Awaiting Batches To Start

Cancel

1 Product Description

Product Description	SPRAY DRIED MANNITOL BLEND
Specification No	
Strength	
Batch Size	170

2 Bill of Material

Raw Materials List

Sr.	Material type	Material Code	Material Name	Qty	Overages	Role	Process
1.	Starting Material	RM00055	Mannitol PF		100 mg		

Packing Materials

Packing Materials List

Country Name: NA	Packing Type:Sale	Batch Size:100	Pack Size:10	Pack Unit:numbers	
Sr.	Code	Name	Unit Qty	Overages	Preorder Qty
1.	PM0020	Form Foil - 160 mm	100 Nos	0	100 Nos

3. ROOM & PRINCIPAL EQUIPMENT

3.1 Room & Principal Equipment (10181)

Room
Blending Room

Prepared By ✓	marlo` 2024-05-01 18:53:40	Checked BY	2024-05-01 18:53:40

Equipment
Powtek Cosmo50-150 Conical Mill
Vacuum01
Balance 01

Prepared By ✓	marlo` 2024-05-01 18:53:47	Checked BY	2024-05-01 18:53:47

3.2 Login to the Blending Room (BI 010) - Logbook (LB 033)

4. CLEANING CHECKS

4.1a Has the first lot to be manufactured after a major clean?

Procedure:
If more than 3 days have elapsed since the equipment was last sanitised, then:
Re-sanitise all product contact surfaces with TOPAL
Record re-sanitisation on each Equipment Cleaning Tag (FM 237) for the IBC, Mill, Column Lifter & Parts and also in the Blending Logbook (LB 033).
Ensure all surfaces are dry.
Attach each Cleaning Tag (FM 237) & Major Cleaning Records (FM 288, FM 298 & FM 286) for the IBC, Mill & Column Lifter to the processing instructions.

Prepared By ✓	marlo` 2024-05-01 18:53:25	Checked BY	marlo` 2024-05-01 18:53:25

5. ROOM CONDITIONS

5.1 Check EMS for alarms (as detailed in SOP-244 – from local connection in BI 034)

Procedure:
If alarms are present on the EMS regarding the pressure differential, temperature and relative humidity in Room BI-016, then it is accepted that all values are within their acceptable ranges for production to occur.
If an alarm is present do not proceed with the batch until the conditions are restored to within acceptable limits (no alarms) or a Deviation report (FM-016) has been raised and approved.

Prepared By ✓	marlo` 2024-05-01 18:54:31	Checked BY	2024-05-01 18:54:31

5.2 Confirm that the Nitrogen supply is turned on

6. ROOM CLEARANCES

6.1 Ensure the room is clear of all unnecessary material – refer to SOP-142. Room clearance is performed as per FM 351 by the second trained person (not involved in completing the above steps)

7. BLENDING PROCEDURE

7.1 Complete Blender set-up as per SOP-262. Ensure all safety precautions are adhered to.

7.2 Install the vibrational hammer on the IBC.

Procedure:
Confirm that the vibrator is operational ≥2013 if not, alert the Production Supervisor and do not proceed with batch until fixed

Prepared By ✓	marlo` 2024-05-01 18:55:14	Checked BY	marlo` 2024-05-01 18:55:14

7.3 Set up the Powtek Cosmo150 Conical Mill (Tag 00405) according to SOP-257.

Procedure:
Set the Mill speed to 500 rpm and use a 3 mm screen (Serial No. 432501 only).
Ensure the Mill is set up correctly by testing it first. Ensure that the screen and rotor are not in contact with each other

Prepared By ✓	marlo` 2024-05-01 18:55:33	Checked BY	marlo` 2024-05-01 18:55:33

7.4 Record the balance to be used for weighing step

Procedure:

Prepared By ✓	marlo` 2024-05-02 17:44:45	Checked BY	marlo` 2024-05-02 17:44:45

Container No	Gross Weight	Tare Weight	Net Weight	Remark
1	100	10	90	
2	10	10	90	
3	190	100	90	

Prepared By ✓	-	Checked BY	-

7.5 Login to the control panel. Perform the following steps as per SOP-262.

Procedure:
If any stoppages are required record the details in the minor incident form.
Stoppages: _____ (N/A if not required)
Refer to Deviation_____ (N/A if not required)

Prepared By ✓	marlo` 2024-05-01 18:56:16	Checked BY	2024-05-01 18:56:16

7.6 Remove the blender printout. Check that Blend Speed, Blend Time and Lot Number are the same as the Blender HMI. Attach printout to PI. Initials a Minor Incident Report if there is a difference observed.

