamin A	0.008	MG

On the *Profile Master* screen, the standard deviation reference value of the profile Adult is as follows:

Item/Nutrient/Nutrient Group	Standard DV	Unit
Omega3	38	MG
D-Glucoamine	32	MG
Turmeric	49	MG
Chondroitin Sulphate	81	MG
Soyabean Oil	25	MG
Carbohydrate	1	MG
Fat	0.560	MG
Fibre	0.800	kcal
Protein	0.38	MG
Vitamin A	0.34	MG

%DV calculation

For the ingredient item Omega3:

The standard DV value specified in the profile master is = 38

The Label claim value at Print Supplement Fact Sheet is = 30

Thus for the serving size 1 Milligram percentage daily reference value of Omega3 in per serving of a formula/product is:

%DV: Percentage of daily reference value of a dietary ingredients consumed in per serving of a formula/product

= (Calculated label claim Value at Print supplement fact sheet * 100) / Standard Value of selected Profile for the property (as Maintained in the Profile Master)

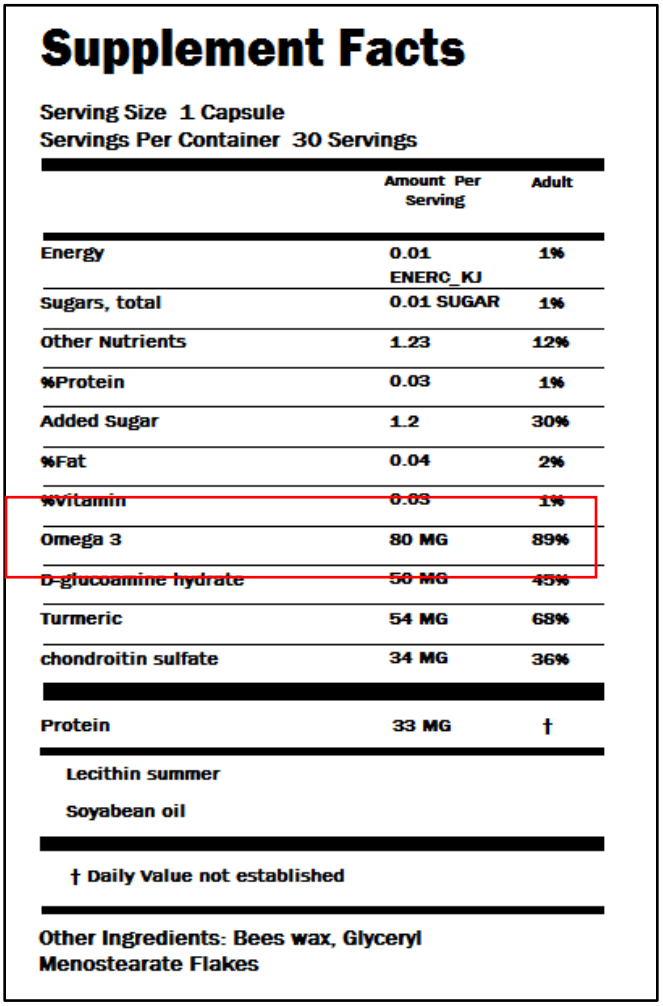
= (30 * 100) / 38

= 78.94 or 79%

Similarly, for the nutrient Carbohydrate, % DV will be

= (0.034 * 100)/ 1

= 3.4 or 3%



Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30 Servings

	Amount Per Serving	Adult
Energy	0.01 ENERC_KJ	1%
Sugars, total	0.01 SUGAR	1%
Other Nutrients	1.23	12%
%Protein	0.03	1%
Added Sugar	1.2	30%
%Fat	0.04	2%
%Vitamin	0.03	1%
Omega 3	80 MG	89%
D-glucoamine hydrate	50 MG	45%
Turmeric	54 MG	68%
chondroitin sulfate	34 MG	36%
Protein	33 MG	†

Lecithin summer

Soyabean oil

† Daily Value not established

Other Ingredients: Bees wax, Glyceryl Menostearate Flakes

Similarly, % DV values are calculated for other dietary ingredients.

You can select the Hide column checkbox to hide % DV value from the report.

#	oup Label ...	Group Unit	Group ...	Property	Label C...	Unit	Sequ...	Type	Total	Hide Column
1	00	mg	0	Carbhohydrate	0.034	mg	1	Nutrient	☐	☑
2	00	mg	0	Fat	0.022	mg	2	Nutrient	☐	☐
3	00	mg	0	Fibre	0.001	kcal	3	Nutrient	☐	☐
4	13	mg	1	Protein	0.005	mg	4	Nutrient	☑	☐
5	13	mg	1	Vitamin A	0.008	mg	5	Nutrient	☑	☐

Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30

	Amount Per Serving	Adult00 1
Carbhohydrate	0.03 mg	
Fat	0.02 mg	4%
Fibre	0.00 kcal	†
Chondroitin Suplphate	14.00 MG	17%
Omega3	30.00 MG	79%
Turmeric	42.00 MG	86%
Basic_comp	0.01 mg	†
Protein	0.00 mg	1%
VitaminA	0.01 mg	2%
PTA	47 MG	†

D-Glucoamine

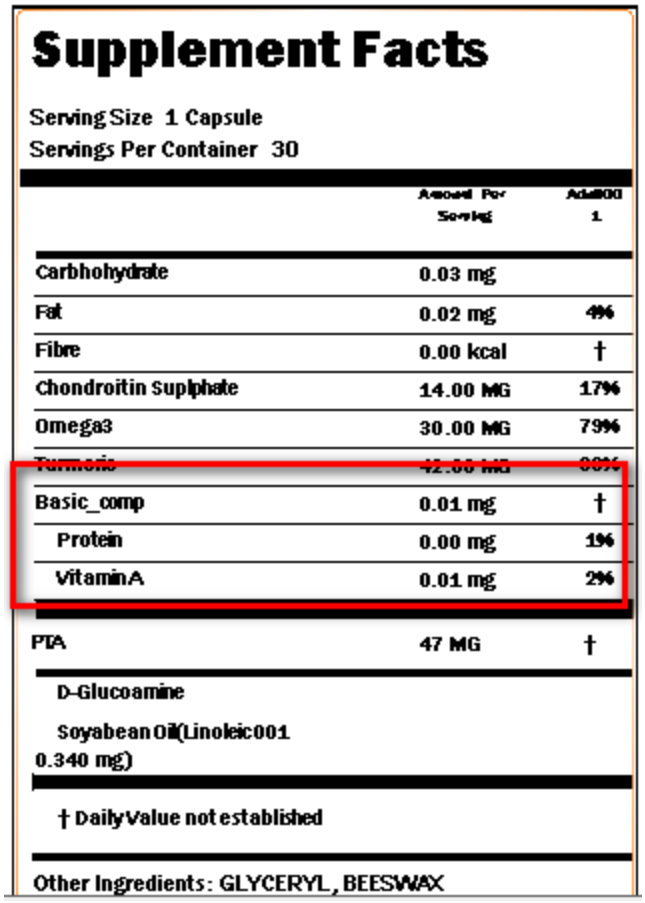
Soyabean Oil(Linoleic001 0.340 mg)

† Daily Value not established

Other Ingredients: GLYCERYL, BEESWAX

Use the Total column checkbox to display selected dietary ingredients values in a group, indented to the right.

#	Group Key	Group Label ...	Group Unit	Group ...	Property	Label C...	Unit	Sequ...	Type	Total	Hi
1	G001	0.000	mg	0	Carbhohydrate	0.034	mg	1	Nutrient	☐	
2	Sat_Fat	0.000	mg	0	Fat	0.022	mg	2	Nutrient	☐	
3	Other_Nutr	0.000	mg	0	Fibre	0.001	kcal	3	Nutrient	☐	
4	Basic_comp	0.013	mg	1	Protein	0.005	mg	4	Nutrient	☑	
5	Basic_comp	0.013	mg	1	Vitamin A	0.008	mg	5	Nutrient	☑	



Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30

	Amount Per Serving	Adult 1
Carbohydrate	0.03 mg	
Fat	0.02 mg	4%
Fibre	0.00 kcal	†
Chondroitin Suplphate	14.00 MG	17%
Omega3	30.00 MG	79%
Turmeric	42.00 MG	88%
Basic_comp	0.01 mg	†
Protein	0.00 mg	1%
Vitamin A	0.01 mg	2%
PTA	47 MG	†

D-Glucoamine

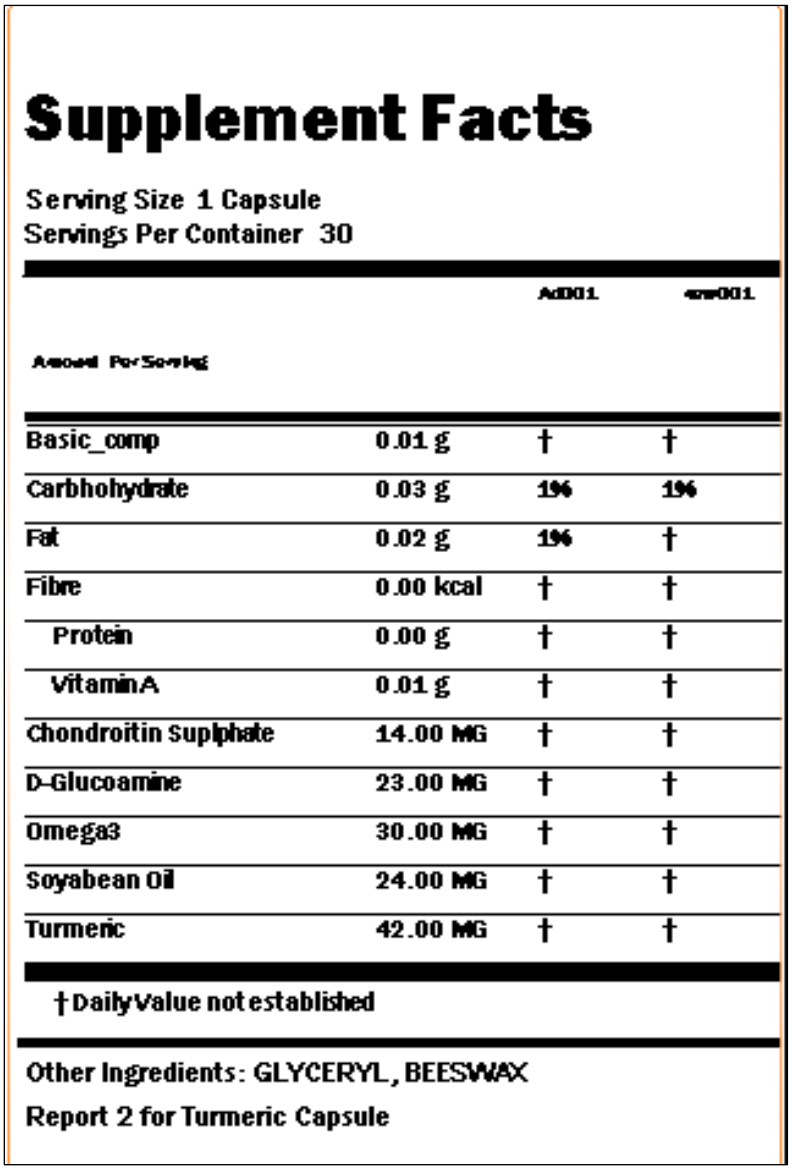
Soyabean Oil(Linoleic001 0.340 mg)

† Daily Value not established

Other Ingredients: GLYCERYL, BEESWAX

The layout of other report formats are as follows.

