Experiment

Status	Released	**ID/Version/Description**	MetaT002/00000001/Meta Basic MBR
Valid from		**Standard batch size**	1 (0.5 - 1.5) kg
		Estimated yield	1 kg

Approval

Status	Text
Master Batch Record 10#MetaT002#Meta Basic MBR#Meta0001#---##00000001	
Draft	Object was created
	Date - User: 04-09-2024 13:18:47 CEST - 110 / MBR_Designers
In circulation **Comment:** In circulation	Put MBR in circulation
	Date - User: 05-09-2024 15:20:38 CEST - 110 / MBR_Designers
In circulation **Comment:** Approved	MBR approval by technical support team
	Date - User: 05-09-2024 15:52:00 CEST - 180 / PASX_Engineering
Draft **Comment:** Rejected because Valerie said it was horrible!!!!!!!!	MBR rejection by technical support team
	Date - User: 05-09-2024 15:53:14 CEST - 180 / PASX_Engineering
In circulation **Comment:** In circ again	Put MBR in circulation
	Date - User: 05-09-2024 15:55:27 CEST - 110 / MBR_Designers
In circulation	MBR approval by technical support team
	Date - User: 09-09-2024 11:30:10 CEST - 180 / PASX_Engineering
Released	MBR approval by technical support team
	Date - User: 09-09-2024 16:02:54 CEST - 227 / Valerie.Bogaerts

Basic operations

Basic operation
BO1 - Weighing **Active:** yes
BO2 - Tableting **Active:** yes

Summing bill of input material

Material no.	Material name	Quantity	Use type	Number of positions
MetaCS01	Cornstarch	0.88 kg	Raw material	1
MetaGL01	Glucose	0.11 kg	Compensating material	1
MetaSA01	Meta Salycilic acid	0.01 kg	Active ingredient with potency and compensating material	1

Summing bill of target material

Material no.	Material name	Quantity	Use type	Number of positions
Meta0001	Meta Aspirin	1 kg	Raw material	1

```
[10] 0.01 kg MetaSA01(Stock)
[20] 0.11 kg MetaGL01(Stock)
[30] 0.88 kg MetaCS01(Stock)

BO1                          Workroom
    Weighing
    PRODUCTION

[40] 0.01 kg PB_SA01(Order)
[50] 0.11 kg PB_GL01(Order)
[60] 0.88 kg PB_CS01(Order)

[70] 0.01 kg PB_SA01(Order)
[80] 0.11 kg PB_GL01(Order)
[90] 0.88 kg PB_CS01(Order)

BO2                          Setup part
    Tableting                Workroom
    PRODUCTION

[100] 1 kg Meta0001(Stock)
```
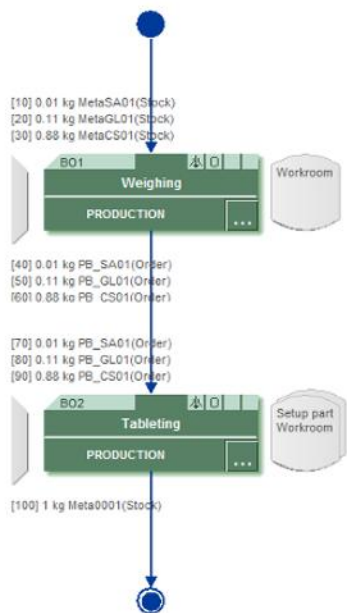
Version history

