



## STANDARD OPERATING PROCEDURE

**Title:** Issuance and Retrieval of Change Parts for Hard Gelatin Capsule Filling Machine

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 4

### 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.

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.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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**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:

NA

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

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