Report 2



Supplement Facts

Serving Size 1 Capsule
Servings Per Container 30

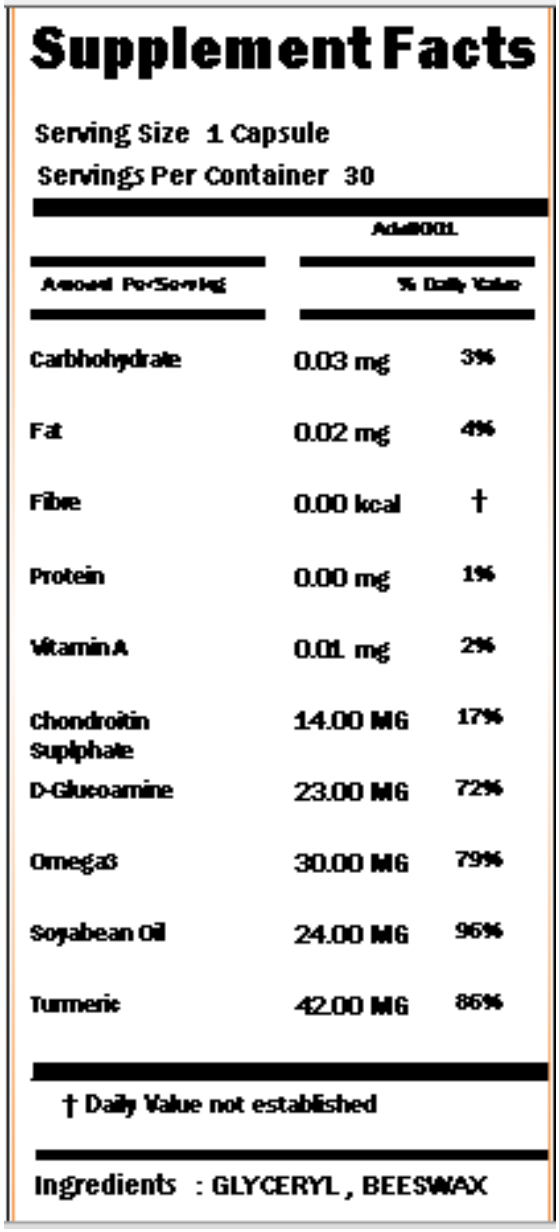
		Ad001	[illegible]001
Amount Per Serving			
Basic_comp	0.01 g	†	†
Carbhohydrate	0.03 g	1%	1%
Fat	0.02 g	1%	†
Fibre	0.00 kcal	†	†
Protein	0.00 g	†	†
VitaminA	0.01 g	†	†
Chondroitin Suplphate	14.00 MG	†	†
D-Glucoamine	23.00 MG	†	†
Omega3	30.00 MG	†	†
Soyabean Oil	24.00 MG	†	†
Turmeric	42.00 MG	†	†

† Daily Value not established

Other Ingredients: GLYCERYL, BEESWAX

Report 2 for Turmeric Capsule

Report 3



Supplement Facts

Serving Size 1 Capsule

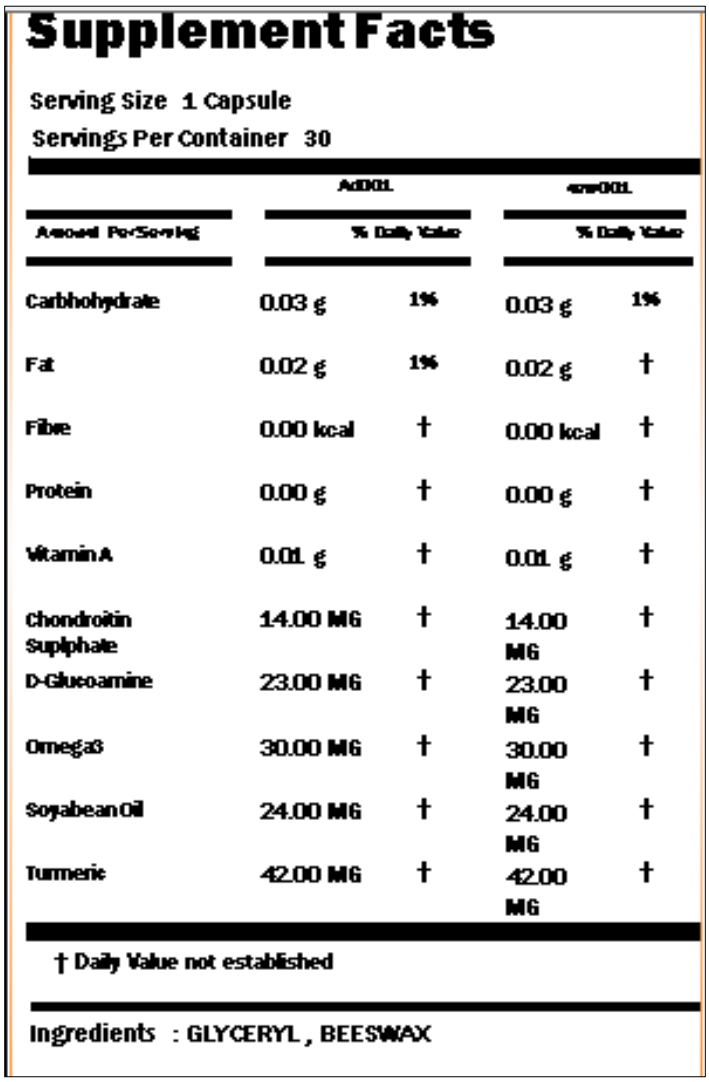
Servings Per Container 30

Amount Per Serving		% Daily Value
Carbhohydrate	0.03 mg	3%
Fat	0.02 mg	4%
Fibre	0.00 kcal	†
Protein	0.00 mg	1%
Vitamin A	0.01 mg	2%
Chondroitin Suplphate	14.00 MG	17%
D-Glucoamine	23.00 MG	72%
Omega3	30.00 MG	79%
Soyabean Oil	24.00 MG	96%
Turmeric	42.00 MG	86%

† Daily Value not established

Ingredients : GLYCERYL , BEESWAX

Report 4



Supplement Facts

Serving Size 1 Capsule

Servings Per Container 30

Amount Per Serving	AdOIL	% Daily Value	[illegible]OIL	% Daily Value
Carbhohydrate	0.03 g	1%	0.03 g	1%
Fat	0.02 g	1%	0.02 g	†
Fibre	0.00 kcal	†	0.00 kcal	†
Protein	0.00 g	†	0.00 g	†
Vitamin A	0.01 g	†	0.01 g	†
Chondroitin Suplphate	14.00 MG	†	14.00 MG	†
D-Glucoamine	23.00 MG	†	23.00 MG	†
Omega3	30.00 MG	†	30.00 MG	†
Soyabean Oil	24.00 MG	†	24.00 MG	†
Turmeric	42.00 MG	†	42.00 MG	†

† Daily Value not established

Ingredients : GLYCERYL , BEESWAX

Report 5

Supplement Facts Serving Size 1 Capsule Servings 30, Amount Per Serving: Carbhohydrate 0.07 g, Carbhohydrate 0.07 mg, Fat 0.04 g, Fat 0.04 mg, Fibre 0.00 kcal, Fibre 0.00 kcal, Protein 0.01 g, Protein 0.01 mg, Vitamin A 0.02 g, Vitamin A 0.02 mg, Chondroitin Suplphate 14.00 MG, D-Glucoamine 23.00 MG, Omega3 30.00 MG, Soyabean Oil 24.00 MG, Turmeric 42.00 MG

16 Batch Manufacturing Record

A key regulatory requirement is to record the cGMP-related activities for production batches. This is accomplished using a Batch Manufacturing Record (BMR). As part of the regulations, you are required to store BMRs for up to five years after a batch is produced. BatchMaster ERP provides the capability to create and maintain BMRs. Following is the basic flow:

Manufacturing Instructions

- Add boilerplates for each instruction in your manufacturing process.

Manufacturing Process

- Group the boilerplates to form sequential and logical SOPs.

Item/Product Type Manufacturing Process

- Group the manufacturing processes for an item or product type to create tables in BMR.

Script Master

- Develop SQL scripts to draw information from multiple modules.

Print BMR Setup

- Map bookmarks in the template file with appropriate table, boilerplate key, field, or SQL key.

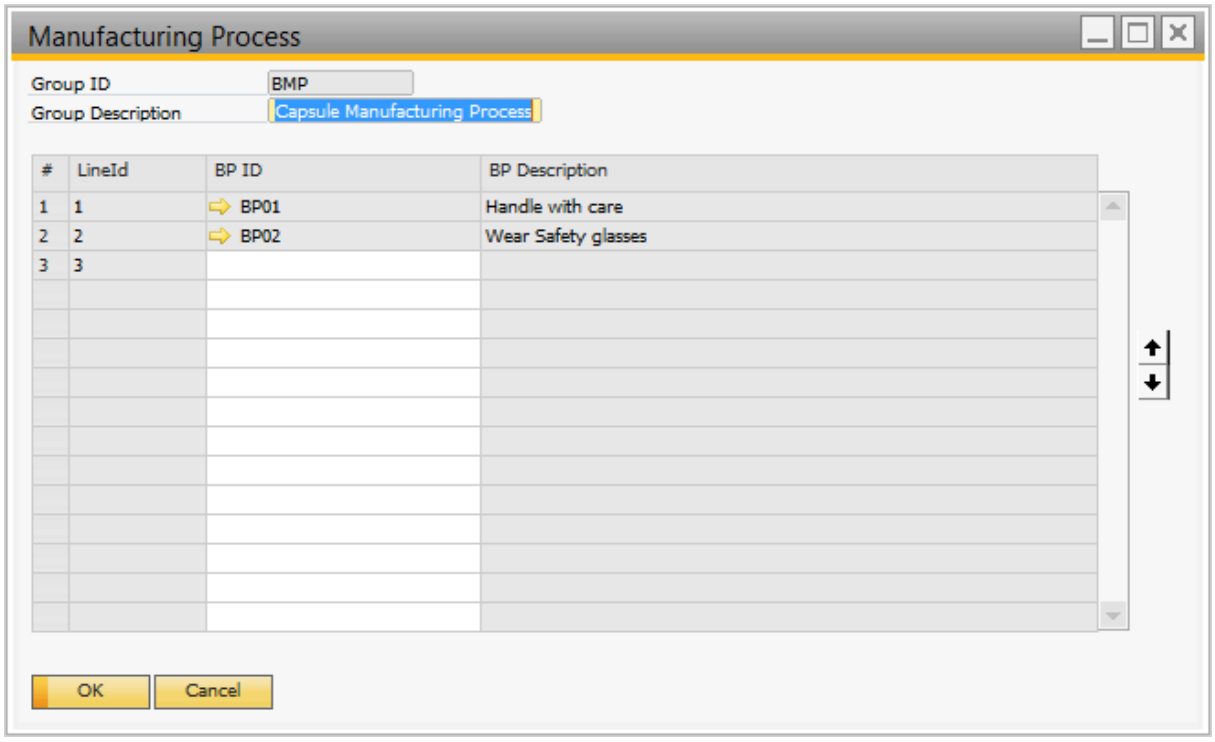
Once you have provided details in the above screens, you can print a BMR for a batch in the template, using the *Print BMR* screen.

As a pre-requisite MS word must be installed on your machine to print the BMR.

16.1 Manufacturing Process (Boilerplate) Entry

Use the *Manufacturing Process* screen to group the boilerplates/manufacturing instructions to form a sequence-based SOP. You can group the instructions any way you need to, including using a boilerplate ID more than once in the group.

