FT PharmaSuite®

MATERIAL TRACKING PHASES
RELEASE 10.01.00
FUNCTIONAL REQUIREMENT SPECIFICATION

Rockwell Automation

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Contents

Introduction

This document details the requirements of the functions implemented by the phases specific to material tracking. The phases are executed in the Production Execution Client of PharmaSuite.

Each requirement is composed of a name and a unique identifier (e.g. Instruction (SR0050.8.1)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g. Process parameters (SR0050.8+)).
For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (page 101).

The revision history (page 104) lists the changes made to the document with PharmaSuite 10.0 as the comparison baseline. Changes related to a requirement are marked as "Editorial", "Update", "New", or "Deleted", changes to the additional context information are marked as "Context information-related".

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as

- window and dialog titles
- menu functions
- panel, tab, and button names
- box labels
- object properties and their values (e.g. status).

`Monospaced typeface`	Designates code examples.

Recipe Configuration for Material Tracking

This section provides an overview of material tracking within process orders.

Phases and Structural Context

The phases of material tracking rely on material data provided by their material parameters. They can be run in three very different structural contexts:

- as sequential process where each phase needs to be completed to pass its material data on to the following phase.

- as simultaneous process, where all phases can be concurrently active in different operations and the material data is passed on as soon as it occurs in one of the phases.

- as simultaneous process, where the same phases can be concurrently active in different operations and operators can work on the same material positions, but with different sublots.

The following phases are available:

- Identify material (page 7)
  The **Identify material** phase needs to hold all materials to be processed as MFC-relevant material input parameters.
  All listed materials and quantities can either be identified during a single phase run or the phase can be placed in a loop or an event-triggered operation and run several times for identifying the materials in several runs of the phase.

- Show GHS data (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (page 101)
  The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.
  The usage of the **Show GHS data** phase during **Material Tracking** is optional.

- Produce material (page 67)
  The **Produce material** phase expects the produced material as MFC-relevant material output parameter. It has an external loop so that it can produce sublots of the output material in several runs and different sublot quality statuses. The phase can also be placed in an event-triggered operation. Thus, it is possible to model a process during which a set of sublots is produced, another phase is used to perform another action on the produced sublots, such as placing them on a pallet, and then the next run of the **Produce material** phase is started to produce another set of sublots.

- Load logistic unit (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (page 101))
  The **Load logistic unit** phase allows an operator to load sublots or a logistic unit onto a target logistic unit.
  The usage of the **Load logistic unit** phase during **Material Tracking** is optional.

- Account material (page 45)
  The **Account material** phase expects the same materials as input parameters that were processed in the **Identify material** phase. In this case, however, the input parameters are not MFC-relevant, since the phase only calculates the usage quantities of the materials while the actual material flow has taken place earlier in the **Identify material** and **Produce material** phases.
  The listed materials can either be accounted during a single phase run or the phase can be placed in a loop or an event-triggered operation to run several times and thus concurrently account the usage quantities of the identified and processed materials.

Figure 1: Operation with sequential material tracking
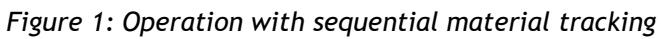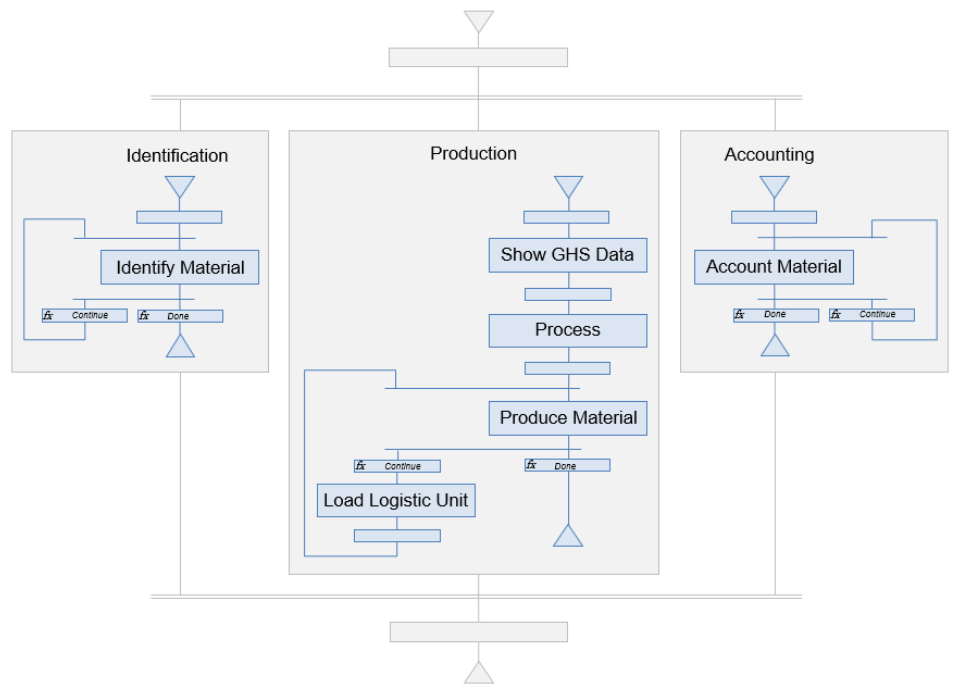
Figure 2: Unit procedure with simultaneous material tracking
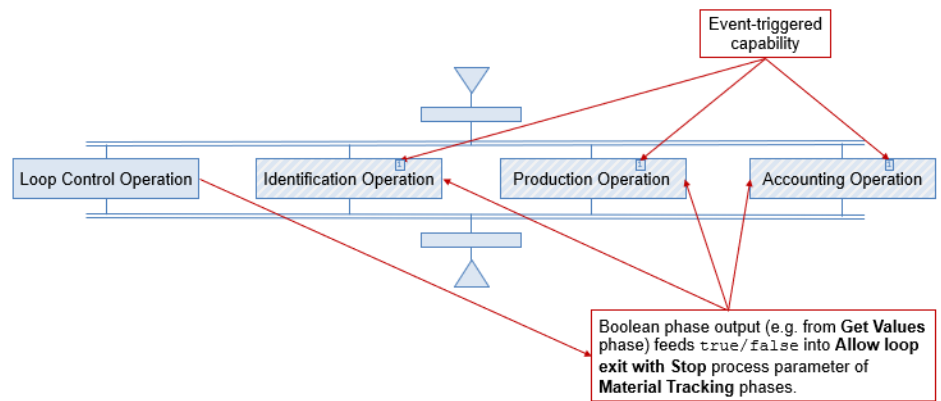
Figure 3: Unit procedure with simultaneous material tracking and event-triggered operations

Identify Material Phase (SR0050+)

The **Identify material** phase allows an operator to identify material on sublot and logistic unit level for further processing.

Example use cases are:

- Identify material prior to dispensing
  The batch status of the materials must be **Released**. This material-specific requirement can be defined and corresponding violations can be tracked as exceptions.

- Identify material before mixing
  Only allocated batches are allowed to be utilized in the mixing process. An allocation check is specified in the phase. Identification of other batches can be tracked as exceptions.

- Unidentify material
  Material that has been identified is bound to an order step. As long as none of the previously identified sublots has been accounted, their identification can be revoked. This unbinds the material from the order step and makes it available for identification elsewhere.

Scanned or manually entered batches and sublots or logistic units (and their sublots) are checked against configurable settings

- batch and sublot status

- expiry date

- batch allocation

and built-in settings

- material is MFC-relevant

- sublot is produced for the current order step (only for intra materials)

- sublots are exclusively used by the current order.

The list of identified sublots and logistic units with their quantities and material-related information is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 13).

Anomalies that occur during processing are covered by the phase exception handling (page 28) (e.g. revoking an identification).

After completion, the phase displays the identified material with the following data in the Execution Window:

- batch and/or sublot identifiers
  - In case a logistic unit has been identified, the phase also displays the logistic unit identifier.
- planned quantity
- identified quantity
- accounted quantity with accounting status (if available).

The Navigator displays the processing result and provides access to the post-completion exceptions.

Pos.	Material	Allocated or identified batch / sublot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	10.0 g		
		BX194 / SL00008697		10.0 g		
20	D005-04 / Talc		(20.0 g)	0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	0 g		

Figure 4: Identify material during execution (sequential processing)

Pos.	Material	Allocated or identified batch / sublot	Planned quantity [Limits]	Identified quantity	Accounted	Accounting status
10	D003-04 / Ethanol 96 %		(10.0 g)	20.0 g	10.0 g	Accounted
		BX238 / SL00008770		10.0 g		
		BX194 / SL00008697		10.0 g		
20	D005-04 / Talc		(20.0 g)	100.0 g	20.0 g	Accounted
		BX196 / SL00008706		100.0 g		
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105.0 g	1,015.0 g	Accounted
		BX201 / SL00008725		200.0 g		
		BX197 / SL00008716		400.0 g		
		BX219 / SL00008750		505.0 g		

D003-04: Re-identify 10.0 g
D005-04: Re-identify 20.0 g
D130-01: Re-identify 200.0 g

Figure 5: Reactivated Identify material during execution with Comment to execution (sequential processing)

Figure 6: Identify material during execution (simultaneous processing)

Figure 7: Identify material during execution (simultaneous processing with Stop)

Layout

The phase provides individual layouts for its representation during execution (page 9), in the Navigator (page 13), and in the sub-report (page 13).

Representation during Execution (SR0050.1+)

The representation during execution depends on the phase mode.

Preview mode (SR0050.1.3)

1. <Instruction text>
   (taken from **Instruction (SR0050.8.1)** process parameter (page 21))

2. Box for scanner input

3. **Refresh** button (disabled)

4. List of materials available for identification (Table of materials (SR0050.1.2) (page 11))
   (taken from material input parameters (SR0050.6.1) (page 19))

5. Material-related comment to execution
   (only visible if comment is maintained for the order step input)

6. **Continue** and **Done** (**Stop**) option buttons (both disabled)
   The buttons are only visible if the **Loop configuration (SR0050.8.17)** process parameter (page 21) is not set to **No loop**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0050.8.20)** process parameter (page 21) is enabled.

7. **Enable** button (disabled).
   The button is not visible in case a phase completion signature was configured during authoring.
   The button is only visible if the **Loop configuration (SR0050.8.17)** process parameter (page 21) is set to **No loop**.

8. **Confirm** button (disabled).

Active mode (SR0050.1.1)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0050.8.1)** process parameter (page 21))

3. Box for scanner input

4. **Refresh** button

5. List of materials available for identification (Table of materials (SR0050.1.2) (page 11))
   (taken from material input parameters (SR0050.6.1) (page 19))

6. Material-related comment to execution
   (only visible if comment is maintained for the order step input)

7. **Continue** and **Done** (**Stop**) option buttons (**Continue** selected)
   The buttons are only visible if the **Loop configuration (SR0050.8.17)** process parameter (page 21) is not set to **No loop**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0050.8.20)** process parameter (page 21) is enabled.

8. **Enable** button (unlocks the **Confirm** button).
   The button is not visible in case a phase completion signature was configured during authoring.
   The button is only visible if the **Loop configuration (SR0050.8.17)** process parameter (page 21) is set to **No loop**.

9. **Confirm** button.

Table of materials (SR0050.1.2)

Data available per batch/sublot:

Content	UI text	Comment
Position	Pos.	Ordered by position, ascending. Taken from **material input parameters (SR0050.6.1)** process inputs (page 19).
Material identifier and short description	Material	Taken from **material input parameters (SR0050.6.1)** process inputs (page 19).
Logistic unit, batch, or sublot identifier(s)	Allocated or identified logistic unit / batch / sublot	Summary line per position: List of all allocated batches or transferred sublots. Line per sublot: Logistic unit ID of the sublot (only if PharmaSuite is configured to communicate with Warehouse Management and the logistic unit is identified instead of the sublot). After the identification of a transferred sublot, the sublot is removed from the summary line.
Planned quantity and range	Planned quantity [Limits]	(Taken and calculated from **material input parameters (SR0050.6.1)** process inputs (page 19)). Summary line per position: Display of quantity depends on **Planned quantity mode**. **None** – A defined planned quantity is only for information and displayed in brackets. **As produced** – Shown as N/A as long as the predecessor position has not been closed. After closing the predecessor position, its produced quantity is displayed here. Additionally, the calculated limits are displayed if the defined tolerance is > 0. **As defined** – Planned quantity. Additionally, the calculated limits are displayed if the defined tolerance is > 0.

Content	UI text	Comment
Identified quantity	Identified quantity	Summary line per position: Total of all identified sublots for a position. Line per sublot: Sublot quantity at the time of identification.
Accounted quantity	Accounted quantity	Summary line per position: Total of all accounted sublots for a position. Line per sublot: Accounted sublot quantity. Column is not displayed in case the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**.
Status of accounting (Set by **Account Material (SR0070+)** phase (page 45)	Accounting status	Summary line per position only. First row: Initially **Empty.** Comparison result between planned and accounted quantity (**Below tolerance**, **In tolerance**, **Above tolerance**). Second row: Initially **Empty.** The last accounting phase instance sets **Accounted.** Column is not displayed in case the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**.

