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Batch Manufacturing Record

Section 5.0: Sifting and Blending

5.1 Area and Equipment Verification

Instruction: Verify the area and equipment are suitable for use for Batch ASP-25-001.

A) Sifter Verification

	≡ Field	≡ Details
1	Equipment Type:	Sifter
2	Equipment ID No.:	SFT-02
3	Logbook Verified:	Ref: LOG-USE-SFT-02
4	Status:	Ready
5	Verified By:	Rajesh Patel
6	Date:	17-Feb-25

B) Bin Blender Verification

	≡ Field	≡ Details
1	Equipment Type:	Bin Blender
2	Equipment ID No.:	BLN-04
3	Logbook Verified:	Ref: LOG-USE-BLN-04
4	Status:	Ready
5	Verified By:	Rajesh Patel
6	Date:	17-Feb-25

5.2 Sifting

A) Co-Sifting of API & Excipients

	≡ Step No.	≡ Instruction / Parameter	≡ Recorded Data / Signature
1	5.2.1	Equipment Used: Sifter	ID No.: SFT-02
2	5.2.2	Sifter Screen Mesh Size Used:	#30 Mesh
3	5.2.3	Start Time of Sifting:	10:10
4	5.2.4	End Time of Sifting:	10:15
5	5.2.5	Co-sift Aspirin, MCC, HPMC, and Cornstarch.	Done
6	5.2.6	CRITICAL INSTRUCTION: Confirm Magnesium Stearate is NOT sifted at this stage.	Confirmed. Material remains segregated.
7	5.2.7	Comments/Observations:	All material passed through the screen without issue.
8	5.2.8	Performed By (Operator):	Rajesh Patel
9	5.2.9	Verified By (Supervisor):	Priya Sharma

B) Sifting of Lubricant (Note: This step is executed later, as recorded in Section 5.5)

5.3 Dry Blending (Pre-Lubrication)

	≡ Step No.	≡ Instruction / Parameter	≡ Set Value	≡ Actual Value / Signature
1	6.1	Equipment Used:	-	Bin Blender
2	6.2	Equipment ID No.:	-	BLN-04
3	6.3	Load the container of "Sifted Materials" into the blender.	-	Done
4	6.4	Blending Speed:	15 RPM	15 RPM
5	6.5	Blending Time:	20 minutes	20 minutes
6	6.6	Start the blending process.	-	Start Time: 10:45
7	6.7	Stop the blending process after the set time.	-	Stop Time: 11:05
8	6.8	After completion, take samples for Blend Uniformity testing.	-	Samples Taken

9	6.9	Performed By (Operator):	-	Rajesh Patel   17-Feb-2025 / 11:10
10	6.10	Verified By (Supervisor):	-	Priya Sharma   17-Feb-2025 / 11:12

5.4 In-Process Quality Control (IPQC) - Blend Uniformity

Instruction: Manufacturing cannot proceed to Lubrication until QC provides an "APPROVED" result.

	☰ Checkpoint	☰ Recorded Data / Signature
1	QC Report Number Referenced:	QCR/BU/25/092
2	Result (Approved/Rejected):	APPROVED
3	QC Report Verified By (Production):	Priya Sharma   17-Feb-25 / 14:20

5.5 Lubrication

	☰ Step No.	☰ Instruction / Parameter	☰ Recorded Data / Signature
1	7.1	Confirm Blend Uniformity test result is "APPROVED".	APPROVED (Ref: QCR/BU/25/092)
2	7.2	Sift Magnesium Stearate through a #60 Mesh screen.	Done
3	7.3	Add the sifted Magnesium Stearate to the "Approved Blend" in the Bin Blender (BLN-04).	Done
4	7.4	Blending Speed (RPM):	Set: 15 RPM, Actual: 15 RPM
5	7.5	Blending Time (minutes):	Set: 3 minutes, Actual: 3 minutes
6	7.6	Start the lubrication blending process.	Start Time: 14:30
7	7.7	Stop the lubrication blending process after the set time.	Stop Time: 14:33
8	7.8	Unload the final "Lubricated Blend" into clean, labeled containers.	Done
9	7.9	Performed By (Operator):	Rajesh Patel  Time: 14:45

10	7.10	Verified By (Supervisor):	Priya Sharma <i>Time: 14:48</i>
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5.6 Final Sign-off for Sifting, Blending, & Lubrication Stage

- **Production Supervisor Final Review:** All steps in Section 5.0 have been completed and documented as per the BMR instructions. The batch is ready for the next stage.
  - **Name:** Priya Sharma
  - **Signature:** *Priya Sharma*
  - **Date / Time:** 17-Feb-2025 / 16:00
  
- **Quality Assurance Final Review:** All records pertaining to the Sifting and Blending of Batch ASP-25-001 have been reviewed. All operations, in-process controls, and documentation are found to be compliant. The batch is approved to proceed to Compression.
  - **Name:** QA Officer
  - **Signature:** *QA Officer*
  - **Date / Time:** 18-Feb-2025 / 10:00

End of Sifting and Blending Section