Go To: Process Manufacturing → Production → Manufacturing Process

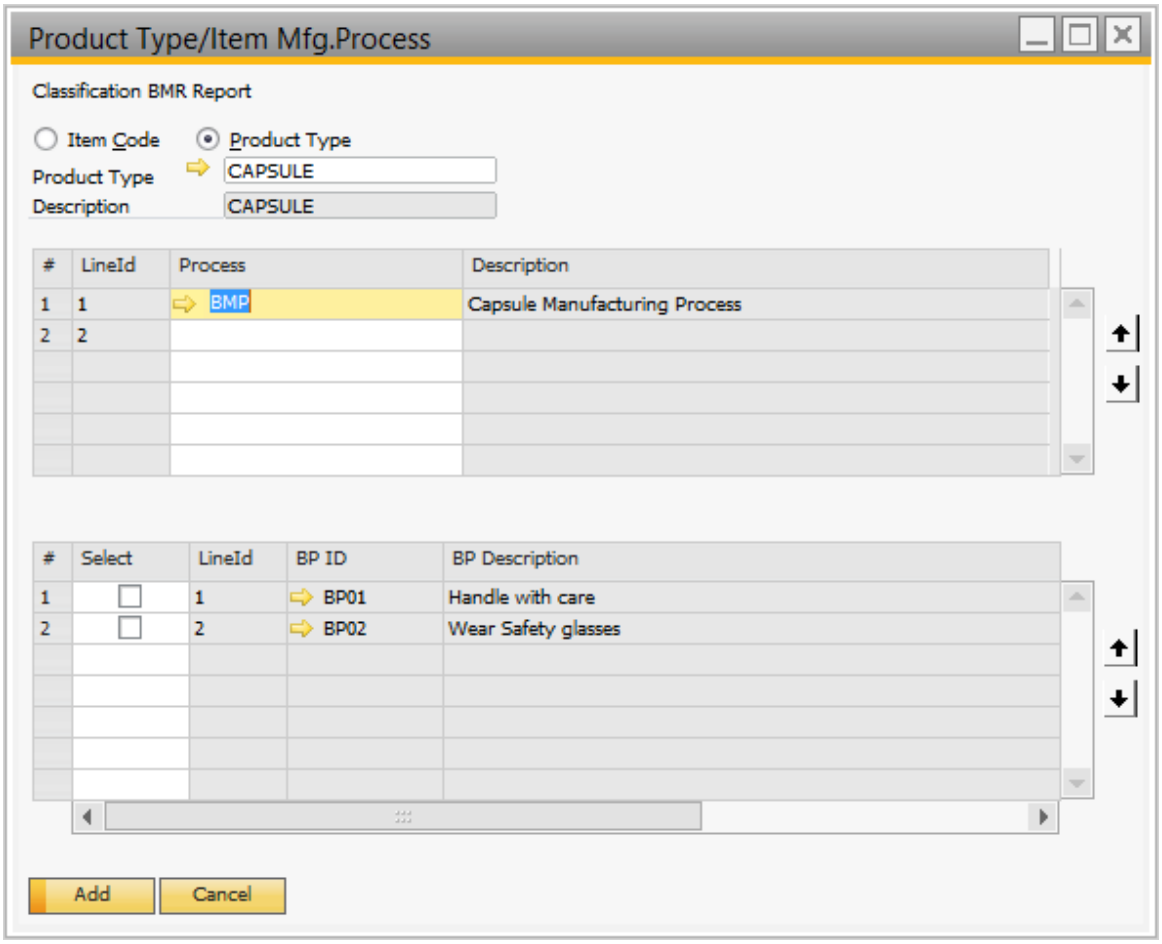


In the *Group ID* field, enter the unique identification code for a manufacturing process. In the *Group Description* field, enter the corresponding description. Add the boilerplate codes row by row in the grid. A lookup is available. You can also create a new boilerplate if required. The *BP Description* field displays the instructions in detail. Click the ADD or UPDATE button to save the manufacturing Process record.

16.2 Product Type/Item Mfg. Process

After creating the manufacturing process, you can now associate them with a specific item or product type. This helps you in creating tables when printing BMR for an item or product type.

Go To: Process Manufacturing → Product Type/ Item Mfg. Process



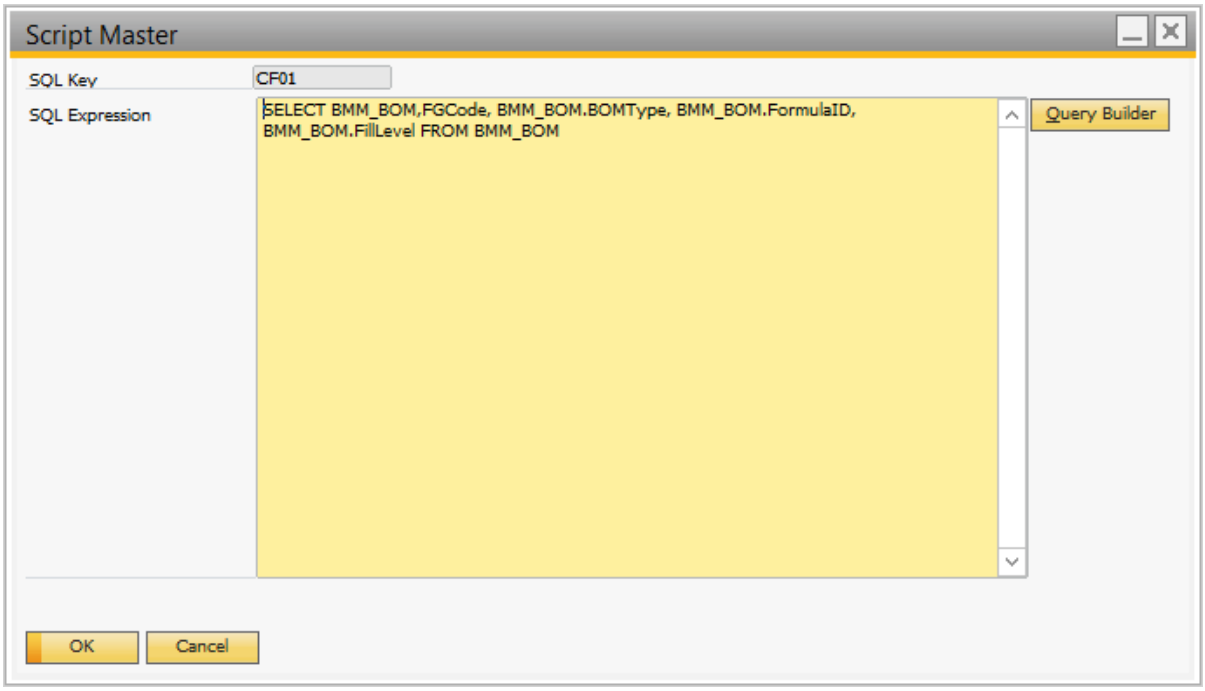
From the options *Item Code* and *Product Type, s*elect the required one to classify the BMR report information. Then select the item or product type in the following field.

In the first grid, add the manufacturing processes in the required sequence to define the procedure for handling the item/product type. In the *Process* field, select the required group of manufacturing instructions. Based on the item/group you have selected in first grid, the second grid will contain the line-level instructions. Click the *Add* button to add the set of instructions. Click the *OK* button to exit.

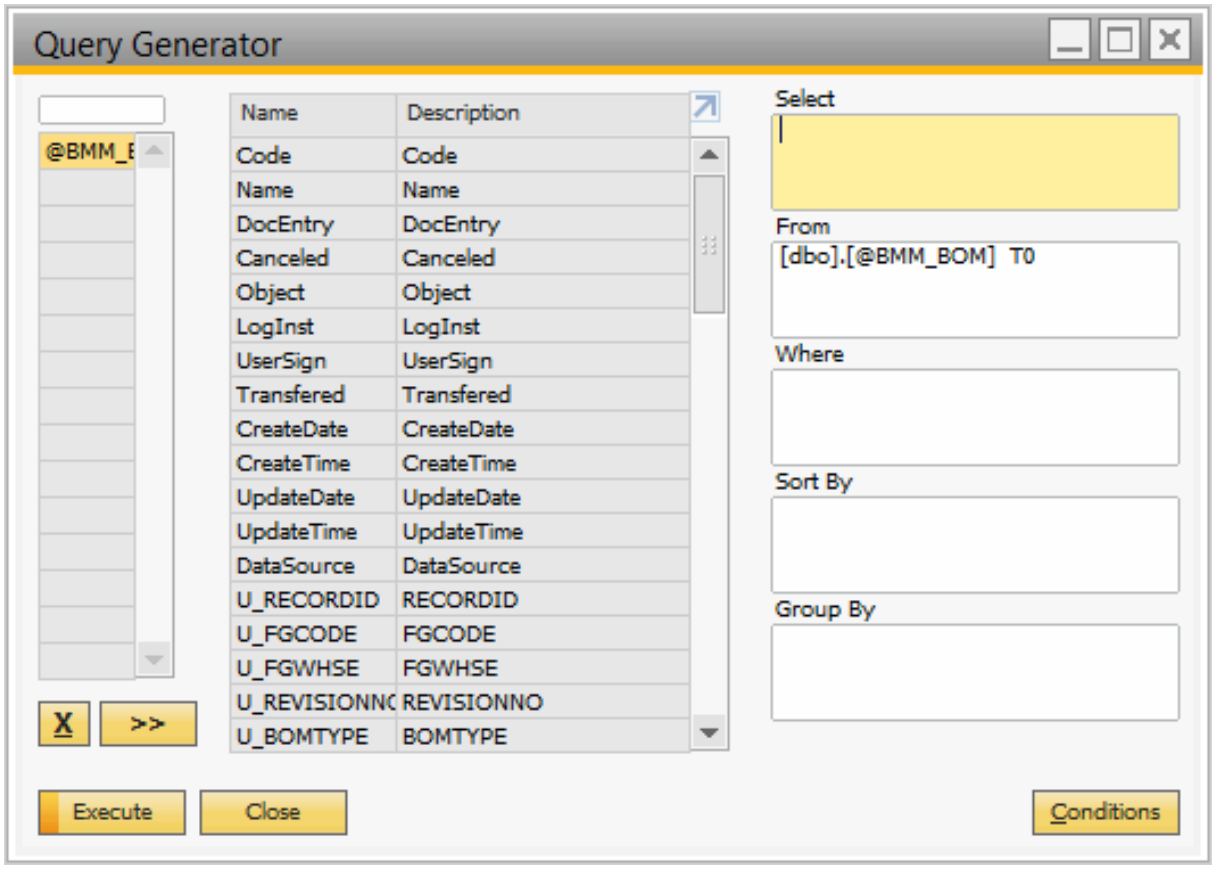
16.3 Script Master

To generate a BMR, you must draw information from various entities, such as formula, production, and QC. SQL queries can be useful in drawing the required information. You can use the *Script Master* to store the SQL commands that you may require for printing BMRs. You can use this screen to create and store queries, which can be used to print BMRs. To access this screen, choose:

Go To: Administration → Setup → Production → Script Master



For example, you may want to include BOM information of the sample in the BMR. In the *SQL Key* field, enter a unique code for the SQL command. If you want to create SQL queries, use the *SQL Expression* field. Alternatively, use the *Query Builder* to access the *Query Generator* and generate SQL queries using the GUI.