Version	Status	Text
Master Batch Record 10#MetaT002#Meta Basic MBR#Meta0001#---##00000001		
00000001	Draft	Object was created
		Date - User: 04-09-2024 13:18:47 CEST - 110 / MBR_Designers
00000001	In circulation	Put MBR in circulation
Comment: In circulation		
		Date - User: 05-09-2024 15:20:38 CEST - 110 / MBR_Designers
00000001	In circulation	MBR approval by technical support team
Comment: Approved		
		Date - User: 05-09-2024 15:52:00 CEST - 180 / PASX_Engineering
00000001	Draft	MBR rejection by technical support team
Comment: Rejected because Valerie said it was horrible!!!!!!!!		
		Date - User: 05-09-2024 15:53:14 CEST - 180 / PASX_Engineering
00000001	In circulation	Put MBR in circulation
Comment: In circ again		
		Date - User: 05-09-2024 15:55:27 CEST - 110 / MBR_Designers
00000001	In circulation	MBR approval by technical support team
		Date - User: 09-09-2024 11:30:10 CEST - 180 / PASX_Engineering
00000001	Released	MBR approval by technical support team
		Date - User: 09-09-2024 16:02:54 CEST - 227 / Valerie.Bogaerts

Active: yes **Reconciliation:** no
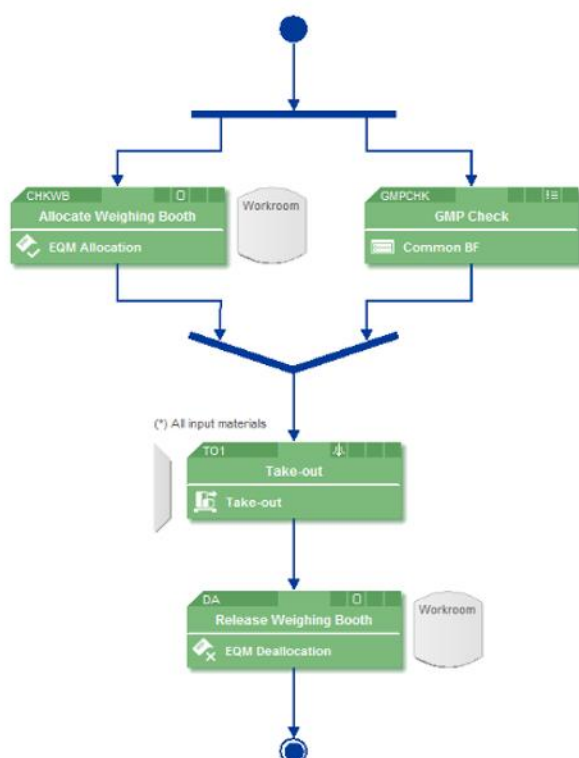**Start condition:** Predecessors started

Bill of input material

Item	ERP pos.	Prio.	Material no.	Material name	Optional	Use type	Quantity	Scrap (%)	Quantification type	Manufacturing date	Target material
0010	0	1	MetaSA01 **Active:** yes	Meta Salycilic acid	no	Active ingredient with potency and compensating material	0.01 kg	0	Weighing	First take-out	PB_SA01
0020	0	2	MetaGL01 **Active:** yes	Glucose	no	Compensating material	0.11 kg	0	Weighing	No	PB_GL01
0030	0	3	MetaCS01 **Active:** yes	Cornstarch	no	Raw material	0.88 kg	0	Weighing	No	PB_CS01

Bill of target material

Item	Material no.	Material name	Optional	Quantity	Usage sign	Material flow type	Hand over	Quantification type	Target BO
0040	PB_SA01 **Active:** yes Container groups	Polybag MetaSA01	no	0.01 kg		Order	no	Manual	BO2

Number of containers	Target quantity per container	Default variant	Container group ID
1		yes	MetaPoly

Item	Material no.	Material name	Optional	Quantity	Usage sign	Material flow type	Hand over	Quantification type	Target BO
0050	PB_GL01 **Active:** yes Container groups	Polybag MetaGL01	no	0.11 kg		Order	no	Manual	BO2

Number of containers	Target quantity per container	Default variant	Container group ID
1		yes	MetaPoly

Item	Material no.	Material name	Optional	Quantity	Usage sign	Material flow type	Hand over	Quantification type	Target BO
0060	PB_CS01 **Active:** yes Container groups	Polybag MetaSC01	no	0.88 kg		Order	no	Manual	BO2