Completed mode (SR0050.1.4)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0050.8.1)** process parameter (page 21))

3. Box for scanner input (disabled)

4. **Refresh** button (disabled)

5. List of materials available for identification (Table of materials (SR0050.1.2)
   (page 11))
   (taken from material input parameters (SR0050.6.1) (page 19))

6. Material-related comment to execution
   (only visible if comment is maintained for the order step input)

7. **Continue** and **Done** (**Stop**) option buttons (keep last selection, both disabled)
    The buttons are only visible if the **Loop configuration (SR0050.8.17)** process parameter (page 21) is not set to **No loop**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0050.8.20)** process parameter (page 21) is enabled.

8. **Enable** button (disabled).
    The button is not visible in case a phase completion signature was configured during authoring.
    The button is only visible if the **Loop configuration (SR0050.8.17)** process parameter (page 21) is set to **No loop**.

9. **Confirm** button (completed).

Representation in Navigator (SR0050.4+)

The Navigator provides the following details:

Phase column (Framework capability)

■ <Phase name>

  ■ Example:
    Identify mixing inputs

Information column (SR0050.4.1)

■ <Continue, Stop, or Done> representing the content of the **Result (SR0050.9.1)** output variable (page 43).

  ■ Example: Done

Action column (SR0050.4.2)

■ Identify, identify another sublot.

■ Undo, revoke identification of a sublot.

Representation in Sub-report (SR0050.5+)

The sub-report contains the following information:

Common sub-report elements (Framework capability)

■ <Start time>

■ <Completion time>

■ <Unit procedure> / <operation> / <phase>

■ <Work center> / <station> / <device> - <phase completion user>

Sub-report elements (SR0050.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Summary line per position with material identifier and short description, planned quantity and identified quantity

- List of identified sublots and logistic units per material position, including batch identifier and identified quantity

- In case the **Loop configuration (SR0050.8.17)** process parameter (page 21) is configured to loop the phase, the last instance (completed with the **Done** button) displays as summary the list of the sublots for all instances.

- Material-related comment to execution (only visible if comment was visible during execution, i.e. was maintained for the order step input at that time)

Business Logic (SR0050.2+)

The phase implements the following business logic.

Identify material (SR0050.2.1)

- Function: Identify pre-defined materials

- Trigger: Phase becomes active

- Postcondition: Pre-defined materials are identified

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0050.1.1)** layout (page 10).
Must loop check	15	In case the phase is configured to **Must loop** after each identification according to the **Loop configuration (SR0050.8.17)** process parameter (page 21) and there was already a successful identification, the phase ignores all further identifications and needs to be completed first. Phase displays the **Loop required (SR0050.3.6.15)** error message (page 42).
Operator scans barcode	20	The **Scan material barcode (SR0050.2.2)** function (page 16) becomes active.
Scanned barcode belongs to a logistic unit	25	Phase retrieves all sublots that are currently loaded on the identified logistic unit and performs for each sublot the checks listed below. If no sublot is found on the logistic unit, phase displays the **No sublot on logistic unit (SR0050.3.6.8)** error message (page 40).

Step	#	Description
Phase performs fixed checks	30	If one of the following checks is violated, phase displays an error message: 1. Identified material must be MFC-relevant, **MFC check failed (SR0050.3.6.1)** error message (page 38). 2. Sublots must be produced for the current order (only for intra materials), **Wrong order (SR0050.3.6.2)** error message (page 39). 3. Sublot must not be identified by another order, **Sublot already identified (SR0050.3.6.3)** error message (page 39). 4. Treatment ID check In the default configuration, the phase skips the check. See also **Enable and Configure Treatment ID Support (SR0050.11.1)** configuration key (page 44). If the check is enabled and fails, the related **Treatment ID check failed (SR0050.3.6.9)** error message (page 41) is displayed.
Minimum batch status check	40	According to **Batch status check configuration (SR0050.8.7)** process parameter (page 22), batch status is greater than or equal to the configured minimum batch status. If the check fails, phase creates the **Failed batch status check (SR0050.3.2.5)** system-triggered exception (page 29).
Batch allocation check	50	According to **Allocation check configuration (SR0050.8.9)** process parameter (page 23), batch allocation must be met. If the check fails, phase creates the **Failed batch allocation check (SR0050.3.2.6)** system-triggered exception (page 29).
Expiry date check	60	According to **Expiry date check configuration (SR0050.8.8)** process parameter (page 23), expiry date must be defined and beyond the current date plus the configured time to expire. If the check fails, phase creates the **Failed expiry date check (SR0050.3.2.7)** system-triggered exception (page 29).
Sublot status check	65	If the check is enabled according to the **Sublot status check configuration (SR0200.8.28)** process parameter (page 24), the check is performed. If the identified sublot has no status set, the check always passes. If the identified sublot has a status lower than the configured minimum sublot status, the check fails (**Blocked** < **Quality Inspection** < **Unrestricted**). If the check fails, phase creates the **Failed sublot status check (SR0050.3.2.8)** system-triggered exception (page 30).
	70	In case a logistic unit has been scanned and for one of the sublots of the logistic unit a check fails, no sublot of the logistic unit is identified.
	80	If all checks have passed successfully, material has been identified.

Scan material barcode (SR0050.2.2)

- Function: Scan of material barcode

- Trigger: Operator scans barcode

- Postcondition: Material barcode is scanned

Step	#	Description
Operator scans barcode	10	Phase reads scanned data.
	20	■ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ■ If barcode reading was technically not successful, phase remains in listening mode. ■ If barcode reading was not successful, phase displays the **Cannot find sublot or logistic unit (SR0050.3.6.4)** error message (page 39).

Unit procedure context (SR0050.2.5)

- Function: Define unit procedure context

- Trigger: Pre-defined materials are identified

- Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that identified materials are only recognized within the given unit procedure.

Auto consumption (SR0050.2.6)

- Function: Support of automatic consumption

- Trigger: Operator confirms phase

- Postcondition: Consumption of entire sublot quantity is recorded automatically

Step	#	Description
Automatic consumption	10	According to **Consumption configuration (SR0050.8.4)** process parameter (page 22), phase records the identified sublot as fully consumed and flags the sublot as **logically deleted**.

Step	#	Description
	20	Only if PharmaSuite is configured to communicate the consumption with Warehouse Management: In case a warehouse-related error has occurred, phase displays the **Warehouse error (SR0050.3.6.6)** error message (page 40). The phase can only be completed when the **Warehouse error (SR0050.3.1.4)** user-triggered exception (page 33) has been recorded.

Phase completion (SR0050.2.7)

■ Function: Completion of phase

■ Trigger: Operator confirms phase

■ Postcondition: Phase is completed

Step	#	Description
Operator confirms phase with **Done** or **No loop** configuration	10	If the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**, phase continues with the **Auto consumption (SR0050.2.6)** function (page 16).
	20	The **Accounting checks (SR0050.2.8)** function (page 18) becomes active.
	30	In order to be completed, the phase requires all system-triggered exceptions to be recorded. Only if PharmaSuite is configured to communicate with Warehouse Management and the **Warehouse error (SR0050.3.1.4)** user-triggered exception (page 33) has not been recorded, phase displays the **Missing warehouse exception recording (SR0050.3.6.7)** error message (page 40). The phase can only be completed when the **Warehouse error (SR0050.3.1.4)** user-triggered exception (page 33) has been recorded.
	40	If all checks have passed successfully and all exceptions have been recorded, the **Result (SR0050.9.1)** output variable (page 43) is set to DONE.
Operator confirms phase with **Continue** or **Stop**	50	If the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**, phase continues with the **Auto consumption (SR0050.2.6)** function (page 16). If all exceptions have been recorded, the **Result (SR0050.9.1)** output variable (page 43) is set to CONTINUE or STOP, respectively.

Accounting checks (SR0050.2.8)

■ Function: Accounting checks at completion of phase

■ Trigger: Operator confirms phase with **Done** or **No loop** configuration

■ Postcondition: Accounting checks are completed

Step	#	Description
Check if predecessor is closed	10	In case a position is configured with the planned quantity mode **As produced** and the planned quantity is not set yet (the predecessor position is not completed), phase displays the **Predecessor position not completed (SR0050.3.6.12)** error message. (page 42)
Check transferred sublots	20	In case for a position that is configured with the planned quantity mode **As produced** not all produced sublots of the predecessor have been identified, phase displays the **Not all transferred sublots identified (SR0050.3.6.11)** error message (page 41).
Check mandatory positions	30	If the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**: ■ If for any position that is configured with the planned quantity modes **As defined** or **As produced** nothing is identified, phase displays the **Auto-Consume and missing material identification (SR0050.3.6.13)** error message (page 42). ■ The system checks if material was identified for a position that is configured with the planned quantity modes **As defined** but the consumed quantity is not within the limits of the planned quantity. If the check fails, phase creates the **Quantity out of tolerance (SR0050.3.2.9)** system-triggered exception (page 30). If the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **No**: ■ In case the accounting status of any position that is configured with the planned quantity modes **As defined** or **As produced** is not **Accounted**, phase displays the **Accounting check failed (SR0050.3.6.10)** error message (page 41).

Recipe Parameters

The phase provides material input parameters as process inputs (page 19) and process parameters (page 19).

Process Inputs (SR0050.6+)

Material input parameters (SR0050.6.1)

The default material input parameters are available to define which materials can be identified during execution.

Quantity definitions of the material input parameters are populated to the **Table of materials (SR0050.1.2)** list (page 11) that is displayed during execution. This includes the reflection of quantity-related calculations during order explosion.

Process Parameters (SR0050.8+)

The following process parameters define the behavior of the phase.

INSTRUCTION TABLE-SPECIFIC PARAMETERS

Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a

Attribute	Type	Comment
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

INSTRUCTION LINK-SPECIFIC PARAMETERS

Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (page 20). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

BASIC PARAMETERS

Instruction (SR0050.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

PROCESSING PARAMETERS

Loop configuration (SR0050.8.17)

Attribute	Type	Comment
Loop configuration	Choice list	Defines if the phase shall use a loop or static mode. Available settings: **No loop**, **Can loop**, **Must loop**. Default setting: **No loop**.

Allow loop exit with Stop (SR0050.8.20)

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the **Done** button is replaced with a **Stop** button. This allows a loop exit with the same behavior as the **Continue** button. Default setting: **No**.

Consumption configuration (SR0050.8.4)

Attribute	Type	Comment
Auto consume	Flag	Controls if the identified sublot is registered as fully consumed when the phase is completed with the **Confirm** button. If you have more than one phase sharing the same material within one operation, all sublots will be consumed even if the flag is set only for one of the phases.

CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

Batch status check configuration (SR0050.8.7)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Minimum batch status** attribute of the **Batch check definition (SR0050.8.3)** process parameter (page 24) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed batch status check (SR0050.3.2.5)** system-triggered exception (page 29).

Expiry date check configuration (SR0050.8.8)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Minimum time to expire** attribute of the **Batch check definition (SR0050.8.3)** process parameter (page 24) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed expiry date check (SR0050.3.2.7)** system-triggered exception (page 29).

Allocation check configuration (SR0050.8.9)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, the check is only performed if there are allocation requirements.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed batch allocation check (SR0050.3.2.6)** system-triggered exception (page 29).

Batch check definition (SR0050.8.3)

Attribute	Type	Comment
Minimum batch status	Choice list	Defines the minimum batch status required for material identification. Default setting: **Released.**
Minimum time to expire	Numeric	Defines the number of days allowed between the actual identification date and expiry date.

Sublot status check configuration (SR0050.8.15)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Minimum sublot status** attribute of the **Sublot check definition (SR0050.8.16)** process parameter (page 25) is set. Default setting: **False**
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Failed sublot status check (SR0050.3.2.8)** system-triggered exception (page 30).

Sublot check definition (SR0050.8.16)

Attribute	Type	Comment
Minimum sublot status	Choice list	Defines the minimum sublot status required for material identification. Available settings: **Blocked**, **Quality Inspection**, **Unrestricted**. Default setting: **Unrestricted**.

Quantity out of tolerance (SR0050.8.18)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Quantity out of tolerance (SR0050.3.2.9)** system-triggered exception (page).

CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

Identify manually (SR0050.8.10)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Identify manually (SR0050.3.1.1)** user-triggered exception (page 31).

Undo identification (SR0050.8.11)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Undo identification (SR0050.3.1.2)** user-triggered exception (page 32).

Warehouse error (SR0050.8.14)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.

See also **Warehouse error (SR0050.3.1.4)** user-triggered exception (page 33).

Force completion (SR0050.8.19)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Force completion (SR0050.3.1.5)** user-triggered exception (page 34).

CONFIGURATION OF POST-COMPLETION EXCEPTIONS

Post - Identify additionally (SR0050.8.12)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Identify additionally (SR0050.3.3.1)** post-completion exception (page).

Post - Undo identification (SR0050.8.13)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Undo identification (SR0050.3.3.2)** post-completion exception (page).