Query Generator
@BMM_
Name
Description
Code
Code
Name
Name
DocEntry
DocEntry
Canceled
Canceled
Object
Object
LogInst
LogInst
UserSign
UserSign
Transfered
Transfered
CreateDate
CreateDate
CreateTime
CreateTime
UpdateDate
UpdateDate
UpdateTime
UpdateTime
DataSource
DataSource
U_RECORDID
RECORDID
U_FGCODE
FGCODE
U_FGWHSE
FGWHSE
U_REVISIONNO
REVISIONNO
U_BOMTYPE
BOMTYPE
X
>>
Select
From
[dbo].[@BMM_BOM] T0
Where
Sort By
Group By
Execute
Close
Conditions

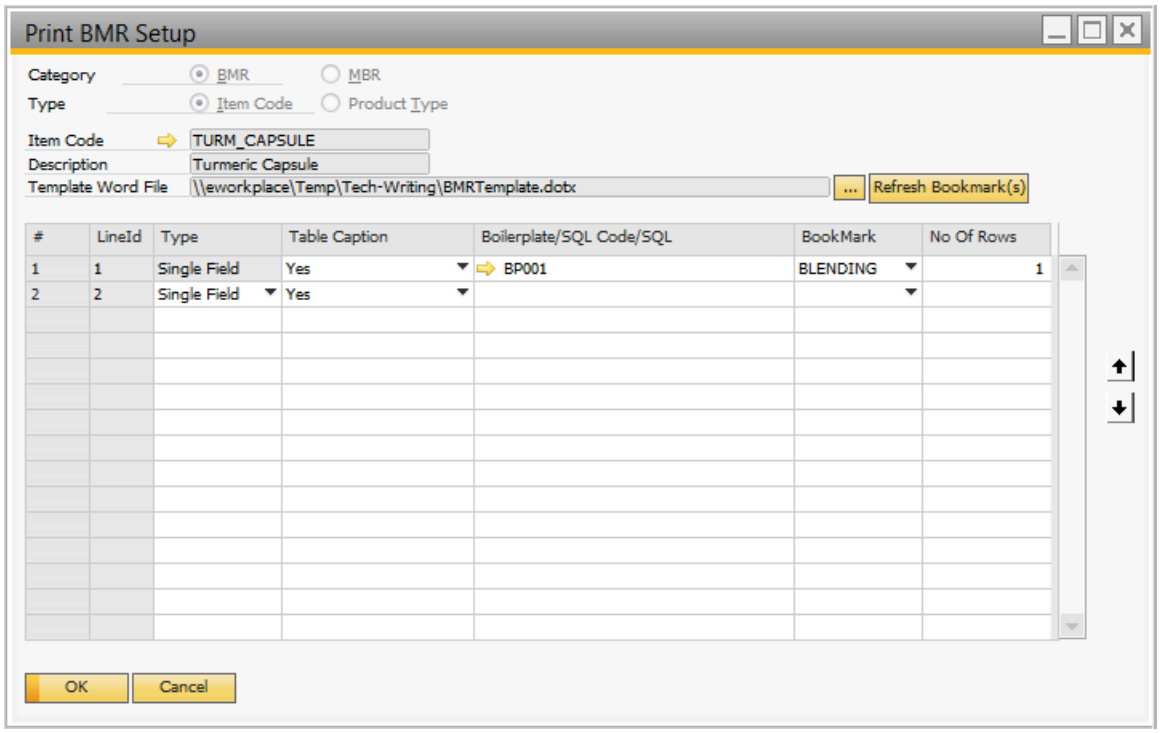
16.4 Print BMR Setup

Before printing the BMR, we have:

- Created manufacturing process records that need to go into a BMR.
- Grouped the manufacturing processes for a specific product type.
- Developed SQL scripts to draw information into a BMR from the other modules.

Now, we need to map the BMR template bookmarks with appropriate elements. You can use the *Print BMR Setup* screen to do the mapping. The mapping can be item based or product type based.

Go To: Administration → Setup → Production → Print BMR Setup



Choose if you want to define settings for a BMR or MBR. Now, enter if you want to define mapping for an item or a product type. If you select the *Item Code* option, then select the desired item. Alternatively, select the desired item for the *Product Type* option.

Next, select the template file using which you want to print the BMR, in the *Template Word File* field. Click the *Refresh Bookmarks* button to display the template bookmarks in the dropdown.

You can use the grid to define mapping between bookmarks and controls, one mapping in each row of the grid. In the *Type* column, enter the type of control you want to map, such as a field, table, boilerplate, or SQL key, using the appropriate bookmark. If the Type selected is Single Field or SQL code, then the search field on the Boilerplate/SQL Code/SQL field will open an SQL generator to help generate an SQL query.

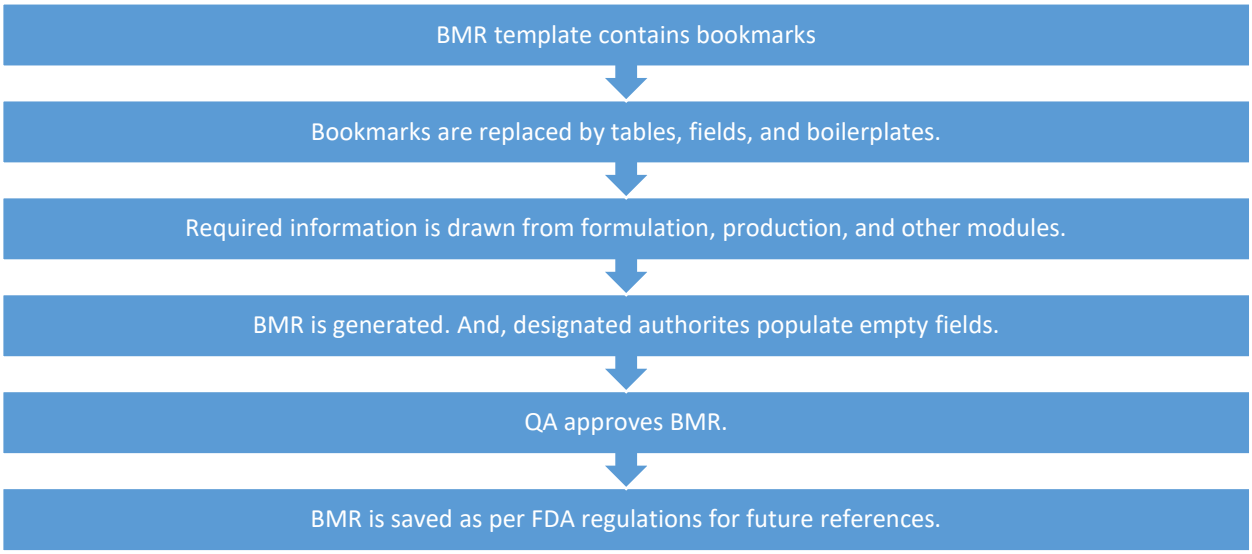
In the *Table Caption* column, enter whether a caption should be included for the table in the BMR. If the control is a table, you will enter *Yes* to print the caption with the table. For other controls, this field is not applicable. In the *Boilerplate/SQL Code/SQL* field, enter the details of the boilerplate or SQL code for displaying the control. Next, enter the bookmark that should be associated with the control. Now, enter the number of blank rows to be printed. Click the *Add* button to save the settings.

You can monitor the process activities and generate the BMR to meet the cGMP requirements. Numerous quality checks can be applied to ensure that the product complies with regulations. You can generate non-conformance records for those products that do not meet the regulations. Also, you can systematically record and attend to the customer complaint about the product, if any.

To comply with the cGMP requirements for BMR, BatchMaster ERP allows you to create and print a hybrid BMR, which is an electronically-generated record of batch production. This record also adheres to the FDA guidelines.

A hybrid BMR uses the word-automation utility (or the document template) that contains bookmarks, which are replaced by corresponding values of tables, single fields, boilerplates, or other information, as required, by the application. A default BMR template is provided for all product types.

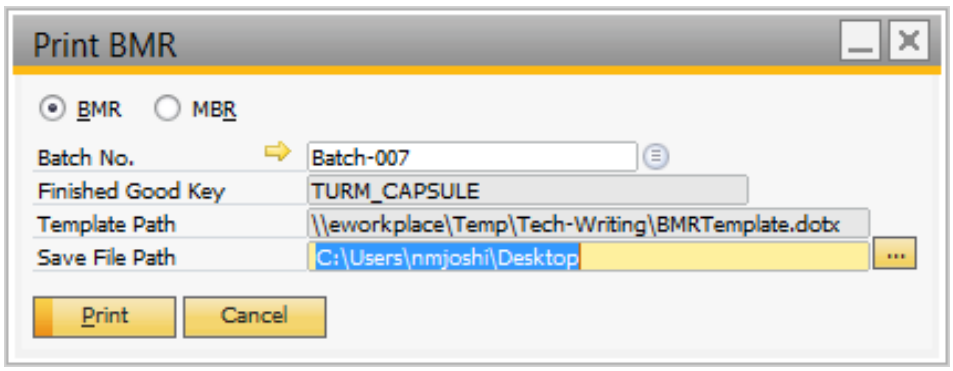
The information to help generate BMRs is drawn from modules, such as *Formulation*, *Production*, *Quality Control*, and capabilities, such as inspection plan, check list, and SOPs. After printing the report, the designated manufacturing authorities can provide appropriate information in the empty fields. BMRs must be approved by the quality assurance department and recorded as per FDA requirements.



16.5 Print BMR

Use the *Print BMR* screen to generate BMR for a batch. The BMR is hybrid. So, information will be partly printed and partly entered manually.

Go To: Process Manufacturing → Production Utilities → Print BMR



Choose to generate either a Batch Manufacturing Record (BMR) or a Master Batch Record (MBR). If you select BMR, then search and select the required batch number in the *Batch No.* field. Otherwise, enter the *Finished Good Key.*

The *Template Path* field is populated automatically from the *Print BMR Setup* screen. In the *Save File Path* field, either type or search and select the location to save the generated BMR. And, click the *Print* button to print the BMR.

17 Advance Batch Manufacturing Record

Using the BatchMaster Advance BMR feature you can map the attached BMR template with the following different objects

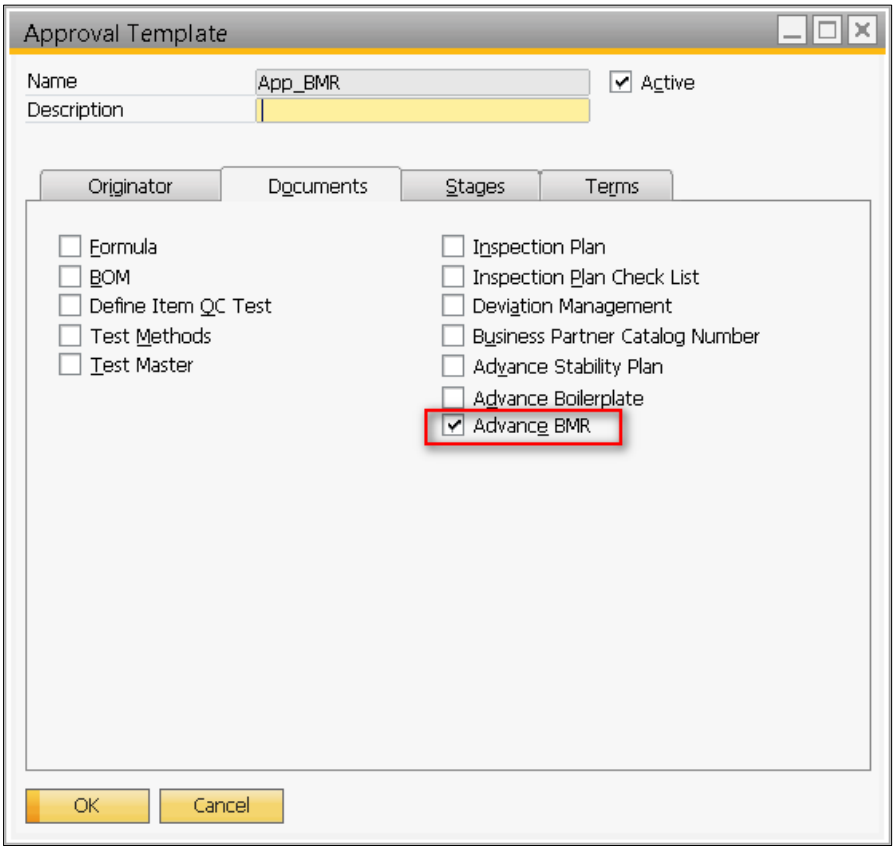
- SQL
- Boilerplate ID
- User Query
- Data Object

Also, an approval procedure can be implemented on the BMR.

