



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Inspection and Storage of Soft Gelatin Capsules	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Inspection and Storage of Soft Gelatin Capsules.

2.0 SCOPE:

This SOP is applicable for Inspection and Storage of Soft Gelatin Capsules in Soft Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

HDPE High Density Polyethylene
Ltd. Limited
OSD Oral Solid Dosage
Pvt. Private
QA Quality Assurance
SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 After drying transfer the capsules to inspection area.

6.2 Check the capsules visually and sort-out the defective capsules such as de-shape, leakage, colour spot, size variation.

6.3 Defected capsules shall be collect in polybag lined HDPE container labeled as “**Rejected Capsules**”.

6.4 Collect the good capsules in double polythene bag and tie with cable tie. The weight of capsules should be not more than 10 kg.

6.5 Affix duly filled & signed status label on each polybag and place the polybag in crate.

6.6 Cover the crates with lid and affix status label.

6.7 Officer / Executive Production shall transfer the crates to storage area and record the temperature & relative humidity of the area in log book.

7.0 ANNEXURES:

Not Applicable.

ENCLOSURES: SOP Training Record



PHARMA DEVILS

PRODUCTION DEPARTMENT

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8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By