Exceptions (SR0050.3+)

The phase supports user-defined, user-triggered (page), system-triggered (page), and post-completion exceptions (page) and their configuration by means of process parameters (page).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

System-triggered Exceptions (SR0050.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

Failed batch status check (SR0050.3.2.5)

Representation of the exception:

- ■ <Exception text>
  (taken from **Batch status check configuration (SR0050.8.7)** process parameter
  (page 22))
  Batch: <batch identifier>,
  Expected value: <status>
  Actual value: <status>

  - ■ Example:
    The current status of the batch is not appropriate.
    Batch: BX127
    Expected value: Released
    Actual value: Quarantined

Failed batch allocation check (SR0050.3.2.6)

Representation during exception handling:

- ■ <Exception text>
  (taken from **Allocation check configuration (SR0050.8.9)** process parameter
  (page 23))
  Batch: <batch identifier>

  - ■ Example:
    The current batch has not been allocated.
    Batch: BX127

Failed expiry date check (SR0050.3.2.7)

Representation of the exception:

- ■ <Exception text>
  (taken from **Expiry date check configuration (SR0050.8.8)** process parameter
  (page 23))
  Batch: <batch identifier>
  Expected value: <number of days>
  Actual value: <date>

  - ■ Example:
    The current expiry date is not sufficient anymore.
    Batch: BX127
    Expected value: 720 days
    Actual value: 10/12/2011

Failed sublot status check (SR0050.3.2.8)

If the check is enabled according to the **Sublot status check configuration (SR0050.8.15)** process parameter (page 24), the check is performed. If the identified sublot has no status set, the check always passes. If the identified sublot has a status lower than the configured minimum sublot status, the check raises the exception (**Blocked** < **Quality Inspection** < **Unrestricted**).

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

- ■ <Exception text>
  (taken from **Sublot status check configuration (SR0050.8.15)** process parameter (page 24))
  Batch: <batch identifier>, material: <material identifier>, sublot: <sublot identifier>
  Expected value: <sublot status>
  Actual value: <sublot status>

  - ■ Example:
    Sublot status check failed.
    Batch: BX123, material: D130-01, sublot: SL00001234
    Expected value: Unrestricted
    Actual value: Quality Inspection

Quantity out of tolerance (SR0050.3.2.9)

If the **Auto consume** attribute of the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**, the planned quantity mode of any material position assigned to the phase is **As defined**, and the identified quantity is not within the range of the planned quantity and its tolerance, an exception is raised.

Representation of the exception:

- ■ <Exception text>
  (taken from **Quantity out of tolerance (SR0050.8.18)** process parameter (page 25))
  The following positions are out of tolerance:
  Material: <material identifier>, Planned quantity: <planned quantity [lower limit .. upper limit]>, Identified quantity: <identified quantity>

  - ■ Example:
    Wrong amount of material identified.
    The following positions are out of tolerance:
    Material: D130-01, Planned quantity: 100.0 kg [99.0 kg .. 105.0 kg], Identified quantity: 50.000 kg

Multiple exceptions (SR0050.3.2.3)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply. In case a logistic unit has been identified, the combined exception contains information about all exceptions of all sublots of the logistic unit and displays the identifier of the logistic unit. In this case, the highest risk is calculated from all related exceptions of all sublots.

User-triggered Exceptions (SR0050.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

Identify manually (SR0050.3.1.1)

The **Identify manually** exception allows an operator to identify material manually as long as the material position is not accounted with a planned quantity mode **As produced** or **As defined**.

Representation during exception handling:

- ■ Instruction:

    - ■ PharmaSuite is not configured to communicate with Warehouse Management:
      To identify manually, enter the sublot identifier.
      Box for barcode input.
      Confirm button.

    - ■ PharmaSuite is configured to communicate with Warehouse Management:
      To identify manually, enter the sublot or logistic unit identifier.
      Box for barcode input.
      Confirm button.

- ■ Exception text:
  <Exception text>
  (taken from **Identify manually (SR0050.8.10)** process parameter (page 25))

    - ■ Identified sublot: <sublot identifier>

    - ■ Identified logistic unit: <logistic unit identifier>

    - ■ Example:
      Manual identification
      Identified sublot or logistic unit: SL00005678

Step	#	Description
Operator confirms exception	10	Phase executes the checks of steps 15 and 25 to 70 of the **Identify material (SR0050.2.1)** function (page 14).
	20	If all checks have passed successfully, phase records the exception according to **Identify manually (SR0050.8.10)** process parameter (page 25).
	30	Material is identified.

Undo identification (SR0050.3.1.2)

The **Undo identification** exception allows an operator to revoke the identification of a sublot as long as the sublot has not been accounted and the material position is not accounted with a planned quantity mode **As produced** or **As defined**.
In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit and that have not been accounted is revoked.

Representation during exception handling:

- Instruction:

  - PharmaSuite is not configured to communicate with Warehouse Management:
    To undo the identification, enter the identifier of the affected sublot.
    Box for barcode input.
    Confirm button.

  - PharmaSuite is configured to communicate with Warehouse Management:
    To undo the identification, enter the identifier of the affected sublot or logistic unit.
    Box for barcode input.
    Confirm button.

- Exception text:
  <Exception text>
  (taken from **Undo identification (SR0050.8.11)** process parameter (page 26))

  - Unidentified sublot: <sublot identifier>; Quantity: <sublot quantity>

  - Unidentified logistic unit: <logistic unit identifier>

  - Example:
    Undo identification
    Unidentified sublot: SL00005678; Quantity: 500 kg

Step	#	Description
Operator confirms exception	10	If the sublot has not been accounted, phase records the exception according to **Undo identification (SR0050.8.11)** process parameter (page 26). In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit and that have not been accounted is revoked. Otherwise phase displays the **Cannot revoke identification (SR0050.3.6.5)** error message (page 39).
	20	Sublot(s) are no longer identified.

Warehouse error (SR0050.3.1.4)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- **Warehouse error (SR0050.3.6.6)** error message (page 40)

Representation of the exception:

- Instruction:
  Confirm to record the warehouse error.
  Confirm button.

- <Exception text>
  (taken from **Warehouse error (SR0050.8.14)** process parameter (page 26))
  A warehouse error has occurred while consuming material.
  <Error message from the warehouse system>

  - Example:
    Document warehouse error
    A warehouse error has occurred while consuming material.
    <Error message from the warehouse system>

Warehouse error - Logic (SR0050.3.1.4.1)

- Trigger: Exception is selected

- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the **Warehouse error (SR0050.8.14)** process parameter (page 26).

Force completion (SR0050.3.1.5)

The **Force completion** exception allows an operator to complete the phase even if one or several of following errors prevent to complete the phase:

- **Accounting check failed (SR0050.3.6.10)** error message (page 41)

- **Not all transferred sublots identified (SR0050.3.6.11)** error message (page 41)

- **Predecessor position not completed (SR0050.3.6.12)** error message (page 42)

- **Auto-consume and missing material identification (SR0050.3.6.13)** error message (page 42)

- The planned quantity is 0 and the planned quantity mode is **As produced** (predecessor is closed with 0 quantity) or **As defined** (no **Planned quantity** defined with material parameter).

Representation of the exception:

- Instruction:
  Force the completion.
  Confirm button.

- <Exception text>
  (taken from **Force completion (SR0050.8.19)** process parameter (page 27))
  Force the completion of the phase in spite of the following errors:
  <error messages that would appear at phase completion>

  - Example:
    Finish the phase manually.
    Force the completion of the phase in spite of the following errors:
    Not all materials have been identified.
    Not all materials have been accounted.
    At least one predecessor of an As Produced position has not been processed yet.

Step	#	Description
Phase checks if the exception is required	10	If none of the following errors would prevent the normal completion of the phase: ■ **Accounting check failed (SR0050.3.6.10)** error message (page 41) ■ **Not all transferred sublots identified (SR0050.3.6.11)** error message (page 41) ■ **Predecessor position not completed (SR0050.3.6.12)** error message (page 42) ■ **Auto-consume and missing material identification (SR0050.3.6.13)** error message (page 42) phase aborts the exception with the **Force completion not required (SR0050.3.6.14)** error message (page 42).
Operator confirms exception	20	Phase records the exception.

Multiple exceptions (SR0050.3.1.3)

In case an **Identify manually (SR0050.3.1.1)** user-triggered exception (page 31) coincides with system-triggered exceptions (page 28), only one combined exception (user-triggered exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

In case a logistic unit has been identified, the combined exception contains information about all exceptions of all sublots of the logistic unit and displays the identifier of the logistic unit. In this case, the highest risk is calculated from all related exceptions of all sublots.

Post-completion Exceptions (SR0050.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

Identify additionally (SR0050.3.3.1)

The **Identify additionally** exception allows an operator to manually identify an additional sublot or logistic unit from the Navigator after the completion of the phase. In case the phase is configured to run in the loop mode, the post-completion exception is only available for the last completed phase instance.

Representation of the exception:

- Instruction:

  - PharmaSuite is not configured to communicate with Warehouse Management:
    To identify an additional sublot, enter the sublot identifier.
    Box for barcode input.
    Confirm button.

  - PharmaSuite is configured to communicate with Warehouse Management:
    To identify an additional sublot or logistic unit, enter its identifier.
    Box for barcode input.
    Confirm button.

- <Exception text>
  (taken from **Post - Identify additionally (SR0050.8.12)** process parameter (page 27))

  - Additionally identified sublot: <sublot identifier>

  - Additionally identified logistic unit: <logistic unit identifier>

  - Example:
    Post additional identification
    Additionally identified sublot: SL00005678

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator enters barcode.
	30	Phase executes the checks of step 25 to 70 of the **Identify material (SR0050.2.1)** function (page 14).
	40	If all checks have passed successfully, phase records the exception according to **Post - Identify additionally (SR0050.8.12)** process parameter (page 27).
	45	Only if the **Consumption configuration (SR0050.8.4)** process parameter (page 22) is set to **Yes**: ■ Phase records the identified sublot as fully consumed and flags the sublot as **logically deleted**. ■ Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred, phase displays the **Warehouse error (SR0050.3.6.6)** error message (page 40). The **Warehouse error (SR0050.3.1.4)** user-triggered exception (page 33) is automatically recorded.
	50	Material is identified.

Undo identification (SR0050.3.3.2)

The **Undo identification** exception allows an operator to revoke the identification of a sublot as long as the sublot has not been accounted from the Navigator after the completion of the phase. In case the phase is configured to run in the loop mode, the post-completion exception is only available for the last completed phase instance.
In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit within the current phase instance and that have not been accounted is revoked.

Representation during exception handling:

- Instruction:

    - PharmaSuite is not configured to communicate with Warehouse Management:
    To undo the identification, enter the identifier of the affected sublot.
    Box for barcode input.
    Confirm button.

    - PharmaSuite is configured to communicate with Warehouse Management:
    To undo the identification, enter the identifier of the affected sublot or logistic unit.
    Box for barcode input.
    Confirm button.

- Exception text:
  <Exception text>
  (taken from **Post - Undo identification (SR0050.8.13)** process parameter (page 28))

    - Unidentified sublot: <sublot identifier>; Quantity: <sublot quantity>

    - Unidentified logistic unit: <logistic unit identifier>

    - Example:
    Undo identification
    Unidentified sublot: SL00005678; Quantity: 500 kg

Step	#	Description
Operator triggers action	10	If the sublot has not been accounted, phase records the exception according to **Post - Undo identification (SR0050.8.13)** process parameter (page 28). In case of a logistic unit, the identification of sublots that were identified previously along with the logistic unit and that have not been accounted is revoked. Otherwise phase displays the **Cannot revoke identification (SR0050.3.6.5)** error message (page 39).
	20	Sublot(s) are no longer identified.

Multiple exceptions (SR0050.3.3.3)

In case an **Identify additionally (SR0050.3.3.1)** post-completion exception (page 35) coincides with system-triggered exceptions (page 28), only one combined exception (post-completion exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

In case a logistic unit has been identified, the combined exception contains information about all exceptions of all sublots of the logistic unit and displays the identifier of the logistic unit. In this case, the highest risk is calculated from all related exceptions of all sublots.

Information Messages

There are no information messages available.

Questions

There are no questions available.

Decisions

There are no decisions available.

Error Messages (SR0050.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

MFC check failed (SR0050.3.6.1)

UI text	Comment
Cannot identify the material, since it has already been processed and completed or does not correspond to the required material input. Select a suitable material input, if available.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotIdentifySublotMaterial Potential error cause: The identified material is not MFC-relevant for this order. It cannot be used at this point.

Wrong order (SR0050.3.6.2)

UI text	Comment
The sublot (<sublot ID>) has not been produced for this order step. Select another sublot.	Message pack: srv_inventory.checks Message ID: CheckMaterialForIntermediateOSI_0 Potential error cause: The identified material (intra material sublot) has not been produced for the current order. It cannot be used at this point.

Sublot already identified (SR0050.3.6.3)

UI text	Comment
Cannot identify the sublot (<sublot ID>), since it has already been identified for another order step. Select another sublot.	Message pack: srv_inventory.checks Message ID: CheckSublotBlockedByProcessing_0 Potential error cause: The identified material has already been identified for another order. It cannot be used at this point.

