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Title Page

Process Name

SOP #

Department

Location

 

Conducted on

 

Prepared by

Purpose

[SAMPLE ONLY. You may customize this template based on your business requirements]

The purpose of this SOP is to ensure that the correct steps are taken when using the tablet press to perform tablet compression.

Scope

The scope of a manufacturing SOP answers the following questions:

1. Where is the SOP to be used? e.g. area, process, department, stage? --- (chemical manufacturing lab)
 2. Who is the SOP for? e.g. operator, manager, QA --- (lab personnel and tablet press operators)
 3. Are there any specific limitations or exceptions to this SOP? (This only applies to the production of pharmaceutical tablets)
-

Cleaning of tablet press

Compression machine was cleaned as per separate SOP (use 70% isopropyl alcohol)

✓ ✗

Dust extractors, pipes, racks, door frames, and return filters of the Air Handling Unit have all been cleaned

✓ ✗

Performed visual check for absence of leakage

✓ ✗

After receiving approval from quality control department, put "cleaned" label on equipment

✓ ✗

Operation

Remove "cleaned" label prior to operating tablet press.

✓ ✗

Affix label to tablet press with PRODUCT NAME and BATCH DETAILS

✓ ✗

Issue the punch set suitable for the compression as per separate SOP.

✓ ✗

Set the machine as per tablet parameters given in BMR.

✓ ✗

Destroy tablets from first few rotations before starting the machine for the first batch.

✓ ✗

Collect tablets generated per batch then pack and label

✓ ✗

Stop compression as material in the hopper reaches the lowest level.

✓ ✗

Clean all outside containers and store them with labels that show batch details.

✓ ✗

Remove punch sets and clean as per separate SOP.

✓ ✗

Completion

Full Name and Signature of Employee

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