Procedure:
Set the blender speed to 15 rpm. Set the blending time to 10 minutes. Enter the Lot Number of the batch to be blended in the following format MYY XXX. The checker shall ensure the correct data as recorded below is manually entered on the Blender HMI
Blend Speed Entered: _____ rpm
Blend Time Entered: _____minute
Lot Number: _____

Prepared By ✓	marlo` 2024-05-01 18:55:59	Checked BY	2024-05-01 18:55:59

7.4 Blend the batch as per SOP 262.

Procedure:
If any stoppages are required record the details in the minor incident form.
Stoppages: _____ (N/A if not required)
Refer to Deviation_____ (N/A if not required)

Prepared By ✓	marlo` 2024-05-01 18:56:16	Checked BY	2024-05-01 18:56:16

7.7 Remove the blender printout. Check that Blend Speed, Blend Time and Lot Number are the same as the Blender HMI. Attach printout to PI. Initials a Minor Incident Report if there is a difference observed.

8. YIELD

8.1 & 1 Calculate the yield. The calculation must be checked by a 2nd Operator.

Total Blend Output. (d)	= (b) + (c), refer 8.2 & 8.3
Total Powder added to IBC:	= (a), refer 7.4
Yield:	= [(d) / (a)] x 100
Yield Limits:	97 – 103 %
Yield within limits	

8.2 & 2 Photocopy the printout from the blender, sign the copy & attach to the PI.

Procedure:

Prepared By ✓	marlo` 2024-05-02 18:28:20	Checked BY	marlo` 2024-05-02 18:28:20

8.2 & 2 Photocopy the printout from the blender, sign the copy & attach to the PI.

Procedure:

Prepared By ✓	marlo` 2024-05-02 18:28:20	Checked BY	marlo` 2024-05-02 18:28:20

9. LABELLING AND STORAGE

9.1 Store the labelled bags in the WIP storage area in the clean room (BI 021)

Procedure:
Ensure all bags from the same batch are store on the same rack.
All the labels completed must be checked by the 2nd trained person for the accuracy of the details entered.

Prepared By ✓	marlo` 2024-05-02 18:54:16	Checked BY	marlo` 2024-05-02 18:54:16

10. CONSUMPTION & OUTPUT

10.1 Calculate the total consumption of all the materials used

Procedure:
All consumptions must be checked by the 2nd person.

Prepared By ✓	marlo` 2024-05-02 18:36:24	Checked BY	marlo` 2024-05-02 18:36:24

Material	Specification Number	Lot Number	Total quantity used per lot (Kg)
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
OUTPUT	SP-104		

11. MINOR INCIDENT REPORT

11.1 Record any observation made during the batch manufacture – refer to SOP-142 for minor incident definition, identification and subsequent action.

Material	Specification Number	Lot Number	Total quantity used per lot (Kg)
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
OUTPUT	SP-104		

Material	Specification Number	Lot Number	Total quantity used per lot (Kg)
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
OUTPUT	SP-104		

11.1 Record any observation made during the batch manufacture – refer to SOP-142 for minor incident definition, identification and subsequent action.

Material	Specification Number	Lot Number	Total quantity used per lot (Kg)
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
OUTPUT	SP-104		

Material	Specification Number	Lot Number	Total quantity used per lot (Kg)
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
Spray Dried Mannitol Individual Batch	SP-103		
OUTPUT	SP-104		

12. NAVISION & TRENDING UPDATE

12.1 Perform Navision Production Journal transactions as per SOP-165 and enter Trending as per SOP-241

12.1 Perform Navision Production Journal transactions as per SOP-165 and enter Trending as per SOP-241

13. BATCH REVIEW

13.1 Verify Navision Production Journal transactions as per SOP-165

Procedure:
Verify Navision Production Journal transactions as per SOP-165

Prepared By ✓	marlo` 2024-05-02 18:53:53	Checked BY	marlo` 2024-05-02 18:53:53

13.2 Ensure production journal is posted & trending is completed accurately.

Procedure:
14.2 Ensure production journal is posted & trending is completed accurately.

Prepared By ✓	marlo` 2024-05-02 18:54:16	Checked BY	marlo` 2024-05-02 18:54:16

13.3 Record any Associated Deviation, CR or CAR – to be completed by Production staff

Procedure:
Record any Associated Deviation, CR or CAR ≥2013 to be completed by Production staff

Prepared By ✓	marlo` 2024-05-02 18:54:28	Checked BY	marlo` 2024-05-02 18:54:28

13.4 The Process Instructions & the associated documents have been reviewed as detailed in SOP-291

Procedure:
The Process Instructions & the associated documents have been reviewed as detailed in SOP-291

Prepared By ✓	-	Checked BY	-

14. APPROVAL BY PRODUCTION MANAGER/PRODUCTION SUPERVISOR

14.1 These Processing Instructions & associated documents have been reviewed & the lot produced in compliance with GMP

Procedure:
These Processing Instructions & associated documents have been reviewed & the lot produced in compliance with GMP

Prepared By ✓	-	Checked BY	-

15. ASSOCIATED DOCUMENTS AND QA REVIEW

15.1 Include details of any associated documents

Procedure:
Include details of any associated documents

Prepared By ✓	-	Checked BY	-

Operator Initials	Incident/Observation – brief description/ actions	Supervisor Evaluation – root cause, product impact, immediate action.	Product Quality Impact – ICV – provide brief justification ICV – reference deviation report
test1	test	test	test