Cannot find sublot or logistic unit (SR0050.3.6.4)

UI text	Comment
Cannot find the sublot or logistic unit in the inventory. Scanned barcode: <identifier> Please check your data.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: BarcodeNotExistTxt

Cannot revoke identification (SR0050.3.6.5)

UI text	Comment
Cannot unidentify the <identifier> sublot, since it has already been consumed.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: SublotsConsumedTxt
Cannot unidentify the <identifier> sublot, since it was not identified by the current phase.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: SublotNotFound

UI text	Comment
Cannot unidentify the <identifier> logistic unit, since none of its sublots have been identified by the current phase.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUUndoIdentNoSublotsTxt
Cannot unidentify the <identifier> logistic unit, since all identified sublots have already been consumed.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUUndoIdentAllSublotsConsumedTxt
An internal error has occurred. Cannot unidentify the <identifier> logistic unit.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUUndoIdentSublotsNotIdentifiedTxt

Warehouse error (SR0050.3.6.6)

UI text	Comment
A warehouse error has occurred while consuming material. <Error message from the warehouse system>	Message pack: PhaseProductIdentifyMaterial<version> Message ID: ConsumeSublotWarehouseError_Error

Missing warehouse exception recording (SR0050.3.6.7)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: PhaseProductMaterial<version> Message ID: SignWarehouseError_Error

No sublot on logistic unit (SR0050.3.6.8)

UI text	Comment
No sublots on logistic unit with <barcode> barcode found.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: LUIdentNoSublotsTxt

Treatment ID check failed (SR0050.3.6.9)

UI text	Comment
Cannot identify the batch <identifier>. The treatment ID <identifier> of the batch does not match the treatment ID <identifier> of the order.	Message pack: srv_inventory.checks Message ID: CheckTreatmentID_1
Cannot identify the batch <identifier> with the treatment ID <identifier>. The current order has no treatment ID.	Message pack: srv_inventory.checks Message ID: CheckTreatmentID_0
Cannot identify any material. The current order has no treatment ID.	Message pack: srv_inventory.checks Message ID: CheckTreatmentID_2

Accounting check failed (SR0050.3.6.10)

UI text	Comment
Cannot confirm the phase, since not all materials have been accounted.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteMatIdentPositionStillOpen_Error

Not all transferred sublots identified (SR0050.3.6.11)

UI text	Comment
Cannot confirm the phase, since not all sublots have been identified: <list of not identified sublot identifiers produced at previous step>.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteSublotsToIdentify_Error

Predecessor position not completed (SR0050.3.6.12)

UI text	Comment
Cannot confirm the phase, since at least one predecessor of an As Produced position is still open.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteAsProducedPredecessorStillOpen_Error

Auto-consume and missing material identification (SR0050.3.6.13)

UI text	Comment
Cannot confirm the phase, since not for all required positions material has been identified.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: CannotCompleteNotAllMaterialIdentified_Error

Force completion not required (SR0050.3.6.14)

UI text	Comment
There are no errors. Please confirm the phase without exception.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: NoErrorsToBeForced_Error

Loop required (SR0050.3.6.15)

UI text	Comment
Cannot identify the material in the current phase run. Confirm the phase and identify in a further run.	Message pack: PhaseProductIdentifyMaterial<version> Message ID: MustLoopAfterIdentification_Error

Output Variables (SR0050.9+)

The following output variables are available to reference the phase's output.

Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

Result (SR0050.9.1)

- Data type: String

- Values: CONTINUE, STOP, DONE

- Usage: The output variable provides the result of the phase processing:

  - The value is CONTINUE if the phase was completed with **Continue**.

  - The value is STOP if the phase was completed with **Stop**.

  - The value is DONE if the phase was completed with **Done** or the **Loop configuration (SR0050.8.17)** process parameter (page 21) is set to **No loop**.

Configuration Keys (SR0050.11+)

The following configuration keys are available to configure the phase's behavior.

Enable and Configure Treatment ID Support (SR0050.11.1)

- **Phase/TreatmentIDSupport**

- **Type**: String

- **Value**: Off

- **Description**: The configuration applies to material identification with the **D Identify material** phase and the **Identify material** phase and to workflow creation with the **Create workflow** phase.
  If the value is set to **Off**, no treatment ID is checked during material identification and a created workflow does not inherit the treatment ID of the order.
  If the value is set to **TreatmentIDMandatory**, all orders need to have a treatment ID set. If the identified batch has a treatment ID, it must be equal to the order's treatment ID.
  If the value is set to **TreatmentIDOptional**, an order does not have to have a treatment ID set. If the identified batch has a treatment ID, it has to be equal to the order's treatment ID.

- **Evaluated**: At sublot or batch identification and at workflow creation.

- **Range**: [Off, TreatmentIDMandatory, TreatmentIDOptional]

Account Material Phase (SR0070+)

The **Account material** phase allows an operator to account identified sublots in terms of consumed, wasted, sampled, and returned quantities.

Example use cases are:

- Consume partial sublots
  For sublots that were not completely used up during processing, the actual amount of material that has been utilized can be declared as consumed and the remainder can be declared as to be returned.

- Consume sublots completely
  If several sublots of one material have been identified and consumed completely, the consumption can be declared per material at once.

- Account samples
  A processing step requires to create samples. The quantity that was used for sampling purposes can be declared separately.

- Account unused sublots
  One of the identified sublots was not used at all during processing. The entire sublot can be returned.

The number of accounted sublots and their material identifiers are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 52).

Depending on the configured planned quantity mode of an order step input position, the accounted quantity is compared with the planned quantity and its limits. In case of a limit violation an exception is recorded.

After completion the phase displays the accounted material with the following data in the Execution Window:

- batch and/or sublot identifiers
- identified quantity
- consumed quantity
- wasted quantity
- sampled quantity
- returned quantity
- accounting status.

The Navigator displays the processing result.

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D003-04 / Ethanol 96 %		(10.0 g)	10.0 g	10.0 g	0.0 g 0.0 g	0.0 g	
		BX194						
		SL00008697		10.0 g	10.0 g	0.0 g 0.0 g	0.0 g	
20	D005-04 / Talc		(20.0 g)	100.0 g				
		BX196						
		SL00008706		100.0 g				
30	D130-01 / Sonolin 100 mg premix		(1,000.0 g)	1,105.0 g				
		BX197						
		SL00008716		400.0 g				
		BX201						
		SL00008725		200.0 g				
		BX219						
		SL00008750		505.0 g				

Figure 8: Account material during execution (sequential processing)

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,100.0 g)	900.0 g	680 g	0 g 20 g	0.0 g	
		BX176						
		SL00008679		200.0 g				
		SL00008670		300.0 g	290 g	0 g 10 g	0.0 g	
		SL00008683		400.0 g	390 g	0 g 10 g	0.0 g	

Figure 9: Account material during execution (simultaneous processing)

Pos.	Material	Batch ID Sublot ID	Planned quantity [Limits]	Identified	Consumed	Wasted Sampled	Returned	Status
10	D130-03 / Sonolin retard 100 mg		(1,000.00 g)	500.0 g	500.0 g	0.0 g 0.0 g	0.0 g	
		BX386						
		SL00000252		500.0 g	500.0 g	0.0 g 0.0 g	0.0 g	

Figure 10: Account material during execution (simultaneous processing with marker)

Figure 11: Account material during execution (simultaneous processing with marker and Stop)

Layout

The phase provides individual layouts for its representation during execution (page 47), in the Navigator (page 51), and in the sub-report (page 52).

Representation during Execution (SR0070.1+)

The representation during execution depends on the phase mode.

Preview mode (SR0070.1.4)

1. <Instruction text>
   (taken from Instruction (**SR0070.8.1**) process parameter (page 58))

2. **Refresh** button (disabled).

3. **Account** button (disabled).

4. List of materials available for accounting (Table of materials (SR0070.1.2) (page 48))
   (taken from material input parameters (SR0070.6.1) (page 55))

5. **Continue** and **Done** (**Stop**) option buttons (both disabled)
   The buttons are only visible in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **Yes**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0070.8.8)** process parameter (page 51) is enabled.

6. **Enable** button (disabled).
   The button is not visible in case a phase completion signature was configured during authoring.
   The button is only visible in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **No**.

7. **Confirm** button (disabled).

Active mode (SR0070.1.1)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from Instruction **(SR0070.8.1)** process parameter (page 58))

3. **Refresh** button.

4. **Account** button.

5. List of materials available for accounting (Table of materials (SR0070.1.2) (page 48))
   (taken from material input parameters (SR0070.6.1) (page 55))

6. **Continue** and **Done** (**Stop**) option buttons (**Continue** selected)
   The buttons are only visible in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **Yes**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0070.8.8)** process parameter (page 51) is enabled. The **Continue** button is marked with "(*)" as soon material is accounted with the current phase instance.

7. **Enable** button (unlocks the **Confirm** button).
   The button is not visible in case a phase completion signature was configured during authoring.
   The button is only visible in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **No**.

8. **Confirm** button.

Table of materials (SR0070.1.2)

Data available per batch/sublot:

Content	UI text	Comment
Position	Pos.	Ordered by position, ascending. Taken from **material input parameters (SR0070.6.1)** process inputs (page 55).
Material identifier and short description	Material	Taken from **material input parameters (SR0070.6.1)** process inputs (page 55).
Identified batch/sublot identifier(s)	Batch ID Sublot ID	Summary line per position: empty Line per batch: Batch identifier Line per sublot: Sublot identifier

Content	UI text	Comment
Planned quantity and range	Planned quantity [Limits]	Taken from **material input parameters (SR0070.6.1)** process inputs (page 55). Summary line per position: Display of quantity depends on **Planned quantity mode**. **None** – A defined planned quantity is only for information and displayed in brackets. **As produced** – Shown as N/A as long as the predecessor position has not been closed. After closing the predecessor position, its produced quantity is displayed here. Additionally, the calculated limits are displayed if the defined tolerance is > 0. **As defined** – Planned quantity. Additionally, the calculated limits are displayed if the defined tolerance is > 0.
Identified quantity	Identified	Summary line per position: Total of all identified sublots for a position. Line per batch: empty Line per sublot: Sublot quantity at the time of identification.
Consumed quantity	Consumed	Summary line per position: Total of all accounted sublots for a position. Line per batch: empty Line per sublot: Consumed quantity as accounted.
Wasted and sampled quantities	Wasted Sampled	Summary line per position: Total of all accounted sublots for a position. Line per batch: empty Line per sublot: Wasted quantity as accounted. Sampled quantity as accounted.

Content	UI text	Comment
Returned quantity	Returned	Summary line per position: Total of all accounted sublots for a position. Line per batch: empty Line per sublot: Returned quantity as accounted.
Accounting status	Status	Summary line per position only. First row: Initially **Empty.** Comparison result between planned and accounted quantity (**Below tolerance**, **In tolerance**, **Above tolerance**). Second row: Initially **Empty.** A completed phase with result = **Done** sets **Accounted** if material was identified.

Accounting dialog (SR0070.1.3)

Data available per accounting step:

- **Identified** quantity and **UoM** toggle button (both read-only)

- **Consumed** quantity and **UoM** toggle button

- **Wasted** quantity and **UoM** toggle button (accessible according to **Calculation configuration (SR0070.8.3)** process parameter (page 60))

- **Sampled** quantity and **UoM** toggle button

- **Returned** quantity and **UoM** toggle button (accessible according to **Calculation configuration (SR0070.8.3)** process parameter (page 60))

- **Account** button

- **Cancel** button

- Phase action signature panel
  (only if a phase action signature is assigned to the phase)

Accounting dialog - Single sublot (SR0070.1.3.1)

If, in the Table of materials (SR0070.1.2) (page 48), a single sublot has been selected for accounting, the following data can be provided:

- **Consumed** quantity

- **Sampled** quantity

- **Wasted** quantity or **Returned** quantity (depends on **Calculation configuration (SR0070.8.3)** process parameter (page 60))

Accounting dialog - Consume all (SR0070.1.3.2)

If, in the Table of materials (SR0070.1.2) (page 48), a single batch, material item, or multiple sublots have been selected for accounting, the dialog opens in a **Consume all** mode. The **Identified** quantities are taken over as **Consumed** quantities. No quantities can be entered manually.

Completed mode (SR0070.1.5)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from Instruction **(SR0070.8.1)** process parameter (page 58))

3. **Refresh** button (completed).

4. **Account** button (completed).

5. List of materials available for accounting (Table of materials (SR0070.1.2) (page 48))
   (taken from material input parameters (SR0070.6.1) (page 55))

6. **Continue** and **Done** (**Stop**) option buttons (keep last selection, both disabled)
   The buttons are only visible in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **Yes**. The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0070.8.8)** process parameter (page 51) is enabled.

7. **Enable** button (disabled).
   The button is not visible in case a phase completion signature was configured during authoring.
   The button is only visible in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **No**.

8. **Confirm** button (completed).

