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Batch Manufacturing Record

Section 7.0: Compression - Machine Trial & Parameter Setup

Instruction: Using a small quantity of the lubricated blend for Batch ASP-25-001, start the machine at a slow speed. Perform In-Process Checks (IPCs) and adjust the machine parameters as necessary until tablets consistently meet the specifications defined below.

7.1 Tablet Quality Specifications (As per Master Specification Document)

	≡ Parameter	≡ Specification / Target
1	Appearance:	White, round, biconvex, plain on both sides, free from defects.
2	Average Weight:	450 mg \pm 3% (i.e., 436.5 mg – 463.5 mg)
3	Hardness:	5.0 – 8.0 kp (kiloPond)
4	Thickness:	4.0 mm \pm 0.3 mm
5	Disintegration Time:	Not More Than (NMT) 15 minutes

7.2 Machine Parameter Adjustment Log

Instruction: Record all adjustments made during the trial run.

	≡ Time	≡ Parameter Adjusted	≡ New Setting	≡ Observation / IPC Result	≡ Operator
1	09:45	Fill Depth	Increased from initial setting.	Avg. Wt. was low (~430 mg). Now in range.	Anil Sharma
2	10:00	Main Compression Force	Increased to 20 kN	Avg. Wt. OK (~452 mg), but Hardness low (~4.2 kp).	Anil Sharma
3	10:15	Main Compression Force	Increased to 25 kN	Avg. Wt: 451.5 mg, Hardness: 6.5 kp, Thickness: 4.1 mm. All parameters are within specification.	Anil Sharma

7.3 Final Approved Machine Parameters for Main Run

Instruction: Record the final, locked-in machine settings that will be used for the main compression run.

	≡ Machine Parameter	≡ Final Approved Setting
1	Machine Speed (RPM):	50 RPM
2	Feeder Speed (RPM):	30 RPM
3	Fill Depth (mm):	12.0 mm
4	Pre-Compression Force (kN):	5 kN
5	Main Compression Force (kN):	25 kN

Authorization to Commence Main Compression Run

Instruction: To be signed by Production and QA after confirming that the trial tablets meet all specifications and the machine parameters are finalized.

1. Production Verification:

"I have verified that the tablets produced during the trial run using the final approved parameters meet all in-process specifications. The machine is ready for the main compression run of batch **ASP-25-001**."

- **Production Supervisor Name:** Sunil Verma
- **Signature:** *Sunil Verma*
- **Date / Time:** 18-Feb-2025 / 10:30

2. Quality Assurance Authorization:

"I have reviewed the in-process data from the machine trial and authorize the start of the main compression run for batch **ASP-25-001**."

- **QA Officer Name:** Meena Iyer
- **Signature:** *Meena Iyer*
- **Date / Time:** 18-Feb-2025 / 10:40

End of Machine Trial Section

(The BMR would continue with the next step: The Main Compression Run Log)