Number of containers	Target quantity per container	Default variant	Container group ID
1		yes	MetaPoly

Production unit

ID	Description	Production area
PRODUCTION	Production	Packaging Pharmacy

Bill of equipment

Pos.	Equipment class	Type	Equipment	Number of objects
1	Workroom	MetaWB / Meta Weighing Booth	--- / --- Active: yes	1

Active: yes **Reconciliation:** no
Start condition: Predecessors started

Detailed BO		
Level	**Step**	**!**

1		(1) MetaT002/BO1/CHKWB Allocate Weighing Booth **Active:** yes **Optional:** no (EQM Allocation)

Subtype: None

	Actual value	Date	Signature

Check and allocation of the weighing booth

Attributes

Identification type: Scan   Allowed status formula: Reuse equipment: no
Equipment item: 1: Workroom MetaWB Meta Weighing Booth

1		(1) MetaT002/BO1/GMPCHK GMP Check **Active:** yes **Optional:** no (Common BF)

Subtype:
Check if material package is accurate

	1.0	SOP - Read SOP **Active:** yes **Subtype:** None	Training Doc (PAS-X v3.1.8 Basic Training.pdf)	---

Set value	Actual value	Entry / Signature
Training Doc (PAS-X v3.1.8 Basic Training.pdf)		

	1.1	MATCHK - Material Check **Active:** yes **Subtype:** None	Material OK	CQA

10 Check the material for apparent damages

Set value	Actual value	Entry / Signature
Material OK		

Date / signature for basic function
User identification: No identification
User ident. group: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
Verification signature: no

Active: yes **Reconciliation:** no
Start condition: Predecessors started

1		(1) MetaT002/BO1/TO1 Take-out **Active:** yes **Optional:** no (Take-out) **Subtype:** None

	Actual value	Date	Signature

Material take-out and dispensing

Attributes

All input materials: yes	Ignore batch status: no	REM unpacking: no
Execution mode: Manual		

1		(1) MetaT002/BO1/DA Release Weighing Booth **Active:** yes **Optional:** no (EQM Deallocation) **Subtype:** None

	Actual value	Date	Signature

Release Weighing Booth

Attributes

Identification type: Scan	Allowed status formula:	Reuse equipment: no

Equipment item: 1: Workroom MetaWB Meta Weighing Booth

Active: yes **Reconciliation:** no
Start condition: Predecessors started

Bill of input material

Item ERP pos.	Prio.	Material no.	Material name	Optional	Use type	Quantity	Scrap (%)	Quantification type	Manufacturing date	Target material
00700	1	PB_SA01 **Active:** yes	Polybag MetaSA01	no	Raw material	0.01 kg	0	Take over	No	
00800	1	PB_GL01 **Active:** yes	Polybag MetaGL01	no	Raw material	0.11 kg	0	Take over	No	
00900	1	PB_CS01 **Active:** yes	Polybag MetaSC01	no	Raw material	0.88 kg	0	Take over	No	

Bill of target material

Item	Material no.	Material name	Optional	Quantity	Usage sign	Material flow type	Hand over	Quantification type	Target BO
0100	Meta0001 **Active:** yes Container groups	Meta Aspirin	no	1 kg		Stock	no	Weighing	---

Number of containers	Target quantity per container	Default variant	Container group ID
1		yes	MetaConS

Production unit

ID	Description	Production area
PRODUCTION	Production	Packaging Pharmacy

Bill of equipment

Pos.	Equipment class	Type	Equipment	Number of objects
1	Workroom	MetaTab / Meta Tablleting	--- / --- Active: yes	1
2	Setup part	MetaSP / Meta set-up parts	--- / --- Active: yes	1