Representation in Navigator (SR0070.4+)

The Navigator provides the following details:

Phase column (Framework capability)

- ■ <Phase name>

  - ■ Example:
    Account materials

Information column (SR0070.4.1)

- <Continue, Stop, or Done> representing the content of the **Result (SR0070.9.1)** output variable (page 66).

  - Example: Continue

Action column

- There are no actions available.

Representation in Sub-report (SR0070.5+)

The sub-report contains the following information:

Common sub-report elements (Framework capability)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

Sub-report elements (SR0070.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Summary line per position with material identifier and short description, planned quantity, planned quantity limits (only if defined), and accounted quantities (**Consumed**, **Wasted**, **Sampled**, **Returned**).

- List of identified sublots and logistic units per material position, including batch identifier and identified quantity

- Confirmed with **Continue** or **Done** (**Stop**)
  Represents the content of the **Result (SR0070.9.1)** output variable (page 66).
  Only displayed in case the **Enable loop (SR0070.8.6)** process parameter (page 59) is set to **Yes**.

- Signed actions
  (only if a phase action signature is assigned to the phase)

Business Logic (SR0070.2+)

The phase implements the following business logic.

Account material (SR0070.2.1)

■ Function: Account pre-defined materials

■ Trigger: Phase becomes active

■ Postcondition: Pre-defined materials are accounted

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0070.1.1)** layout (page 48).
Operator starts accounting	20	Only if PharmaSuite is configured to communicate with Warehouse Management and, during the previous accounting, the **Warehouse error (SR0070.3.1.1)** user-triggered exception (page 62) has not been recorded, phase displays the **Missing Warehouse exception recording (SR0070.3.6.2)** error message (page 64). The phase can only account material when the **Warehouse error (SR0070.3.1.1)** user-triggered exception (page 62) has been recorded. Otherwise, phase displays the **Accounting dialog (SR0070.1.3)** form (page 50) to declare consumed, wasted, sampled, and returned quantities.
Operator completed accounting dialog	30	Phase continues with the **Determine accounting status (SR0070.2.5)** function (page 55) and sets the result as accounting status for the related material position.
	40	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred, phase displays the **Warehouse error (SR0070.3.6.1)** error message (page 64). The phase can only be completed when the **Warehouse error (SR0070.3.1.1)** user-triggered exception (page 62) has been recorded.

Detect unaccounted materials (SR0070.2.2)

■ Function: Detect if there are unaccounted materials

■ Trigger: Operator confirms phase

■ Postcondition: Unaccounted materials are recorded as exception

Step	#	Description
Operator confirms phase (not with **Continue** or **Stop**)	10	According to **Accounting check configuration (SR0070.8.2)** process parameter (page 58), phase checks if there are no unaccounted materials left. If the check fails, phase creates the **Unaccounted material (SR0070.3.2.1)** system-triggered exception (page 61).

Unit procedure context (SR0070.2.3)

- Function: Define unit procedure context

- Trigger: Materials have been accounted

- Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that accounted materials are only recognized within the given unit procedure.

Phase completion (SR0070.2.4)

- Function: Completion of phase

- Trigger: Complete material accounting

- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	In case one or more locally accounted sublots were accounted from another phase instance, phase displays the **Simultaneous accounting on same sublot (SR0070.3.4.1)** information message (page 63) of the warning type. In order to be completed, the phase requires all system-triggered exceptions to be recorded. Only if PharmaSuite is configured to communicate with Warehouse Management and a warehouse-related error has occurred during the last accounting, phase can only be completed when the **Warehouse error (SR0070.3.1.1)** user-triggered exception (page 62) has been recorded. If the exception is not recorded, phase displays the **Missing Warehouse exception recording (SR0070.3.6.2)** error message (page 64).
Operator confirms phase (not with **Continue** or **Stop**)	20	Phase determines the accounting status for all **material input parameters (SR0070.6.1)** process inputs (page 55) with the **Determine accounting status (SR0070.2.5)** function (page 55). If for any material input to check, the status is **Undefined**, **Below tolerance** or **Above tolerance**, phase creates the **Quantity out of tolerance (SR0070.3.2.3)** system-triggered exception (page 59). If no exception is created or the created exception is recorded, the status of all positions with accounted material is set to **Accounted** and the **Result (SR0070.9.1)** output variable (page 66) is set to DONE.
Operator confirms phase (with **Continue** or **Stop**)	30	If all exceptions are recorded, the **Result (SR0070.9.1)** output variable (page 66) is set to CONTINUE or STOP, respectively.

Determine accounting status (SR0070.2.5)

■ Function: Determine the accounting status for a material position

■ Trigger: Operator accounts material or confirms phase (not with **Continue** or **Stop**)

■ Postcondition: Accounting status is known

Step	#	Description
	10	If for the position to check, the planned quantity mode is configured as **None** at the **material input parameters (SR0050.6.1)** process inputs (page 55) the status is not needed.
	20	If for the position to check, the planned quantity mode is configured as **As defined** or **As produced** at the **material input parameters (SR0050.6.1)** process inputs (page 55) the status is determined. If the planned quantity is not set or no material is identified, the result is **Undefined**, otherwise it is calculated: ■ The accounted quantity is calculated as a total value of all accounted sublots for a material position. If the **Include sample and waste quantities (SR0070.8.7)** process parameter (page 60) is enabled: accQty = consumedQty + SampledQty + WastedQty If the **Include sample and waste quantities (SR0070.8.7)** process parameter (page 60) is not enabled: accQty = consumedQty ■ The planned quantity and its tolerances are retrieved from the related **material input parameters (SR0050.6.1)** process inputs (page 55). plannedRangeMin = planned quantity – lower tolerance plannedRangeMax = planned quantity + upper tolerance ■ accQty < plannedRangeMin: **Below tolerance** accQty > plannedRangeMax: **Above tolerance** else: **In tolerance**

Recipe Parameters

The phase provides material input parameters as process inputs (page 55) and process parameters (page 56).

Process Inputs (SR0070.6+)

Material input parameters (SR0070.6.1)

The default material input parameters are available to define which materials can be accounted during execution.

Process Parameters (SR0070.8+)

The following process parameters define the behavior of the phase.

INSTRUCTION TABLE-SPECIFIC PARAMETERS

Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (page 57). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

BASIC PARAMETERS

Instruction (SR0070.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction:** Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

Accounting check configuration (SR0070.8.2)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Unaccounted material (SR0070.3.2.1)** system-triggered exception (page 61).

Quantity out of tolerance (SR0070.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Quantity out of tolerance (SR0070.3.2.3)** system-triggered exception (page).

PROCESSING PARAMETER

Enable loop (SR0070.8.6)

Attribute	Type	Comment
Enabled	Flag	Defines if the **Continue**/**Done** buttons will be available and the phase can be looped without accounting checks. Default setting: **No**.

Allow loop exit with Stop (SR0070.8.8)

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the **Done** button is replaced with a **Stop** button. This allows a loop exit with the same behavior as the **Continue** button. Default setting: **No**.

Include sample and waste quantities (SR0070.8.7)

Attribute	Type	Comment
Enabled	Flag	Defines if the **Quantity out of tolerance** check against the planned quantity for the accounted quantity shall include besides the consumed quantity also the sampled and wasted quantities. Default setting: **No.**

Calculation configuration (SR0070.8.3)

Attribute	Type	Comment
Result	Choice list	Defines whether the returned quantity or the wasted quantity is calculated. **Return(ed) qty** = Identified qty - Consumed qty - Sampled qty - Wasted qty **Waste(d) qty** = Identified qty - Consumed qty - Sampled qty - Returned qty Default setting: **Return.**

CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

Warehouse error (SR0070.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

> This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.
>
> See also **Warehouse error (SR0070.3.1.1)** user-triggered exception (page 62).

Exceptions (SR0070.3+)

The phase supports user-defined, user-triggered (page 62), system-triggered (page 61), and post-completion exceptions (page 63) and their configuration by means of process parameters (page 56).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

System-triggered Exceptions (SR0070.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

Unaccounted material (SR0070.3.2.1)

Representation during exception handling:

- ■ <Exception text>
  (taken from **Accounting check configuration (SR0070.8.2)** process parameter (page 58))
  <Number> sublots have not been accounted yet.

  - ■ Example:
    Unaccounted materials.
    2 sublots have not been accounted yet.

Step	#	Description
Operator triggers exception	10	Phase records the exception.

Quantity out of tolerance (SR0070.3.2.3)

If the planned quantity mode (defined with the **Identify material** phase (page 7)) of any material position assigned to this phase is **As produced** or **As defined** and the identified quantity is not within the range of the planned quantity and its tolerance or the planned quantity is 0, an exception is raised.

Representation of the exception:

- ■ <Exception text>
  (taken from **Quantity out of tolerance (SR0070.8.5)** process parameter (page 59))
  The following positions are out of tolerance or cannot be checked:
  Material: <material identifier>; Planned quantity: <planned quantity [lower limit .. upper limit]>; Accounted quantity: <accounted quantity>
  Material: <material identifier>; Planned quantity: <planned quantity>; Accounted quantity: < accounted quantity>
  Material: <material identifier>; Planned quantity: undefined; Accounted quantity: <accounted quantity>

- ■ Example:
  Unexpected accounted quantities.
  The following positions are out of tolerance or cannot be checked:
  Material: D130-01; Planned quantity: 100.0 kg [99.0 kg .. 105.0 kg];
  Accounted quantity: 50.000 kg

Multiple exceptions (SR0070.3.2.4)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

User-triggered Exceptions (SR0070.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

Warehouse error (SR0070.3.1.1)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- ■ **Warehouse error (SR0070.3.6.1)** error message (page 64)

Representation of the exception:

- Instruction:
  Confirm to record the warehouse error.
  Confirm button.

- <Exception text>
  (taken from **Warehouse error (SR0070.8.4)** process parameter (page 60))
  A warehouse error has occurred while accounting material.
  <Error message from the warehouse system>

  - Example:
    Document warehouse error
    A warehouse error has occurred while accounting material.
    <Error message from the warehouse system>

Warehouse error - Logic (SR0070.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the **Warehouse error (SR0070.8.4)** process parameter (page 60).

Post-completion Exceptions

There are no post-completion exceptions available.

Information Messages (SR0070.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

Simultaneous accounting on same sublot (SR0070.3.4.1)

UI text	Comment
One or more of the sublots you have accounted were modified afterwards. Please review the modifications. Modified sublot(s): <list of sublot identifiers>	Message pack: PhaseProductAccountMaterial<version> Message ID: ModificationsDetectedOnComplete

UI text	Comment
One or more of the sublots you have accounted were modified afterwards. Please review the modifications. Modified sublot(s): <list of sublot identifiers>	Message pack: PhaseProductAccountMaterial<version> Message ID: ModificationsDetectedOnRefresh

Questions

There are no questions available.

Decisions

There are no decisions available.

Error Messages (SR0070.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

Warehouse error (SR0070.3.6.1)

UI text	Comment
A warehouse error has occurred while accounting material. <Error message from the warehouse system>	Message pack: PhaseProductAccountMaterial<version> Message ID: AccountSublotsWarehouseError_Error

Missing warehouse exception recording (SR0070.3.6.2)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: PhaseProductMaterial<version> Message ID: SignWarehouseError_Error

Accounting already closed for selection (SR0070.3.6.3)

UI text	Comment
Cannot account the selected sublot(s), since it has/they have already been accounted.	Message pack: PhaseProductAccountMaterial\<version\> Message ID: AllRowsAccountedTxt

Output Variables (SR0070.9+)

The following output variables are available to reference the phase's output.

Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

Result (SR0070.9.1)

- Data type: String

- Values: `CONTINUE`, `STOP`, `DONE`

- Usage: The output variable provides the result of the phase processing:

    - The value is `CONTINUE` if the phase was completed with **Continue**.

    - The value is `STOP` if the phase was completed with **Stop**.

    - The value is `DONE` if the phase was completed with **Done** or the **Enable loop (SR0070.8.6)** process parameter (page) is not set to **Yes**.

Produce Material Phase (SR0060+)

The **Produce material** phase allows an operator to produce intra materials or the final product during recipe execution.

Example use cases are:

- Produce intra materials
  The intra materials produced in a processing step will be used in a subsequent processing step. Create the sublots of the intra materials and print their labels. Now, the intra materials are prepared for identification in the next processing step.

- Produce intra materials with defined quality status
  The quality status of the intra materials must be **Released**. This requirement can be defined and will be assigned to the produced sublots.

- Produce final product
  For final products, the quantity can be declared and labels printed per sublot. Then, the product can be delivered to the warehouse.

- Produce final product using packaging levels
  The packaging levels defined for an ERP BOM or a material are visible during phase execution in order to support the operator when he enters the produced quantity. In case **Blister** and **Shipping carton** packaging levels are defined, he can quantify the quantity in the packaging levels even if the outgoing material is accounted in each.

- Reprint a sublot label
  If there was a problem during label printing that renders the printed labels unusable, the required labels can be printed again.

The number of produced sublots and their material identifiers are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 74).

Anomalies that occur during processing are covered by the phase exception handling (page 89) (e.g. label reprint).