17.1 Formula Defaults

You can enable the Advance BMR features from the *Formula Defaults* screen.

Go To: Main Menu → Administration → Setup → Formula → Formula Defaults



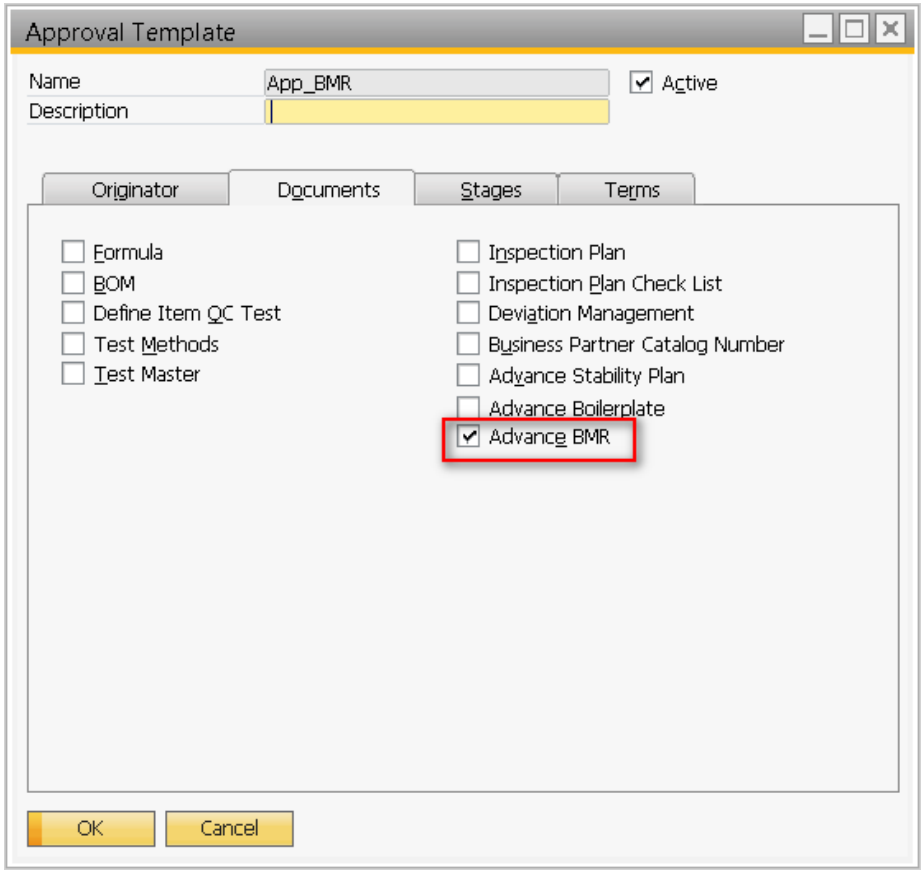
17.2 Approval Template

An Approval procedure can be also applied to the *Advance BMR*. For this,

Go To: Main Menu → Administration → Setup → Process Mfg Appr. Proce. → Approval Template

In the *Approval Template* screen, on the *Documents* tab, select the *Advance BMR* checkbox.

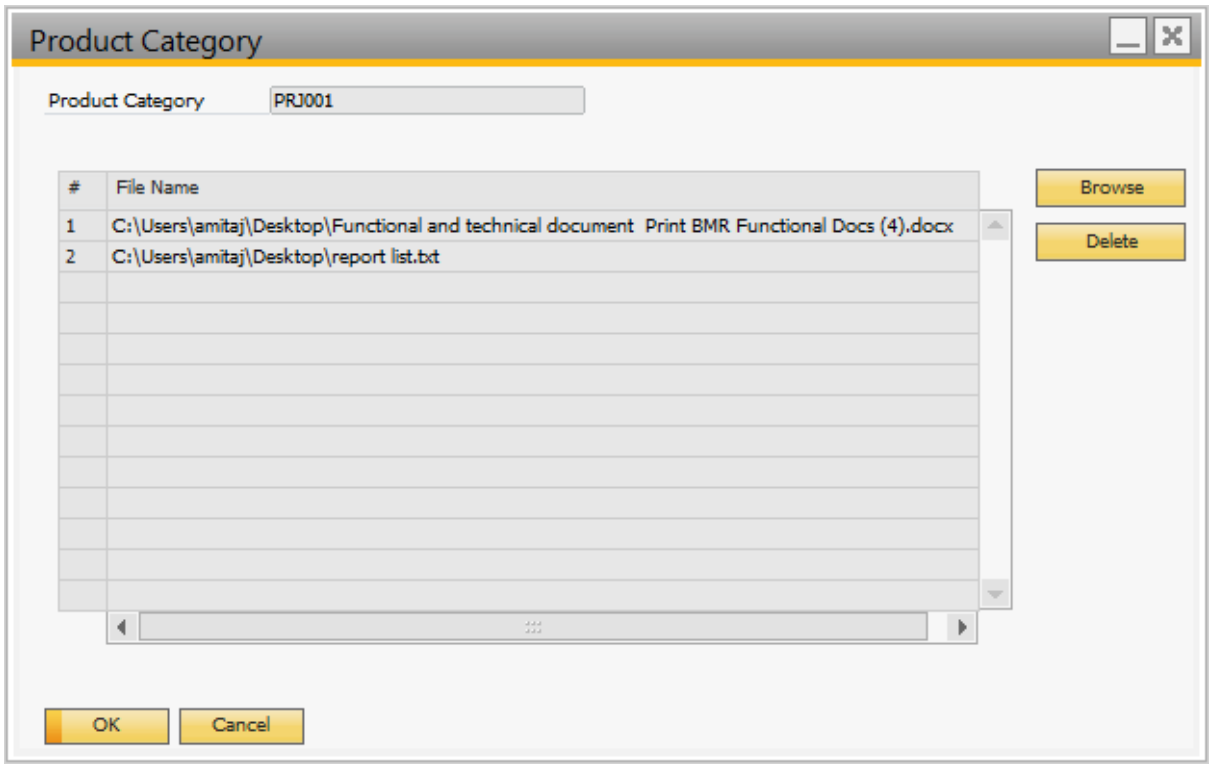
Associate an appropriate approval template with the *Advance BMR* and *Update* the settings.



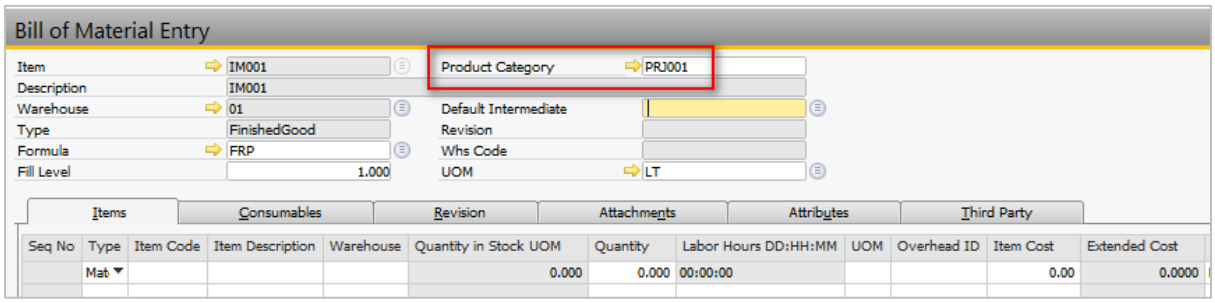
17.3 Product Category

Use the *Product Category* Master screen to attach multiple documents to it.

Go To: Main Menu → Administration → Setup → Production → Product Category



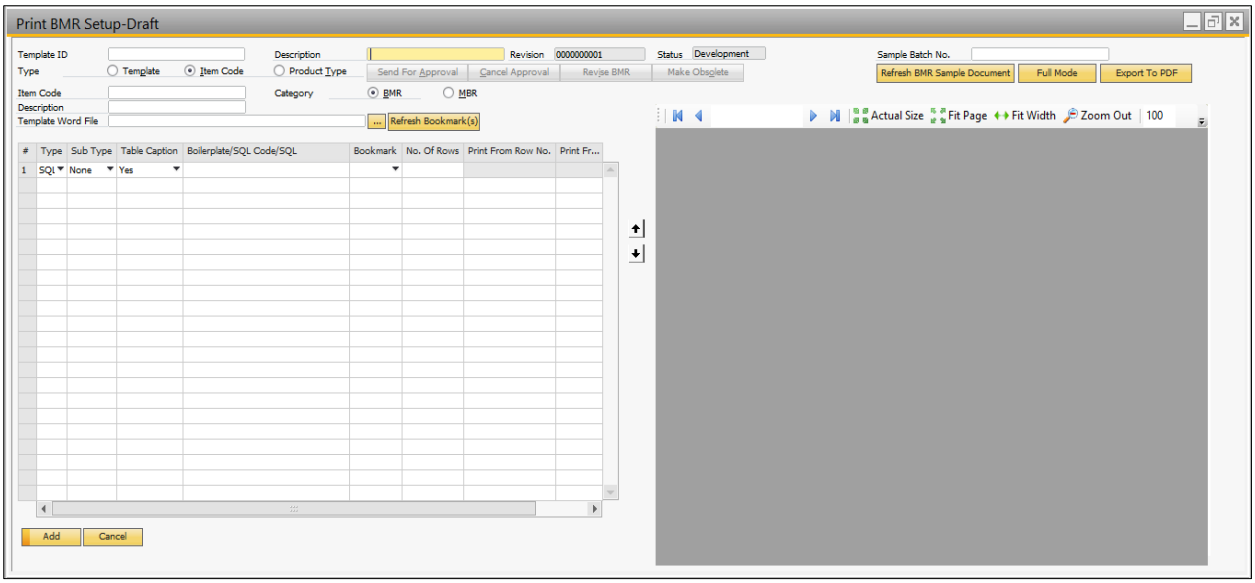
The defined Product Category can be attached to a BOM on the Bill of Material Entry screen.



Using the respective BOM, when you create a batch and print the BMR, the system will automatically open all the documents attached with the selected Product Category.

17.4 Print BMR Setup

With the Advance BMR option, the Print BMR Setup Screen displays as below.



Template ID: Enter a unique identification key for the BMR Template you are defining here.

Description: Enter a name or description for the BMR Template.

Type: The BMR/MBR can be of type *Template*, *Item Code* or *Product Type*. You can create a BMR/MBR for any specific Item or Product or can create it as a template to be used further for any required batch.

Category: You can select and specify that the template you are defining here is required to be used for BMR or MBR.

Sample Batch No/Sample Formula Id: If you selected the *Category* as BMR then the field caption will be displayed as Sample Batch No and it lets you search for or select the batch for which a BMR needs to be printed. If the Category is selected as MBR, the field caption will be displayed as Sample Formula ID and it lets you select the Formula for which to print the MBR.

Send for Approval: Click this button to send the record for approval.