Active: yes **Reconciliation:** no
Start condition: Predecessors started
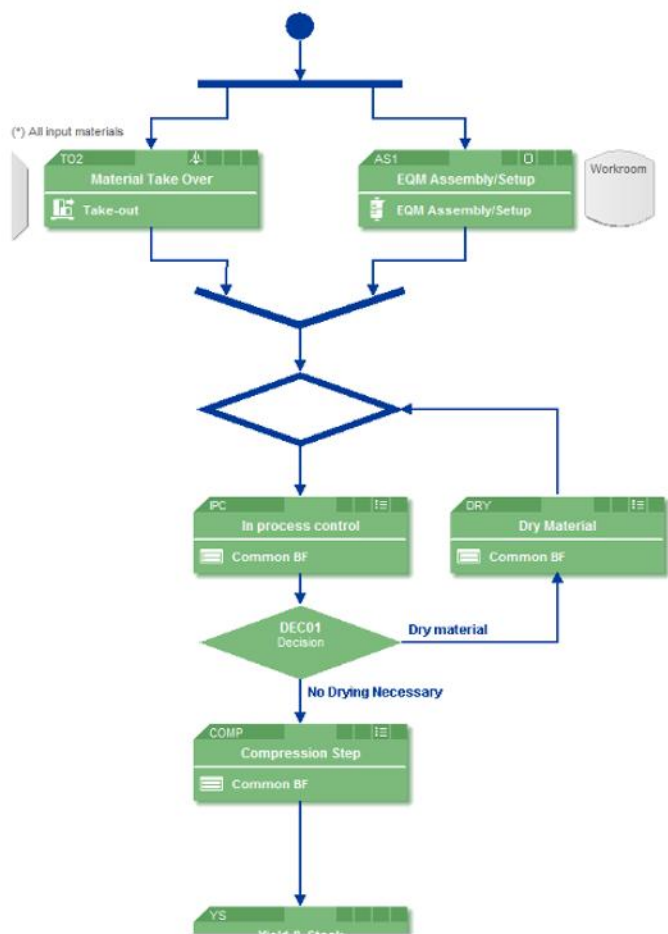
Active: yes **Reconciliation:** no
Start condition: Predecessors started
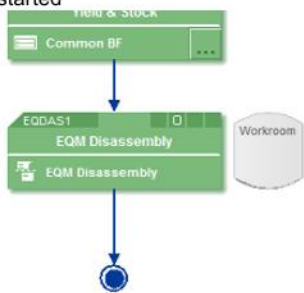
Detailed BO		
Level	**Step**	**!**

1	(1) MetaT002/BO2/TO2 Material Take Over **Active:** yes **Optional:** no (Take-out)
	Subtype: None

		Actual value	Date	Signature

Take over materials

Attributes		
All input materials: yes	Ignore batch status: no	REM unpacking: no
Execution mode: Manual		

1	(1) MetaT002/BO2/AS1 EQM Assembly/Setup **Active:** yes **Optional:** no (EQM Assembly/Setup)
	Subtype: None

		Actual value	Date	Signature

Install Setup Part in tablet press

Attributes		
Identification type: Scan	Allowed status formula:	Implicit allocation: yes
Status check: Diagram based	Reuse equipment: no	

Equipment item: 1: Workroom MetaTab Meta Tablleting

Bill of equipment

Pos.	Equipment class	Type	Equipment	Number of objects
2	Setup part	MetaSP / Meta set-up parts	--- / --- Active: yes	1

Active: yes   **Reconciliation:** no
Start condition: Predecessors started

1		

(1)   MetaT002/BO2/IPC   In process control   Active: yes   **Optional:** no   (Common BF)
Subtype:

Check humidity of the material

| 1.0 | HUM01 - Check Humidity   **Active:** yes   **Subtype:** None | 45.0 (>= 10.0 ; <= 90.0) | CPP |

10   Check humidity with hygrometer device H6643G and enter value

Set value	Actual value	Entry / Signature
45.0 (>= 10.0 ; <= 90.0)		