After completion the phase displays the produced material with the following data in the Execution Window:

- batch identifiers

- planned quantity

- already produced quantity

- sublot identifier and quantity (of newly produced sublots)

- number of sublots
  or
  packaging level data.

The Navigator displays the quantity produced during this run and provides access to the post-completion exceptions.

Figure 12: Produce material during execution

Figure 13: Reactivated Produce material during execution with Comment to execution

Figure 14: Produce material with packaging levels during execution

Figure 15: Produce material with packaging levels during execution (simultaneous processing with Stop)

Layout

The phase provides individual layouts for its representation during execution (page 69), in the Navigator (page 73), and in the sub-report (page 74).

Representation during Execution (SR0060.1+)

The representation during execution depends on the phase mode.

Preview mode (SR0060.1.3)

1. <Instruction text>
   (taken from **Instruction (SR0060.8.1)** process parameter (page 85))

2. Data of produced quantities (in the unit of measure of the target material):

   - **No packaging levels are defined**

     - Text box for the number of sublots (disabled).

     - Text box for the quantity per sublot (disabled).

     - **UoM** button (disabled).

   - **Packaging levels are defined**

     - List of defined and visible packaging levels

     - Text box (disabled) and information about contained number within the
       next lower level
       (taken from material output parameters (SR0060.7.1) (page 83) and the
       packaging levels-specific Master Recipe - Header Attributes
       (SR3146.9.3.1) in "Functional Requirement Specification Recipe and
       Workflow Management" [A2] (page 101))

3. Quantity summary information

4. **Refresh** button (disabled)

5. List of materials available for production (Table of materials (SR0060.1.2) (page
   72))
   (taken from material output parameters (SR0060.7.1) (page 83))

6. Material-related comment to execution
   (only visible if comment is maintained for the order step output and if the order
   step is reactivated)

7. **Continue** and **Done** (**Stop**) option buttons (both disabled)
   The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop
   (SR0060.8.11)** process parameter (page 86) is enabled.

8. **Confirm** button (disabled).

9. Phase completion signature panel
   (only if a phase completion signature is assigned to the phase)

Active mode (SR0060.1.1)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0060.8.1)** process parameter (page 85))

3. Data of produced quantities (in the unit of measure of the target material):

- **No packaging levels are defined**

  - Text box for the number of sublots

  - Text box for the quantity per sublot

  - **UoM** toggle button

- **Packaging levels are defined**

  - List of defined and visible packaging levels

  - Text box and information about contained number within the next lower level
    (taken from material output parameters (SR0060.7.1) (page 83) and, in case the output material is equal to the target material of the order, the packaging levels-specific Master Recipe - Header Attributes (SR3146.9.3.1) in "Functional Requirement Specification Recipe and Workflow Management" [A2] (page 101))

4. In case the **Planned quantity mode** of the material output parameters (SR0060.7.1) (page 83) is set to **As defined**, phase displays the range for the produced quantity:
   Limits: [<lower limit> .. <upper limit>]

5. In case a target sublot status is defined:

   - Sublot status: <defined target sublot status>

6. Quantity summary information

7. **Refresh** button

8. List of materials available for production (Table of materials (SR0060.1.2) (page 72))
   (taken from material output parameters (SR0060.7.1) (page 83))

9. Material-related comment to execution
   (only visible if comment is maintained for the order step output and if the order step is reactivated)

10. **Continue** and **Done** (**Stop**) option buttons
    (**Continue** selected)
    The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0060.8.11)** process parameter (page 86) is enabled.

11. **Confirm** button.

12. Phase completion signature panel
    (only if a phase completion signature is assigned to the phase)

Table of materials (SR0060.1.2)

Data available per sublot:

- Material ID (taken from material output parameters (SR0060.7.1) (page 83))

- Material short description (taken from material output parameters (SR0060.7.1) (page 83))

- Batch ID of material to be produced

- Planned quantity (taken from material output parameters (SR0060.7.1) (page 83))

- Produced quantity (total)

- List of sublots produced with this phase instance including quantities

Completed mode (SR0060.1.4)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0060.8.1)** process parameter (page 85))

3. Data of produced quantities (in the unit of measure of the target material):

   - **No packaging levels are defined**

     - Text box for the number of sublots (disabled).

     - Text box for the quantity per sublot (disabled).

     - **UoM** button (disabled).

   - **Packaging levels are defined**

     - List of defined and visible packaging levels

     - Text box (disabled) and information about contained number within the next lower level
       (taken from material output parameters (SR0060.7.1) (page 83) and, in case the output material is equal to the target material of the order, the packaging levels-specific Master Recipe - Header Attributes (SR3146.9.3.1) in "Functional Requirement Specification Recipe and Workflow Management" [A2] (page 101))

4. In case a target sublot status is defined:

   - Sublot status: <defined target sublot status>

5. Quantity summary information

6. **Refresh** button

7. List of materials available for production (Table of materials (SR0060.1.2) (page 72))
   (taken from material output parameters (SR0060.7.1) (page 83))

8. Material-related comment to execution
   (only visible if comment is maintained for the order step output and if the order step is reactivated)

9. **Continue** and **Done** (**Stop**) option buttons
   (Used option button selected, both disabled)
   The **Stop** button replaces the **Done** button if the **Allow loop exit with Stop (SR0060.8.11)** process parameter (page 86) is enabled.

10. **Confirm** button (completed).

11. Phase completion signature panel
    (disabled and only if a phase completion signature is assigned to the phase)

Representation in Navigator (SR0060.4+)

The Navigator provides the following details:

Phase column (Framework capability)

- ■ <Phase name>

  - ■ Example:
    Verify coating output

Information column (SR0060.4.1)

- ■ <Overall produced quantity with this phase instance>

  - ■ Example: 980 ea

Action column (SR0060.4.2)

- ■ Reprint, reprints a sublot label.

- ■ Cancel, cancels the production of a sublot.

Representation in Sub-report (SR0060.5+)

The sub-report contains the following information:

Common sub-report elements (Framework capability)

- ◾ <Start time>

- ◾ <Completion time>

- ◾ <Unit procedure> / <operation> / <phase>

- ◾ <Work center> / <station> / <device> - <phase completion user>

Sub-report elements (SR0060.5.1)

- ◾ Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- ◾ Material: <identifier> / <short description>

- ◾ Planned and produced quantity (overall)

- ◾ Only in case packaging levels are defined:

  - ◾ Packaging levels with entered values (if any)

- ◾ List of sublots produced with this phase instance including quantities

- ◾ Material-related comment to execution (only visible if comment was visible
  during execution and if the order step was reactivated, i.e. was maintained for the
  order step output at that time)

Only in case the phase was completed with the **Done** option:

- ◾ List of sublots produced with all instances of this phase and operation including
  quantities

Business Logic (SR0060.2+)

The phase implements the following business logic.

Produce material (SR0060.2.1)

- ■ Function: Produce pre-defined material

  - ■ No packaging levels are defined
    see **Produce material without packaging levels (SR0060.2.1.1)** function (page 75)

  - ■ Packaging levels are defined
    see **Produce material with packaging levels (SR0060.2.1.2)** function (page 77)

- ■ Trigger: Phase becomes active

- ■ Postcondition: Pre-defined material is produced

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0060.1.1)** layout (page 70).
	20	Phase checks if the defined target sublot status is valid. If not, phase displays the **Target sublot status invalid (SR0060.3.6.7)** error message (page 96).
	30	It checks if packaging levels are defined either ■ on material level of the output material or ■ on ERP BOM (master recipe) level and the output material is equal to the target material of the order. If so, it continues with the **Produce material with packaging levels (SR0060.2.1.2)** function (page 77). Otherwise it continues with the **Produce material without packaging levels (SR0060.2.1.1)** function (page 75).

Produce material without packaging levels (SR0060.2.1.1)

Step	#	Description
Operator entered data and cursor leaves box	10	Based on the **Number of sublots** and **Quantity per sublot**, phase calculates and displays the updated quantity summary.

Step	#	Description
Operator confirms phase	20	The phase performs the following checks: ■ The **Confirm after warehouse error (SR0060.2.8)** function (page 82) checks if there are warehouse error-related exceptions that have not been recorded. ■ In case the status of the output material was set to a final state by a simultaneously or previously running phase, a system user-signed exception record with this information will automatically be added to the phase. Continue with step 58. ■ In case the **Done** or **Stop** option button is selected: If the **Number of sublots** or **Quantity per sublot** data is not a positive number and not both fields are empty, phase displays the **Invalid sublot data (SR0060.3.6.3)** error message (page 95). ■ In case the **Continue** option button is selected: If the **Number of sublots** or **Quantity per sublot** data is not a positive number, phase displays the **Invalid sublot data (SR0060.3.6.3)** error message (page 95). ■ If the planned quantity is violated, phase displays the **Check planned quantity (SR0060.3.2.3)** system-triggered exception (page 91). The planned quantity check is only executed if the **Planned quantity mode** is **As defined**. The range for the allowed quantity is calculated as follows: Lower tolerance = min (absolute lower tolerance value (recipe), relative lower tolerance value (recipe)) and Upper tolerance = min (absolute upper tolerance value (recipe), relative upper tolerance value (recipe)) If neither the absolute nor the relative tolerance value is defined in the recipe, the tolerance for this value is 0. If only the absolute or only the relative value is defined, the value that is not defined is ignored. In case the **Done** option button is selected, the calculated quantity must be in the following range of [planned quantity – lower tolerance .. planned quantity + upper tolerance]. In case the **Continue** or **Stop** option button is selected, the calculated quantity must be lower than or equal to the planned quantity + upper tolerance. ■ If the single sublot check is enabled (**Limit quantity to single sublot (SR0060.8.5)** process parameter (page 86)) and if more than one sublot is going to be produced, phase displays the **Limit quantity to single sublot (SR0060.3.2.1)** system-triggered exception (page 89).
	30	The **Create sublot (SR0060.2.2)** function (page 79) becomes active.
	40	The **Assign storage location (SR0060.2.3)** function (page 81) becomes active.

Step	#	Description
	50	The **Assign batch status (SR0060.2.5)** function (page 81) becomes active.
	55	The **Unit procedure context (SR0060.2.4)** function (page 81) becomes active.
	57	The **Produce material done (SR0060.2.7)** function (page 80) becomes active.
	58	The **Unforeseen simultaneous execution checks (SR0060.2.9)** function (page 82) becomes active.
	60	Phase updates the output variables: ■ The **Result (SR0060.9.2)** variable (page 98) is set to `CONTINUE` if the phase was completed with **Continue**, to `STOP` if the phase was completed with **Stop**, and to `DONE` if the phase was completed with **Done**. ■ The **Sublot identifiers (SR0060.9.1)** variable (page 98) contains the identifiers of the created sublots.

Produce material with packaging levels (SR0060.2.1.2)

Step	#	Description
Phase activation	10	In case the unit of measure of the output material is not equal to the unit of measure configured with the **Base unit of measure (SR0060.11.1)** configuration key (page 99) or there is no matching conversion factor defined for the output material, phase displays the **UoM conversion not possible (SR0060.3.6.4)** error message (page 96).
Operator entered value for a packaging level and cursor leaves box	20	Phase calculates and displays the updated quantity summary.

Step	#	Description
Operator confirms phase	30	The phase performs the following checks: ■ The **Confirm after warehouse error (SR0060.2.8)** function (page 82) checks if there are warehouse error-related exceptions that have not been recorded. ■ In case the status of the output material was set to a final state by a simultaneously or previously running phase, a system user-signed exception record with this information will automatically be added to the phase. Continue with step 58. ■ In case the **Continue** option is selected: A positive number must have been entered for at least one packaging level value. Otherwise, phase displays the **Invalid sublot data (SR0060.3.6.3)** error message (page 95). ■ If the planned quantity is violated, phase displays the **Check planned quantity (SR0060.3.2.3)** system-triggered exception (page 91). The planned quantity check is only executed if the **Planned quantity mode** is **As defined**. The range for the allowed quantity is calculated as follows: Lower tolerance = min (absolute lower tolerance value (recipe), relative lower tolerance value (recipe)) and Upper tolerance = min (absolute upper tolerance value (recipe), relative upper tolerance value (recipe)) If neither the absolute nor the relative tolerance value is defined in the recipe, the tolerance for this value is 0. If only the absolute or only the relative value is defined, the value that is not defined is ignored. In case the **Done** option button is selected, the calculated quantity must be in the following range of [planned quantity – lower tolerance .. planned quantity + upper tolerance]. In case the **Continue** or **Stop** option button is selected, the calculated quantity must be lower than or equal to the planned quantity + upper tolerance. ■ If the single sublot check is enabled (**Limit quantity to single sublot (SR0060.8.5)** process parameter (page 86)) and if more than one sublot is going to be produced, phase displays the **Limit quantity to single sublot (SR0060.3.2.1)** system-triggered exception (page 89). ■ If the single logistic unit check is enabled (**Limit quantity to single logistic unit (SR0060.8.6)** process parameter (page 86)) and if more material than one logistic unit can hold is going to be produced, phase displays the **Limit quantity to single logistic unit (SR0060.3.2.2)** system-triggered exception (page 90).