Cancel Approval: Click this button to cancel the document approval.

Revise BMR: Use this button to generate the new revised BMR template.

Make Obsolete: Use this button to obsolete the record.

Revision: Displays the approved revision number of the template.

Status: Shows the current status of the Template.

Refresh BMR Sample Document: Use this button to refresh the document and display data with latest selections.

Full Mode/Compact Mode: Use this button to display the BMR/MBR Sample document in full/compact view.

Export to PDF: Use this button to generate a pdf file of the BMR Sample document to export.

Template Word File: Search and select the template file on which a bookmark is added.

Refresh Bookmark: Click on this button to clear the added template file path to add a new one.

Grid Details

BMR Type: Using the dropdown available here, select the boilerplate type as one of *SQL, Boilerplate, User Query, Data Object.*

Sub Type: The BMR sub type depends upon the BMR Type you select. The sub type can be *None*, *Single* or *Table*.

Table Caption: Select *Yes* if you want to print the caption of the column along with its value, otherwise select *No*.

Boilerplate/SQL Code/SQL: Displays the specified boilerplate/SQL criteria on the basis of which the bookmark will be printed.

Bookmark: Select the bookmark where the BMR value will be printed.

No of rows: For the *Table* type of BMR, here you can specify the number of records required to be printed.

Print From Row No: Specify the row number from where records will start printing.

Print From Column No: Specify the column number from where records will start printing.

17.4.1.1 Setting the Print BMR Setup

To begin with, enter a unique identification code for the *BMR/MBR template* you are creating and give it a *Description*. Next, specify that you are creating the BMR for a specific *Item* or *Product* or wish to create it as a *Template* to be used further for any required batch. If you select the *Item Code* option, then select the desired item; for the *Product Type* option, specify the Product Category and related details.

Select the *Category* from *BMR* or *MBR* to specify that the template you are creating will be used for BMR or MBR.

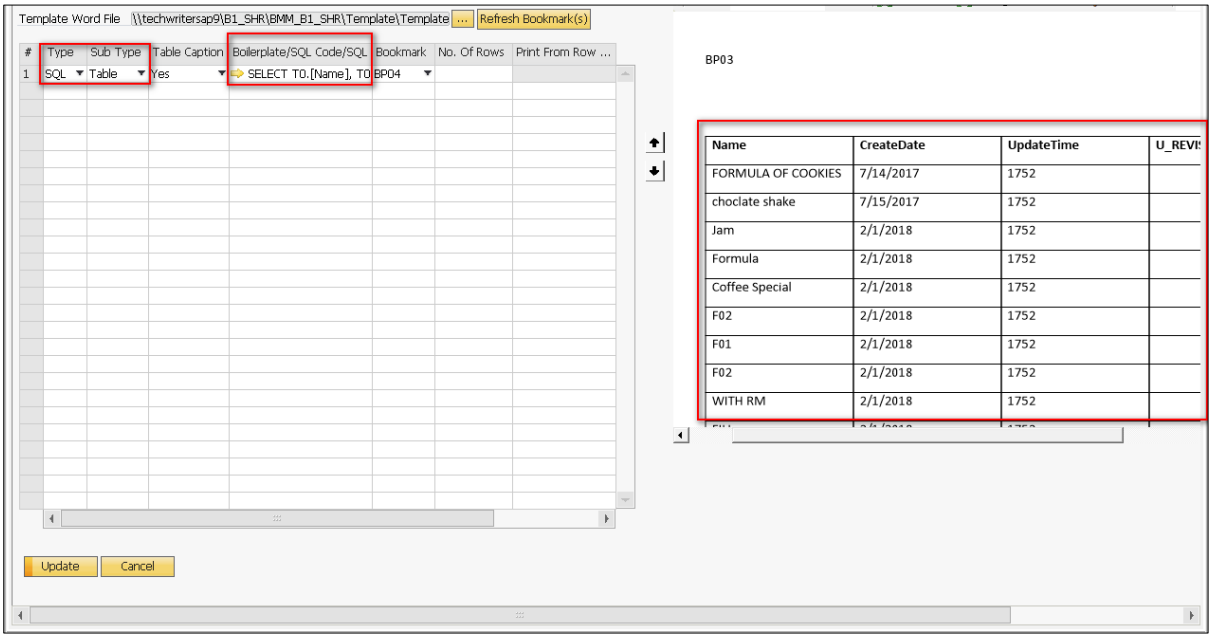
Select the template file with which you want to print the BMR, in the *Template Word File.* Click the *Refresh Bookmarks* button to display the template bookmarks in the dropdown.

Now, you need to map the BMR template bookmarks with appropriate elements.

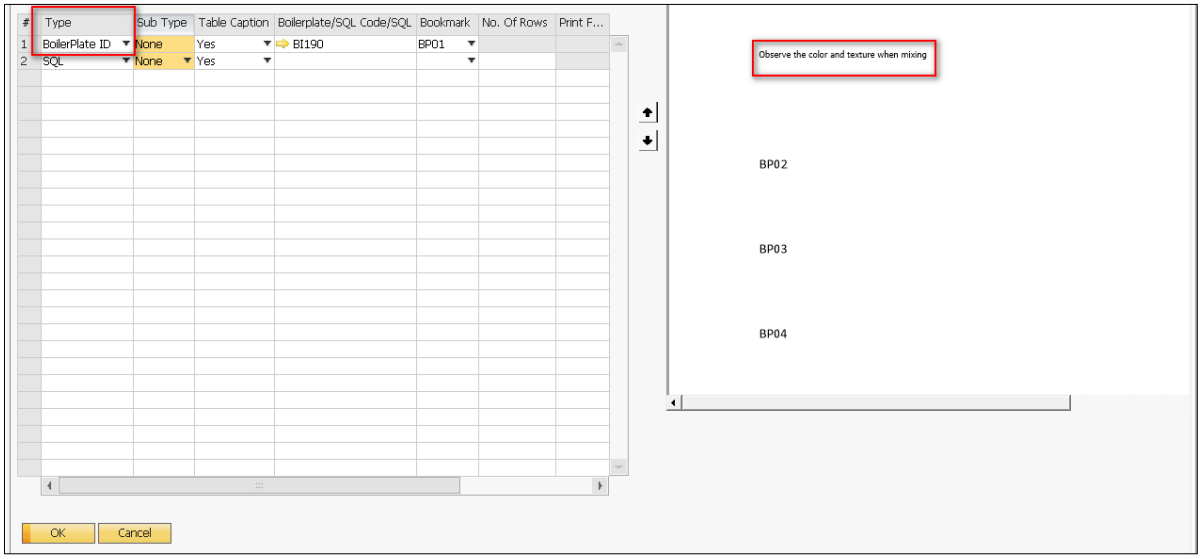
You can use the grid to define the mapping between bookmarks and controls, one mapping in each row of the grid. In the *Type* column, enter the type of control you want to map, such as a *Boilerplate, SQL key, User Query* or *Data object*. Specify the sub type as *None*, *Single* or *Table*.

In the *Table Caption* column, enter whether a caption should be included for the table in the BMR. If the control is a table, you will enter *Yes* to print the caption with the table. In the *Boilerplate/SQL Code/SQL* field, enter the details of the *Boilerplate, SQL code, Data object* or *User query* for displaying the control.

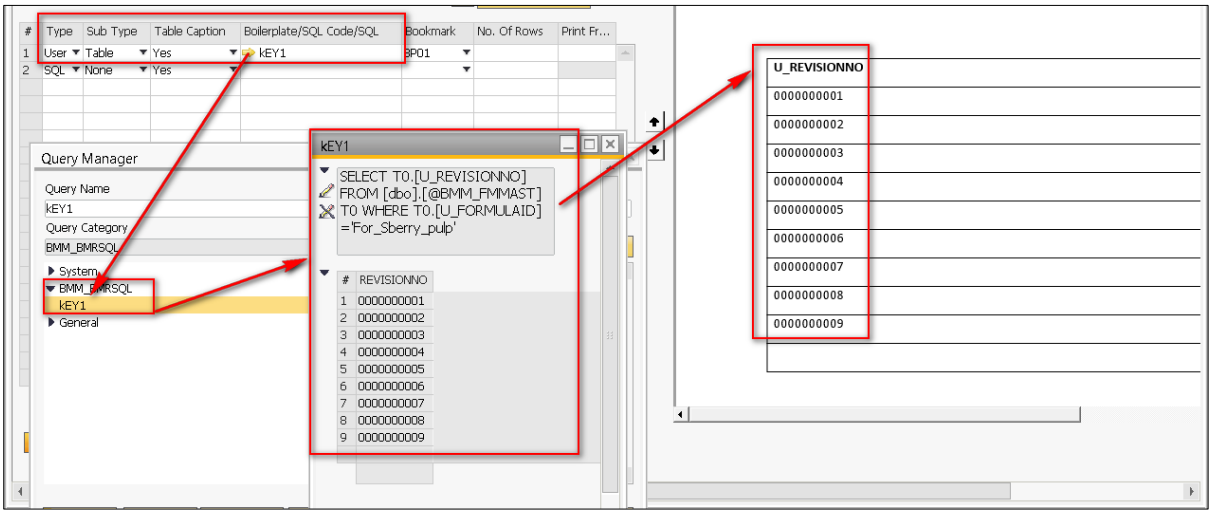
If the selected *Type* is SQL, you can directly write the SQL query in the Boilerplate/SQL Code/SQL field and accordingly fill the value in the selected bookmark. Alternatively, use the *Query Builder* to access the *Query Generator* and generate SQL queries using the GUI.



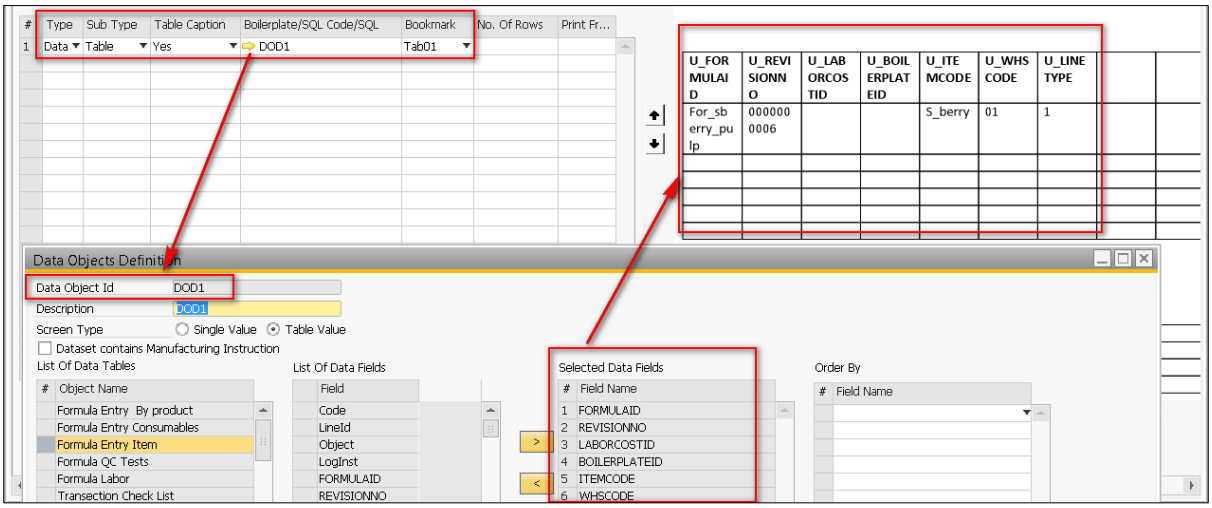
For the *Type* selected as *Boilerplate*, you can print the bookmark value as a boilerplate text. Selecting it, the *Boilerplate/SQL Code/SQL field* shows a list/lookup of all Boilerplates for you to select from.