Date / signature for basic function
User identification: No identification
User ident. group:
Verification signature: no   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

---

(1)   MetaT002/BO2/DEC01   Decision   Optional: NO   (DECISION)
Subtype: NONE

	Actual value	Date	Signature

ID: DEC01   **Decision type:** Formula   **Predecessor:** IPC   **Recurrences Exact: Min.: Max.: Rec.:**
Formula: if {Value activity Measured value activity MetaT002 / BO2 / IPC / HUM01} > {Measured value: max. intervention Measured value activity MetaT002 / BO2 / IPC / HUM01}
 then "DRY"
 else "NoDry"
 endif

Successors

ID	Condition	Description	Long description
DRY	DRY	Dry material	
COMP	NoDry	No Drying Necessary	

Date / signature for basic function
User identification: No identification
User ident. group:
Verification signature: no   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
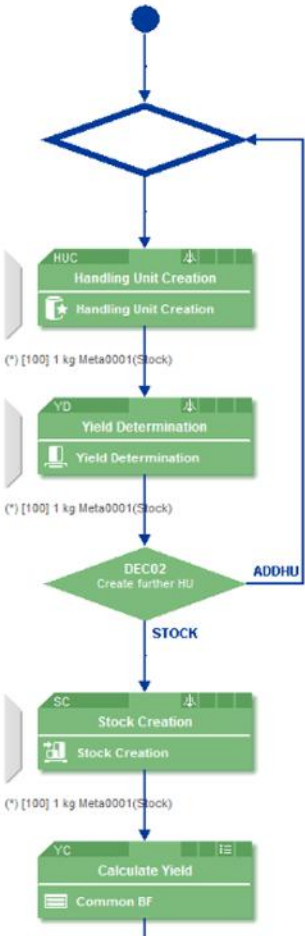
---

(1)   MetaT002/BO2/DRY   Dry Material   Active: yes   **Optional:** no   (Common BF)
Subtype:

If the humidity is above 60%, dry material for max. 30 minutes

| 1.0 | REW01 - Dry Material   **Active:** yes   **Subtype:** None | Done | --- |

10   Dry material in dryer D100 for max. 30 minutes

Set value	Actual value	Entry / Signature
Done		

Date / signature for basic function
User identification: No identification
User ident. group:
Verification signature: no   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Active: yes **Reconciliation:** no
Start condition: Predecessors started

1		(1) MetaT002/BO2/COMP Compression Step **Active:** yes **Optional:** no (Common BF)
		Subtype:
		Setup tablet press process parameter and proceed with compression

	1.0	ORD01 - Batch ID **Active:** yes **Subtype:** None	Batch ID	---
		10 The current running batch number		

Set value	Actual value	Entry / Signature
Batch ID		

	1.1	PRECOMP - Precompression Force **Active:** yes **Subtype:** None	1.0 (>= 0.8 ; <= 1.2) kN	---
		10 Set precompression force		

Set value	Actual value	Entry / Signature
1.0 (>= 0.8 ; <= 1.2) kN		

	1.2	MCF01 - Main Compression Force **Active:** yes **Subtype:** None	2.5 (>= 2.0 ; <= 3.0) kN	---
		10 Set main ompression force		

Set value	Actual value	Entry / Signature
2.5 (>= 2.0 ; <= 3.0) kN		

	1.3	TX01 - Program Number **Active:** yes **Subtype:** None	METAGRAM01	---
		10 Set program number on compression equipment		

Set value	Actual value	Entry / Signature
METAGRAM01		

	1.4	Start - Compression start time **Active:** yes **Subtype:** None		---
		10 Please enter the timestamp of the start of compression		

Set value	Actual value	Entry / Signature

	1.5	Color - Check Tablet Color **Active:** yes **Subtype:** None	Metagram Blue; Metagram White	---
		10 Select current tablet color from defined list		