Step	#	Description
	35	In case the **Continue**, the **Stop**, or the **Done** option is selected and a value has been entered for at least one packaging value: ■ Phase calculates the number of sublots to be produced including quantity based on the **Sublot** inventory level and the entered values. If the **Sublot** inventory level is not defined, phase produces one sublot. ■ The **Create sublot (SR0060.2.2)** function (page 79) becomes active. ■ Continue with step 40. Otherwise continue with step 60.
	40	The **Assign storage location (SR0060.2.3)** function (page 81) becomes active.
	50	The **Assign batch status (SR0060.2.5)** function (page 81) becomes active.
	55	The **Unit procedure context (SR0060.2.4)** function (page 81) becomes active.
	57	The **Produce material done (SR0060.2.7)** function (page 80) becomes active.
	58	The **Unforeseen simultaneous execution checks (SR0060.2.9)** function (page 82) becomes active.
	60	Phase updates the output variables: ■ The **Result (SR0060.9.2)** variable (page 98) is set to CONTINUE if the phase was completed with **Continue**, to STOP if the phase was completed with **Stop**, and to DONE if the phase was completed with **Done**. ■ The **Sublot identifiers (SR0060.9.1)** variable (page 98) contains the identifiers of the created sublots. ■ The **LU quantity (SR0060.9.3)** variable (page 98) contains the produced quantity (only if the **Logistic unit** inventory level is defined).

Create sublot (SR0060.2.2)

■ Function: Creation of sublots

■ Trigger: Operator confirms phase

■ Postcondition: Sublots are created

Step	#	Description
Operator provided data and confirms phase	10	Phase checks the number of sublots to be created. If the length of the **Sublot identifiers (SR0060.9.1)** output variable (page 98) would be exceeded, phase displays the **Too many sublots (SR0060.3.6.2)** error message (page 95).

Step	#	Description
	15	The target sublot status is set to the value defined as target sublot status with the material output parameter. In case the **Overwrite target sublot status (SR0060.8.10)** process parameter (page 85) is enabled, the target sublot status is replaced by the value set there.
	20	Phase creates sublots and prints a label for each produced sublot. In case the status of the output material was set to a final state by a simultaneously running phase, the phase stops creating sublots and a system user-signed exception record with this information will automatically be added to the phase. Only if PharmaSuite is configured to communicate with Warehouse Management and a warehouse-related error has occurred during sublot creation, phase displays the **Warehouse error (SR0060.3.6.5)** error message (page 96). The phase can only be completed when the **Warehouse error (SR0060.3.1.2)** user-triggered exception (page 92) has been recorded.

Produce material done (SR0060.2.7)

- Function: Produce material done

- Trigger: Operator confirms phase

- Precondition: **Done** option button is selected

- Postcondition: Status of the output material is set to a final state

Step	#	Description
Operator confirms phase (**Done** option button is selected)	10	PharmaSuite updates the status of the output material position as follows: - **In tolerance**: produced quantity is within tolerances. - **Overweight**: produced quantity is greater than upper tolerance. - **Underweight**: produced quantity is less than lower tolerance. - **Done**: no planned quantity is maintained. The updated status is visible in the **D Identify material** phase in case of concurrent processing in combination with the **D Identify material** phase and Inline Weighing. See also "Functional Requirement Specification Dispense and Inline Weighing" [A3] (page 101).

Assign storage location (SR0060.2.3)

- Function: Assignment of storage location

- Trigger: New sublot has been created

- Postcondition: Storage location is assigned

Step	#	Description
Sublots have been created	10	Phase assigns the pre-defined storage location to each sublot, per configuration on work center level.

Assign batch status (SR0060.2.5)

- Function: Assignment of batch status

- Trigger: New batch has been created

- Precondition: No order-related batch exists yet for the product material

- Postcondition: Batch status is assigned

Step	#	Description
Unit procedure context has been defined	10	According to **Batch definition (SR0060.8.2)** process parameter (page 85), phase assigns a pre-defined batch status to the newly created batch. (Does not apply to already existing batches that have been defined on order level.)
	20	If no status is pre-defined, **Quarantined** is assigned as the default status.

Unit procedure context (SR0060.2.4)

- Function: Define unit procedure context

- Trigger: A new sublot is created

- Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that produced materials are only recognized within the given unit procedure.

Confirm after warehouse error (SR0060.2.8)

- Function: Completion of phase after warehouse error

- Trigger: Phase is completed after warehouse error

- Postcondition: All warehouse error-related exceptions are recorded

Step	#	Description
Phase checks if there are warehouse error-related exceptions that have not been recorded	10	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred during the last material production and the **Warehouse error (SR0060.3.1.2)** user-triggered exception (page 92) has not been recorded, phase displays the **Missing Warehouse exception recording (SR0060.3.6.6)** error message (page 96).

Unforeseen simultaneous execution checks (SR0060.2.9)

- Function: Unforeseen simultaneous execution checks

- Trigger: Operator confirms phase

- Precondition: Phase used in ETOs

- Postcondition: Unforeseen simultaneous execution results recorded

Step	#	Description
Operator confirms phase (ETO)	10	Since the phase can run simultaneously in several ETOs, the following check is executed: ■ In case a planned quantity is defined and the produced quantity violates the upper tolerance that was not already recorded with the **Check planned quantity (SR0060.3.2.3)** system-triggered exception (page 91), a system user-signed exception record with this information will automatically be added to the phase. In case an exception was recorded automatically due to the above described quantity violation or the output material was set to a final state by a simultaneously running phase, the phase displays the **Unforeseen simultaneous execution result (SR0060.3.6.8)** error message (page 97).
	20	If the output material is set to a final state, the phase will be completed with the **Done** option, but without the sub-report section listing all sublots produced with all instances of this phase and operation.

Recipe Parameters

The phase provides material output parameters as process outputs (page 83) and process parameters (page 83).

Process Outputs (SR0060.7+)

Material output parameters (SR0060.7.1)

The default material output parameters are available to define which material can be produced during execution.

Quantity definitions of the material output parameters are populated to the **Table of materials (SR0060.1.2)** list (page 72) that is displayed during execution. This includes the reflection of quantity-related calculations during order explosion.

Process Parameters (SR0060.8+)

The following process parameters define the behavior of the phase.

INSTRUCTION TABLE-SPECIFIC PARAMETERS

Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a

Attribute	Type	Comment
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

INSTRUCTION LINK-SPECIFIC PARAMETERS

Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (page 84). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

Instruction (SR0060.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 2000 characters (including HTML tags).

PROCESSING PARAMETER

Batch definition (SR0060.8.2)

Attribute	Type	Comment
Batch status	Choice list	Defines the batch status of the newly created batch. Default setting: **Quarantined**. **Important**: The batch status setting only applies to newly created batches, but not to already existing batches.

Overwrite target sublot status (SR0060.8.10)

Attribute	Type	Comment
Enabled	Flag	Controls if the defined target sublot status of the **Material output parameters (SR0060.7.1)** process output (page 83) will be overwritten by the sublot status selected with the **Sublot status** attribute. Default setting: **No**.
Sublot status	Choice list	Defines the target sublot status. Available settings: ---, **Blocked**, **Quality Inspection**, **Unrestricted**. Default setting: **---**. Can be defined by information flow. The meaning, not the localized value, of the choice element value needs to be provided. For keeping the sublot status empty, set "null".

Allow loop exit with Stop (SR0060.8.11)

Attribute	Type	Comment
Enabled	Flag	If the phase is configured to loop, it controls the phase completion action. If enabled, the **Done** button is replaced with a **Stop** button. This allows a loop exit with the same behavior as the **Continue** button. Default setting: **No**.

CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

Limit quantity to single sublot (SR0060.8.5)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. Default setting: **No**.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

Limit quantity to single logistic unit (SR0060.8.6)

➢ Applies only if packaging levels are defined and the **Logistic unit** inventory level is assigned to one of the packaging levels (independent of the visibility of this packaging level).

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. Default setting: **No**.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit quantity to single logistic unit (SR0060.3.2.2)** system-triggered exception (page 90).

Check planned quantity (SR0060.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Check planned quantity (SR0060.3.2.3)** system-triggered exception (page 91).

CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

Warehouse error (SR0060.8.9)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.

See also **Warehouse error (SR0060.3.1.2)** user-triggered exception (page 92).

CONFIGURATION OF POST-COMPLETION EXCEPTIONS

Reprint (SR0060.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Reprint label (SR0060.3.3.1)** post-completion exception (page 93).

Cancel sublot (SR0060.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Cancel sublot (SR0060.3.3.2)** post-completion exception (page 93).

Exceptions (SR0060.3+)

The phase supports user-defined, user-triggered (page 92), system-triggered (page 89), and post-completion exceptions (page 93) and their configuration by means of process parameters (page 83).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

System-triggered Exceptions (SR0060.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

Limit quantity to single sublot (SR0060.3.2.1)

Representation of the exception:

- ◼ <Exception text>
  (taken from **Limit quantity to single sublot (SR0060.8.5)** process parameter (page 86))
  The produced quantity (<produced quantity>) exceeds the quantity allowed for one sublot (<quantity of one sublot>).

■ Example:
The produced quantity (100 kg) exceeds the quantity allowed for one sublot (50 kg).

Limit quantity to single sublot - Logic (SR0060.3.2.1.1)

■ Trigger: Operator confirms phase

■ Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator triggers exception	20	Phase records the exception.

Limit quantity to single logistic unit (SR0060.3.2.2)

➢ Applies only if packaging levels are defined and the **Logistic unit** inventory level is assigned to one of the packaging levels (independent of the visibility of this packaging level).

Representation of the exception:

■ <Exception text>
(taken from **Limit quantity to single logistic unit (SR0060.8.6)** process parameter (page 86))
The produced quantity (<produced quantity>) exceeds the quantity allowed for one logistic unit (<quantity of one LU>).

■ Example:
Only allowed to produce one logistic unit load.
The produced quantity (400 kg) exceeds the quantity allowed for one logistic unit (300 kg).

Limit quantity to single logistic unit - Logic (SR0060.3.2.2.1)

➢ Applies only if packaging levels are defined and the **Logistic unit** inventory level is assigned to one of the packaging levels (independent of the visibility of this packaging level).

■ Trigger: Operator confirms phase

■ Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator triggers exception	20	Phase records the exception.

Check planned quantity (SR0060.3.2.3)

Representation of the exception:

■ <Exception text>
(taken from **Check planned quantity (SR0060.8.7)** process parameter (page 87))

 ■ In case the phase is completed and the planned quantity is exceeded:
 The produced quantity (<produced quantity>) has already reached or exceeds the allowed range for the planned quantity (<planned quantity [lowest .. highest]>).

 ■ In case the phase was completed with **Done** and the planned quantity is not reached:
 The produced quantity (<produced quantity>) is not yet within the allowed range for the planned quantity (<planned quantity [lowest .. highest]>).

 ■ Example:
 Planned quantity violation.
 The produced quantity (500 kg) has already reached or exceeds the allowed range for the planned quantity (400 kg [390 kg .. 420 kg]).

Check planned quantity - Logic (SR0060.3.2.3.1)

■ Trigger: Operator confirms phase

■ Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator triggers exception	20	Phase records the exception.

Multiple exceptions (SR0060.3.2.4)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

User-triggered Exceptions (SR0060.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

Warehouse error (SR0060.3.1.2)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- **Warehouse error (SR0060.3.6.5)** error message (page 96)

Representation of the exception:

- Instruction:
  Confirm to record the warehouse error.
  Confirm button.

- \<Exception text\>
  (taken from **Warehouse error (SR0060.8.9)** process parameter (page 88))

  - A warehouse error has occurred while canceling sublots.
    \<Error message from the warehouse system\>

  - A warehouse error has occurred while producing sublots.
    \<Error message from the warehouse system\>

  - Example:
    Document warehouse error
    A warehouse error has occurred while producing sublots.
    \<Error message from the warehouse system\>

Warehouse error - Logic (SR0060.3.1.2.1)

- Trigger: Exception is selected

- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the **Warehouse error (SR0060.8.9)** process parameter (page 88).

Post-completion Exceptions (SR0060.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

Reprint label (SR0060.3.3.1)

The **Reprint label** exception allows an operator to reprint a sublot label from the Navigator after the completion of the phase.

Representation of the exception:

■ Instruction:
To reprint a sublot label, enter the ID of the produced sublot.
Box for barcode input.
Confirm button.

■ <Exception text>
(taken from **Reprint (SR0060.8.4)** process parameter (page 88))
Label of < sublot identifier> sublot reprinted.

   ■ Example:
Label reprinted
Label of SL00008765 sublot reprinted.

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	20	Phase reprints label.

Cancel sublot (SR0060.3.3.2)

The **Cancel sublot** exception allows an operator to set the quantity of a produced sublot to zero.

Representation during exception handling:

■ Instruction:
To cancel a sublot, enter the ID of the produced sublot.
Box for barcode input.
Confirm button.