For the *Type* selected as *User Query*, the *Boilerplate/SQL Code/SQL list*/lookup displays all user queries saved in BMM_BMRSQL of Query manager, to select from.



If you select the type as *Data Object*, then the list/lookup shows all data objects created in the system on the "Data Object Definition" screen.



Next, enter the bookmark that should be associated with the control. Now, enter the number of blank rows to be printed, number of rows and columns from where data starts printing. Click the *Add* button to save the settings.

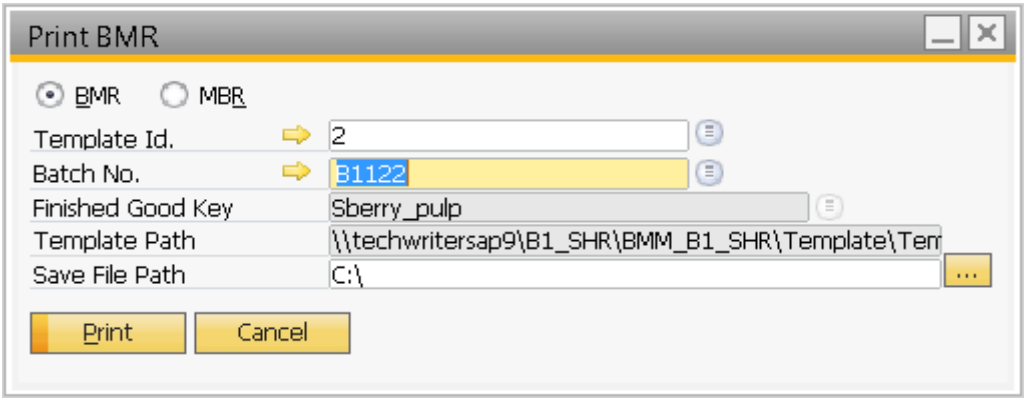
The *Send for Approval* button is activated, click on it to initiate the approval process. Follow the approval cycle. Once the document is approved by all authorized users, its status changes to Active. You can create a new revision of the BMR using the Revise BMR. The *Cancel Approval* button is available to cancel the approval request.

If you selected the *Category* as BMR then search and select the *Sample Batch No* to specify the batch for which the BMR needs to be printed. If the option selected was MBR then select the *Sample Formula ID*. Use the *Refresh BMR Sample Document* button to reload the preview on the basis of the selected criteria. You can modify the view of the BMR/MBR with the available options.

17.5 Print BMR

Use the *Print BMR* screen to generate a BMR for a batch. The BMR is hybrid, so information will be partly printed and partly entered manually.

Go To: Process Manufacturing → Production Utilities → Print BMR



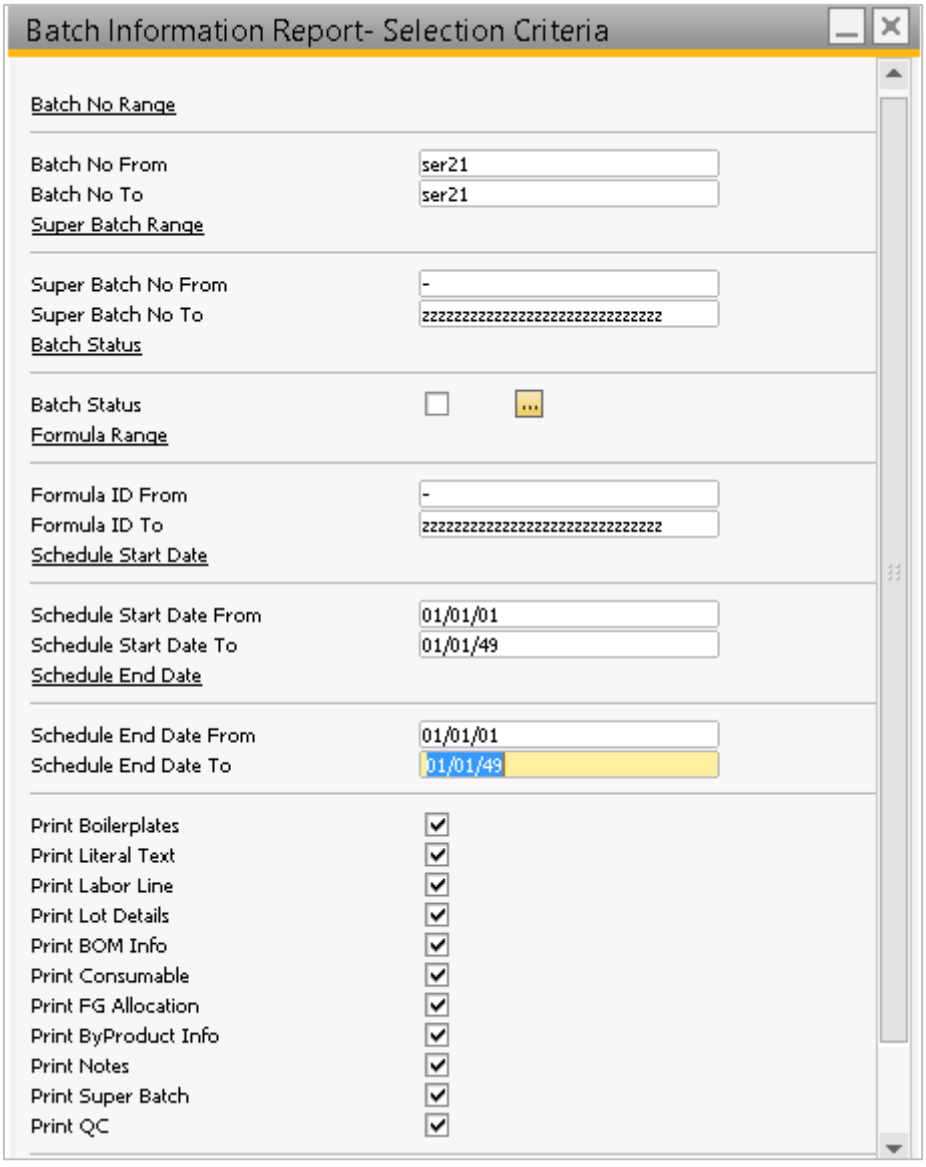
Select the BMR option. Select the BMR template and then search and select the required batch number in the *Batch No.* field. Otherwise, enter the *Finished Good Key.*

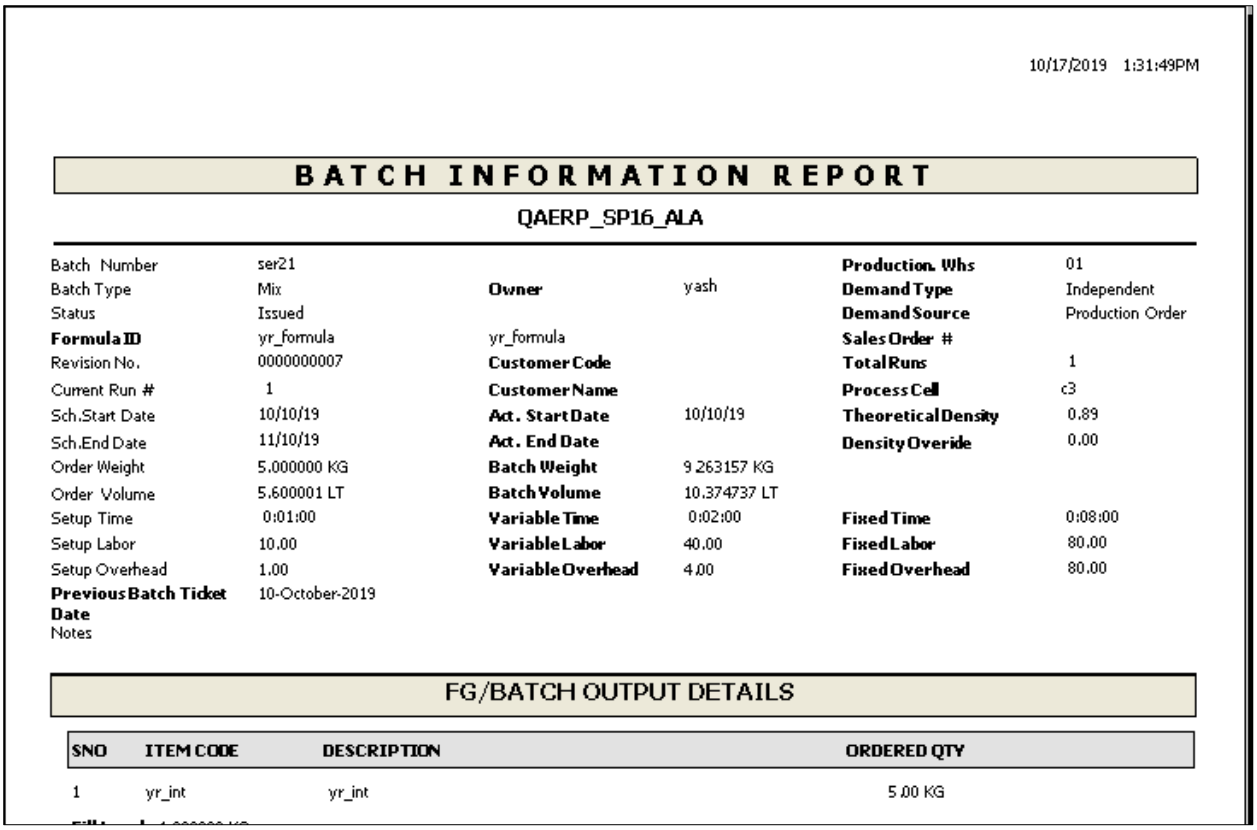
The *Template Path* field is populated automatically from the *Print BMR Setup* screen. In the *Save File Path* field, either type or search and select the location to save the generated BMR, then click the *Print* button to print the BMR.

18 Batch Information Report

Using the *Batch Information Report* screen you can now print these details along with Batch Information:

- Inspection details
- NC information
- CAPA Information
- Checklist Information
- Down time information
- Deviation Information.