Set value	Actual value	Entry / Signature
Metagram Blue; Metagram White		

Date / signature for basic function		
User identification:	No identification	
User ident. group:		_ _ _ _ _ _ _ _ _ _ _ _ _ _ _
Verification signature:	no	

Active: yes **Reconciliation:** no
Start condition: Predecessors started

1			(1) MetaT002/BO2/YS Yield & Stock **Active:** yes **Optional:** no (Common BF)
			Subtype:
			Determine yield and create stock
			Date / signature for basic function
			User identification: No identification
			User ident. group: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
			Verification signature: no

(1) MetaT002/BO2/YS   Yield & Stock   **Active:** yes   **Optional:** no   (Common BF)

Subtype:

Determine yield and create stock

Date / signature for basic function

Active: yes   **Reconciliation:** no
Start condition: Predecessors started

Active: yes   **Reconciliation:** no
Start condition: Predecessors started

(2) MetaT002/BO2/YS/HUC Handling Unit Creation **Active:** yes **Optional:** no (Handling Unit Creation)		
Subtype: None		

	Actual value	Date	Signature

Create Handling unit and stick the label onto the required container
Target material: [100] 1 kg Meta0001 (Meta Aspirin)

Attributes

Execution mode: Manual

(2) MetaT002/BO2/YS/YD Yield Determination **Active:** yes **Optional:** no (Yield Determination)		
Subtype: None		

	Actual value	Date	Signature

Weigh the filled container
Target material: [100] 1 kg Meta0001 (Meta Aspirin)

Attributes

Handling Unit Creation: no   Execution mode: Manual

Active: yes **Reconciliation: no**
Start condition: Predecessors started

L 2 | (2) MetaT002/BO2/YS/DEC02 Create further HU **Optional: NO** (DECISION)
Subtype: NONE

Actual value	Date	Signature

If further Handling Units are needed, repeat step
ID: DEC02 **Decision type:** User selection **Predecessor:** YD **Recurrences Exact:** **Min.:** **Max.:** **Rec.:**

Successors

ID	Condition	Description	Long description
MER02	ADDHU	ADDHU	Create further HU
SC	STOCK	STOCK	Create stock without further HU

Date / signature for basic function
User identification: No identification
User ident. group:
Verification signature: no   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

L 2 | (2) MetaT002/BO2/YS/SC Stock Creation **Active: yes** **Optional: no** (Stock Creation)
Subtype: None

Actual value	Date	Signature

Create stock for all target material containers
Target material: [100] 1 kg Meta0001 (Meta Aspirin)

Attributes

AQL: yes	REM packing: no	Stock creation type: Handling unit
Execution mode: Manual		

L 2 | (2) MetaT002/BO2/YS/YC Calculate Yield **Active: yes** **Optional: no** (Common BF)
Subtype:

System calculates yield according to the actual produced quantity and batch size

| 2.0 | YC01 - Calculate Yield **Active: yes** **Subtype: None** | {MO Actual order size Master Batch Record MetaT002} / {MO Order size Master Batch Record MetaT002} * 100 --- |

10 Execute formula for yield calculation

Set value	Actual value	Entry / Signature
{MO Actual order size Master Batch Record MetaT002} / {MO Order size Master Batch Record MetaT002} * 100		

| 2.1 | END - Production Finished **Active: yes** **Subtype: None** | --- |

10 Please confirm the end date of the current production

Set value	Actual value	Entry / Signature

Date / signature for basic function
User identification: No identification
User ident. group:
Verification signature: no   _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

1 | (1) MetaT002/BO2/EQDAS1 EQM Disassembly **Active: yes** **Optional: no** (EQM Disassembly)
Subtype: None

Actual value	Date	Signature

Uninstall Punch Set from the tablet press

Attributes

Identification type: Scan	Allowed status formula:	Implicit release: no
Multi-step EQM disass.: no	Reuse equipment: no	
Equipment item: 1: Workroom MetaTab Meta Tablleting		