



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Issuance and Retrieval of Change Parts for Hard Gelatin Capsule Filling Machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Issuance and Retrieval of Change Parts for Hard Gelatin Capsule Filling Machine.

2.0 SCOPE:

This SOP is applicable for Issuance and Retrieval of Change Parts for Hard Gelatin Capsule Filling Machine manufacturing Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

HG	Hard Gelatin Capsule
Ltd.	Limited
Pvt.	Private
SOP	Standard Operating Procedure

6.0 PROCEDURE:

- 6.1 Officer / Executive Production shall prepare a list of change parts as per **Annexure – I. “List of Change Parts”**.
- 6.2 When change parts are required, Officer / Executive Production shall issue the change parts to concerned operator and make the entry in **Annexure – II. “Issuance and Retrieval Record of Hard Gelatin Capsule filling machine.**
- 6.3 Officer / Executive QA shall verify the change parts visually before use & after use and make the entry in **Annexure – II.**
- 6.4 Transfer the change parts to HG capsule filling cubicle by trolley.
- 6.5 Set the required change parts on the machine.
- 6.6 After removing change parts from the machine shall be cleaned as per respective SOP.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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6.7 Transfer the change parts to change part room by trolley and make entry in **Annexure – II “Issuance and Retrieval Record of HG capsule machine Change Parts”**.

6.8 IMPORTANT

6.8.1 All the change part handled consciously.

6.8.2 Issue new change part to operator after receiving the previous change part.

6.8.3 All change part stored separately.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Change Parts	
Annexure-II	Issuance and Retrieval Record of HG capsule filling machine	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

10.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By
01					

CHANGE HISTORY LOG