■ Exception text:
<Exception text>
(taken from **Cancel sublot (SR0060.8.8)** process parameter (page 89))
<Sublot identifier> (<quantity>) sublot canceled.

■ Example:
Destroy the label of the sublot.
SL000078 (20 ea) sublot canceled.

Cancel sublot - Logic (SR0060.3.3.2.1)

■ Trigger: Phase is completed, a sublot has been created before

■ Postcondition: Sublot is canceled

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	20	Phase consumes total sublot quantity and marks the sublot as **logically deleted**. The produced quantity of the material output is reduced accordingly.
	30	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred during sublot cancelation, phase displays the **Warehouse error (SR0060.3.6.5)** error message (page 96) and the **Warehouse error (SR0060.3.1.2)** user-triggered exception (page 92) is automatically recorded.

Information Messages

There are no information messages available.

Questions

There are no questions available.

Decisions

There are no decisions available.

Error Messages (SR0060.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

No sublots identified (SR0060.3.6.1)

UI text	Comment
Cannot proceed, since no sublots of the ingoing material(s) are currently identified.	Message pack: PhaseProductProduceMaterial<version> Message ID: NoOSI_Msg

Too many sublots (SR0060.3.6.2)

UI text	Comment
Cannot proceed, since the defined number of sublots (<number of sublots to produce>) exceeds the maximum number of sublots that can be produced in one phase run (<number of allowed sublots>).	Message pack: PhaseProductProduceMaterial<version> Message ID: TooManySublotsMsg

Invalid sublot data (SR0060.3.6.3)

UI text	Comment
Cannot proceed, since the number of sublots must be a positive number.	Message pack: PhaseProductProduceMaterial<version> Message ID: InvalidNumOfSublots_Txt
Cannot proceed, since the quantity per sublot must be a positive number.	Message pack: PhaseProductProduceMaterial<version> Message ID: InvalidQty_Txt
Cannot proceed, since no values for packaging levels have been entered.	Message pack: PhaseProductProduceMaterial<version> Message ID: NoPackagingLevelValues_Txt

UoM conversion not possible (SR0060.3.6.4)

UI text	Comment
Cannot proceed, since the required unit of measure conversion is not defined for the output material. Please contact your data administrator.	Message pack: PhaseProductProduceMaterial<version> Message ID: UoMConversionNotPossible_Txt

Warehouse error (SR0060.3.6.5)

UI text	Comment
A warehouse error has occurred while canceling sublots. <Error message from the warehouse system>	Message pack: PhaseProductProduceMaterial<version> Message ID: CancelSublotWarehouseError_Error
A warehouse error has occurred while producing sublots. <Error message from the warehouse system>	Message pack: PhaseProductProduceMaterial<version> Message ID: ProduceSublotWarehouseError_Error

Missing warehouse exception recording (SR0060.3.6.6)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: PhaseProductMaterial<version> Message ID: SignWarehouseError_Error

Target sublot status invalid (SR0060.3.6.7)

UI text	Comment
The sublot status parameter attribute contains an invalid value: <value defined by information flow>. Please use the Repair function to correct the issue.	Message pack: PhaseProductProduceMaterial<version> Message ID: InvalidSublotStatus

Unforeseen simultaneous execution result (SR0060.3.6.8)

UI text	Comment
The output material position has been closed in the meantime.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteMeantime_Error This message can be combined with other messages.
Not all sublots have been produced.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOClompleteSomeSublotsProduced_Error This message is combined with other messages.
No sublots have been produced here.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteNoSublotsProduced_Error This message is combined with other messages.
The produced quantity exceeds the upper tolerance.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteOverweight_Error This message can be combined with other messages.
Phase run will be completed.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOCompleteStoppedProd _Error This message is combined with other messages.
The produced quantity exceeds the upper tolerance.	Message pack: PhaseProductProduceMaterial<version> Message ID: OSOSTROverweight_Error

Output Variables (SR0060.9+)

The following output variables are available to reference the phase's output.

Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

Sublot identifiers (SR0060.9.1)

- Data type: String

- Usage: The output variable provides a comma-separated list of identifiers of the created sublots. The separator is configurable with the **OutputSeparator** configuration key.

  > For configuration details, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Manual Configuration and Extension" [A4] (page 101).

Result (SR0060.9.2)

- Data type: String

- Values: CONTINUE, STOP, DONE

- Usage: The output variable provides the result of the phase processing:

  - The value is CONTINUE if the phase was completed with **Continue**.

  - The value is STOP if the phase was completed with **Stop**.

  - The value is DONE if the phase was completed with **Done**.

LU quantity (SR0060.9.3)

- Data type: MeasuredValue

- Usage: The output variable provides the produced quantity for a maximum logistic unit load as a **MeasuredValue** object.

Configuration Keys (SR0060.11+)

The following configuration keys are available to configure the phase's behavior.

Base unit of measure (SR0060.11.1)

- ■ **Phase/ProduceMaterial/BaseUnitOfMeasure**

- ■ **Type**: String

- ■ **Value**: ea

- ■ **Description**: The countable unit of measure to be used for the calculation result in case packaging levels are defined.
  If the unit of measure of the defined output material is not equal to the configured unit of measure, a conversion factor between the configured unit of measure and the unit of measure of the defined output material must be available.

- ■ **Evaluated**: When the **Produce material** phase is started in the Production Execution Client.

- ■ **Range**: Valid countable unit of measure.

Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM006B-EN-E
A2	PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM010B-EN-E
A3	PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM008B-EN-E
A4	PharmaSuite Technical Manual Configuration & Extension - Volume 4	PSCEV4-GR010B-EN-E

> **TIP**
>
> To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

Document Information

The document information covers various data related to the document.

Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Jürgen Stieber	Technical Lead
Ignaz Wangler	Test Lead

Version Information

Object	Version
PharmaSuite	10.01.00
Identify material	7.1
Account material	7.1
Produce material	7.1
Functional Requirement Specification	1.0

Revision History

The following tables describe the history of this document.

Changes related to the document:

Object	Description	Document
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Changes related to "Recipe Configuration for Material Tracking":

Object	Description	Document
Phases and Structural Context (page 3)	Update Third structural context added. **Produce material** description updated: The phase has an external loop so that it can produce sublots of the output material in several runs and different sublot quality statuses. Structure graphic for unit procedure with simultaneous material tracking and event-triggered operations added.	1.0

Changes related to "Identify Material Phase" (page 7):

Object	Description	Document
Preview Mode (SR0050.1.3) (page 9)	Update **Continue** and **Done (Stop)** option buttons (disabled) added.	1.0
Active Mode (SR0050.1.1) (page 10)	Update Instruction link panel added. **Continue** and **Done (Stop)** option buttons added.	1.0
Completed Mode (SR0050.1.4) (page 12)	Update Instruction link panel added. **Continue** and **Done (Stop)** option buttons added.	1.0
Information Column (SR0050.4.1) (page 13)	Update **Stop** output value added.	1.0
Sub-report Elements (SR0050.5.1) (page 14)	Update In case the **Loop configuration (SR0050.8.17)** process parameter is configured to loop the phase, the last instance (completed with the **Done** button) displays as summary the list of the sublots for all instances.	1.0

Object	Description	Document
Phase Completion (SR0050.2.7) (page 17)	Update Step 50: If all exceptions have been recorded, the **Result (SR0050.9.1)** output variable is set to CONTINUE or STOP, respectively.	1.0
Instruction Text with Links (Framework Capability) (page 20)	New process parameter	1.0
Instruction Link Definition (Framework Capability) (page 20)	New process parameter	1.0
Allow Loop Exit with Stop (SR0050.8.20) (page 21)	New process parameter	1.0
Quantity out of Tolerance (SR0050.3.2.9) (page 30)	Editorial Requirement number of **Quantity out of tolerance (SR0050.8.18)** process parameter corrected.	1.0
Identify Manually (SR0050.3.1.1) (page 31)	Update Step 10: Phase executes the checks of steps 15 and 25 to 70 of the **Identify material (SR0050.2.1)** function.	1.0
Force Completion (SR0050.3.1.5) (page 34)	Update List of error cases extended: The planned quantity is 0 and the planned quantity mode is **As produced** (predecessor is closed with 0 quantity) or **As defined** (no **Planned quantity** defined with material parameter).	1.0
Result (SR0050.9.1) (page 43)	Update STOP value added.	1.0

Changes related to "Account Material Phase" (page 45):

Object	Description	Document
Preview Mode (SR0070.1.4) (page 47)	Update **Continue** and **Done (Stop)** option buttons (disabled) added.	1.0
Active Mode (SR0070.1.1) (page 48)	Update **Continue** and **Done (Stop)** option buttons added.	1.0
Completed Mode (SR0070.1.5) (page 51)	Update **Continue** and **Done (Stop)** option buttons added.	1.0
Information Column (SR0070.4.1) (page 52)	Update **Stop** output value added.	1.0
Sub-report Elements (SR0070.5.1) (page 52)	Update Confirmed with **Continue** or **Done** (**Stop**)	1.0

Object	Description	Document
Detect Unaccounted Materials (SR0070.2.2) (page 53)	Update Step 10: **Stop** option added to step title.	1.0
Phase Completion (SR0070.2.4) (page 54)	Update Step 10: In case one or more local accounted sublots were accounted from another phase instance, phase displays the **Simultaneous accounting on same sublot (SR0070.3.4.1)** information message of the warning type. Step 20: **Stop** option added to step title. Step 30: If all exceptions have been recorded, the **Result (SR0050.9.1)** output variable is set to CONTINUE or STOP, respectively.	1.0
Determine Accounting Status (SR0070.2.5) (page 55)	Update Trigger: Operator accounts material or confirms phase (not with **Continue** or **Done**).	1.0
Instruction Text with Links (Framework Capability) (page 57)	New process parameter	1.0
Instruction Link Definition (Framework Capability) (page 57)	New process parameter	1.0
Allow Loop Exit with Stop (SR0070.8.8) (page 59)	New process parameter	1.0
Quantity out of Tolerance (SR0070.3.2.3) (page 62)	Update Exception situation extended: If the planned quantity mode (defined with the **Identify material** phase) of any material position assigned to this phase is **As produced** or **As defined** and the identified quantity is not within the range of the planned quantity and its tolerance or the planned quantity is 0, an exception is raised.	1.0
Information Messages (SR0070.3.4+) (page 63)	New grouping requirement	1.0
Simultaneous Accounting on Same Sublot (SR0070.3.4.1) (page 63)	New information message	1.0
Accounting Already Closed for Selection (SR0070.3.6.3) (page 65)	New error message	1.0
Result (SR0070.9.1) (page 66)	Update STOP value added.	1.0

Changes related to "Produce Material Phase" (page 67):

Object	Description	Document
Preview Mode (SR0060.1.3) (page 70)	Update **Refresh** button (disabled) added. **Continue** and **Done (Stop)** option buttons (disabled) added.	1.0
Active Mode (SR0060.1.1) (page 70)	Update Instruction link panel added. Display of target sublot status added. **Refresh** button added. **Continue** and **Done (Stop)** option buttons added.	1.0
Completed Mode (SR0060.1.4) (page 72)	Update Instruction link panel added. Display of target sublot status added. **Refresh** button added. **Continue** and **Done (Stop)** option buttons added.	1.0
Produce Material (SR0060.2.1) (page 75)	Update Step 10: Checks moved to step 30. Step 20 added. Step 30 added.	1.0
Produce Material Without Packaging Levels (SR0060.2.1.1) (page 75)	Update Step 20: Check added: In case the status of the output material was set to a final state by a simultaneously or previously running phase, a system user-signed exception record with this information will be added automatically to the phase. **Stop** option button added. Step 58 added. Step 60: STOP output added.	1.0
Produce Material With Packaging Levels (SR0060.2.1.2) (page 77)	Update Step 30: Check added: In case the status of the output material was set to a final state by a simultaneously or previously running phase, a system user-signed exception record with this information will be added automatically to the phase. **Stop** option button added. Step 35: **Stop** option button added. Step 58 added. Step 60: STOP output added.	1.0

Object	Description	Document
Create Sublot (SR0060.2.2) (page 79)	Update Step 15: In case the **Overwrite target sublot status (SR0060.8.10)** process parameter is enabled, the target sublot status is replaced by the value set there. Step 20: In case the status of the output material was set to a final state by a simultaneously running phase, the phase stops creating sublots and a system user-signed exception record with this information will automatically be added to the phase.	1.0
Unforeseen Simultaneous Execution Checks (SR0060.2.9) (page 82)	New function	1.0
Overwrite Target Sublot Status (SR0060.8.10) (page 85)	New process parameter	1.0
Instruction Text with Links (Framework Capability) (page 84)	New process parameter	1.0
Instruction Link Definition (Framework Capability) (page 84)	New process parameter	1.0
Allow Loop Exit with Stop (SR0060.8.11) (page 86)	New process parameter	1.0
Target Sublot Status Invalid (SR0060.3.6.7) (page 96)	New error message	1.0
Unforeseen Simultaneous Execution Result (SR0060.3.6.8) (page 97)	New error message	1.0
Result (SR0060.9.2) (page 98)	Update `STOP` value added.	1.0

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