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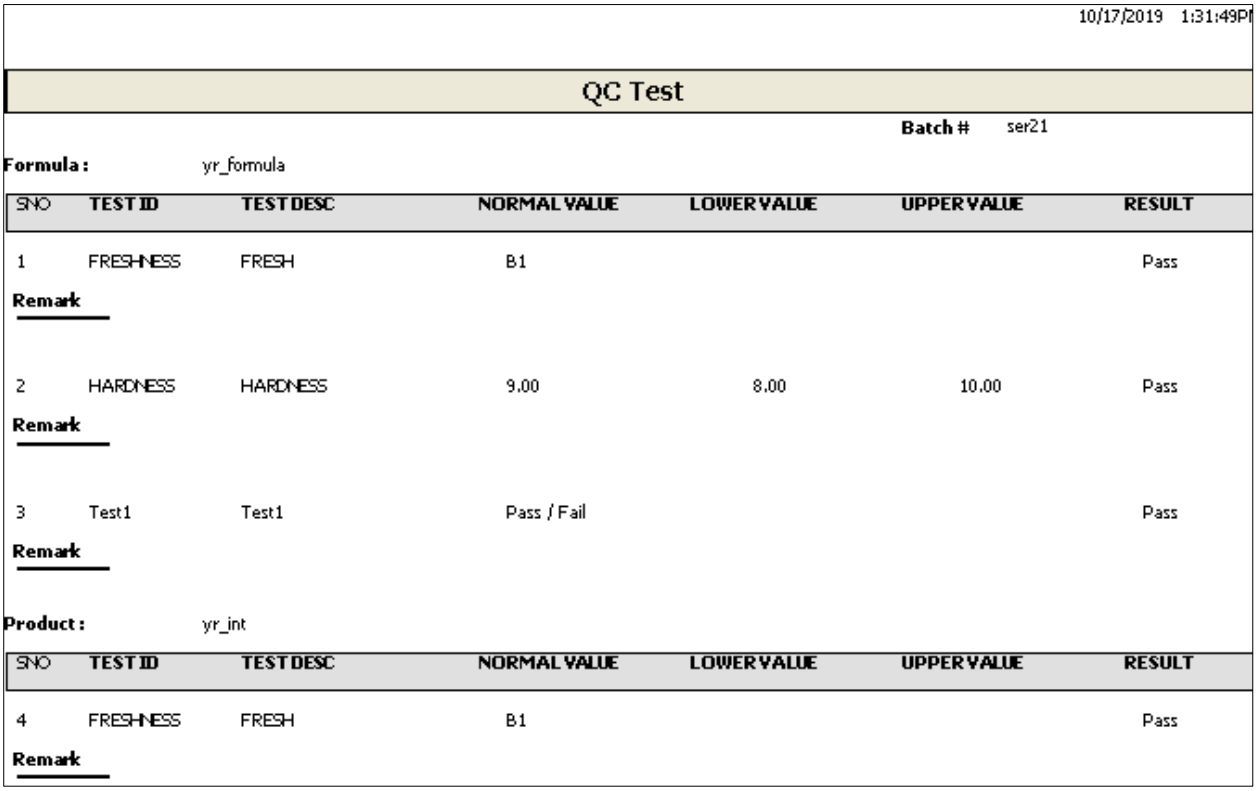
BATCH INFORMATION REPORT

QAERP_SP16_ALA

Batch Number	ser21			**Production. Whs**	01
Batch Type	Mix	**Owner**	yash	**Demand Type**	Independent
Status	Issued			**Demand Source**	Production Order
Formula ID	yr_formula	yr_formula		**Sales Order #**	
Revision No.	0000000007	**Customer Code**		**Total Runs**	1
Current Run #	1	**Customer Name**		**Process Cell**	c3
Sch.Start Date	10/10/19	**Act. Start Date**	10/10/19	**Theoretical Density**	0.89
Sch.End Date	11/10/19	**Act. End Date**		**Density Overide**	0.00
Order Weight	5.000000 KG	**Batch Weight**	9.263157 KG		
Order Volume	5.600001 LT	**Batch Volume**	10.374737 LT		
Setup Time	0:01:00	**Variable Time**	0:02:00	**Fixed Time**	0:08:00
Setup Labor	10.00	**Variable Labor**	40.00	**Fixed Labor**	80.00
Setup Overhead	1.00	**Variable Overhead**	4.00	**Fixed Overhead**	80.00
Previous Batch Ticket Date	10-October-2019				
Notes					

FG/BATCH OUTPUT DETAILS

SNO	ITEM CODE	DESCRIPTION	ORDERED QTY
1	yr_int	yr_int	5.00 KG



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QC Test

Batch # ser21

Formula : yr_formula

SNO	TEST ID	TEST DESC	NORMAL VALUE	LOWER VALUE	UPPER VALUE	RESULT
1	FRESHNESS	FRESH	B1			Pass
Remark						
2	HARDNESS	HARDNESS	9.00	8.00	10.00	Pass
Remark						
3	Test1	Test1	Pass / Fail			Pass
Remark						

Product : yr_int

SNO	TEST ID	TEST DESC	NORMAL VALUE	LOWER VALUE	UPPER VALUE	RESULT
4	FRESHNESS	FRESH	B1			Pass
Remark						

INSPECTION INFORMATION

DocNo/ Date	Item Code	Whs	Status	Submitted By	Verify By /Verified Date	Approved	Test	Value	Comment
Inspection Plan :- 12									
12			Approved	yash	yash	yash	STRENGTH	2	
10/10/201				10/10/2019	10/10/2019	10/10/2019			
12			Approved	yash	yash	yash	HARDNESS	10	
10/10/201				10/10/2019	10/10/2019	10/10/2019			
12			Approved	yash	yash	yash	COLOR	1	
10/10/201				10/10/2019	10/10/2019	10/10/2019			

NC INFORMATION

Source :- Deviation

NON Conformance :-

DocNo	24	**NC Date**	10/10/2019	**ItemCode**	yr_int	**Desc**	yr_int		
Qc Test Code	COLOUR	**Min Value**	0.00	**MaxValue**	0.00	**Act .Value**	0	**Status**	3
Customer		**Lot no**	yr_int 10-10	**Machine**		**Reported By**	yash	**Owner**	manager
NC Desc	A non-conformance (or 'nonconformity') means that something went wrong. The non-conformance could be in a service, a product, a process, goods from a supplier, or in the management system itself. It occurs when something does not meet the specifications or requirements in some way.								

Root Causes Analysis :-

Root Cause		**Analysed By**	yash	**Analysed .Date**	10/10/2019	**CAPA NO.**	CAPAOct2019
Root Cause Detail	North Carolina (/ˌkærəˈlaɪnə/ (About this soundlisten)) is a state located in the southeastern region of the United States. North Carolina is the 28th largest and 9th-most populous of the 50 United States. It is bordered by Virginia to the north, the Atlantic Ocean to the east, Georgia and South Carolina to the south, and Tennessee to the west. Raleigh is the state's capital and Charlotte is its largest city. The Charlotte metropolitan area, with an estimated population of 2,569,213 in 2018, is the most populous metropolitan area in North Carolina, the 23rd-most populous in the United States, and the largest banking center in the						

User yash

Source :- Inspection

NON Conformance :-

DocNo	25	**NC Date**	10/10/2019	**ItemCode**		**Desc**			
Qc Test Code	COLOR	**Min Value**	0.00	**MaxValue**	0.00	**Act .Value**	1	**Status**	3
Customer		**Lot no**		**Machine**		**Reported By**	yash	**Owner**	yash
NC Desc	sdfasdfasdfasdfasdfasdfasdfasdf								

Root Causes Analysis :-

Root Cause		**Analysed By**	yash	**Analysed .Date**	10/10/2019	**CAPA NO.**	
Root Cause Detail	Details						

Action Taken :-

Action taken

CAPA INFORMATION

DocNum	9	Status	5	Priority	1	Owner	yash

Source :- Deviation

Origin :-

Category	CAPA CATEGC	Assigned To	yash	Dept.	-2	Branch	-2
Assigned To	CAPA TYPE	Sch. Comp DT	10/10/2019				

CAPA Desc Corrective and preventive action (CAPA, also called corrective action/preventive action or simply corrective action) consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. It is usually a set of actions that laws or regulations require an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring nonperformance. Non-conformance is identified after systematic evaluation and analysis of the root cause of the non-conformance. Non-conformance may be a market complaint or customer complaint or a failure of a machinery or a quality management system, or misinterpretation of written instructions to carry out a work. The corrective and preventive action is designed by a team that includes quality assurance personnel and personnel involved in the actual observation point of nonconformance. It must be systematically implemented

Category	CAPA CATEGC	Assigned To	yash	Dept.	-2	Branch	-2
Assigned To	CAPA TYPE	Sch. Comp DT	10/10/2019				

CAPA Desc Corrective and preventive action (CAPA, also called corrective action/preventive action or simply corrective action) consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. It is usually a set of actions that laws or regulations require an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring nonperformance. Non-conformance is identified after systematic evaluation and analysis of the root cause of the non-conformance. Non-conformance may be a market complaint or customer complaint or a failure of a machinery or a quality management system, or misinterpretation of written instructions to carry out a work. The corrective and preventive action is designed by a team that includes quality assurance personnel and personnel involved in the actual observation point of nonconformance. It must be systematically implemented and observed for its ability to eliminate further recurrence of such non-conformation.

Corrective action: Action taken to eliminate causes of non-conformities or other undesirable situations. Preventive action: Action taken to prevent further reoccurrence of such non-conformities.

Investigation :-

Category	CAPA REASON	Inv. By	yash	Inv. DT.	10/10/2019	Act. Taken	Y

Invst. Detail
CAPA Details
Detail (record producer), AKA Noel Fisher
Auto detailing, process of thoroughly cleaning a car
Level of detail, 3D computer graphics concept
Security detail, military or private team assigned to protect an individual or group
Detail man, industry-deprecated term for a pharmaceutical sales representative

Corrective Action :

Investigation :-

Category	CAPA REASON	**Inv. By**	yash	**Inv. DT.**	10/10/2019	**Act. Taken**	Y

Invst. Detail

CAPA Details
Detail (record producer), AKA Noel Fisher
Auto detailing, process of thoroughly cleaning a car
Level of detail, 3D computer graphics concept
Security detail, military or private team assigned to protect an individual or group
Detail man, industry-deprecated term for a pharmaceutical sales representative

Corrective Action :

Action Taken Corrective Action taken

User	yash	**Corr.Date**	10/10/2019	**Act. Taken**	Y

Preventive Action :-

Action Taken Preventive action Taken

Verify By	yash	**Ver.Date**	10/10/2019	**Act. Taken**	Y

Verification :-

Comment CAPA Verification required

Verify By	yash	**App. By**	manager	**Act. Taken**	Y

CHECK LIST INFORMATION

Doc No 17 Checked By yash Date 10/10/2019 Verify By yash Date 10/10/2019

Approved By yash Date 10/10/2019

Boiler Plate	Checked	Verify	Approved	Desc.	Checked By	Checked Date
a1	Y	Y	Y		yash	10/10/2019
BP06	Y	Y	Y		yash	10/10/2019
BP07	Y	Y	Y		yash	10/10/2019

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DOWN TIME INFORMATION

DocNum	DT Code	Remarks	Start Date	End Date	Start Time	End Time	Process Cell	Desc
5	DT Dode	Remark1	10/10/2019	10/10/2019	960	1,080	c3	DT Code

DEVIATION INFORMATION

DocNum	Date	Status	Comp Dt.	Type	Req.By	Assign To	NC NO	CAPA NO	Reason	Dev Dtl.
5	10/10/2013		10/10/2012		yash	manager	NCOct20	CAPAOct2(	Reason is the c	Relative standard deviation, in probability theory and statistics is the absolute value of the coefficient of variation

Impact : "Imapct Wrestling results 6/25". "WWE SmackDown Live #955 « Events Database « CAGEMATCH

Root Cause : Griffin Investigations, the most prominent group of private investigators specializing in the gambling industry

DPosition A disposition is a quality of character, a habit, a preparation, a state of readiness, or a tendency to act in a specified way that may be learned

Notes : Musical note, a pitched sound (or a symbol for a sound) in music

19 GLOSSARY

Glossary Term	Definition
BOM	(Bill of Materials) A list of the raw materials, intermediate assemblies, consumables and packaging materials needed to produce quantity "1" of a finished good or intermediate item.
Finished Good	An inventoried item that results at the end of a manufacturing process and is ready to be sold.
Formula	A list of ingredients, their proportions, and instructions for making an intermediate or finished product.
Process Cell	A group of one or more machines with a common purpose. Used in planning and scheduling as well as to define and monitor capacity.
Raw Material	An inventoried item, purchased from a supplier, which has not been modified by your process.
SRM	Sales Request Management (SRM) is a process of capturing and tracking sales requests from customers.
Third Party Manufacturing	Third party manufacturing is a process of getting the complete or a part of manufacturing work done by a contract manufacturer.
Stability Testing	A measure of how a product maintains its quality attributes over time.