

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Production	SOP No.:			
Title: Disposal of Rejected Soft Gelatin Capsules	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

1.0 **OBJECTIVE**:

To lay down a Procedure for Disposal of rejected capsules.

2.0 SCOPE:

This SOP is applicable in soft gelatin capsule section after completion of each batch.

3.0 **RESPONSIBILITY:**

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

ETP Effluent Treatment Plant

Ltd. Limited Pvt. Private

SS Stainless Steel

SOP Standard Operating Procedure

6.0 PROCEDURE:

- **6.1** Collect the rejected capsule and weigh product wise.
- Take potable water in a SS jacketed container and heat up to 60° C.
- **6.3** Dip the rejected capsules in container.
- **6.4** Stir the rejected capsules by spatulas manually for 5 minutes.
- **6.5** After 30 minutes again stir by spatula, if it is completely dissolved.
- **6.6** Check it whether it is completely soaked & dissolved, if ok then
- **6.7** Transfer it to the ETP.
- **6.8** Record the all observation in log book.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Log for Disposal of Rejected Soft Gelatin Capsules	



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ENCLOSURES: SOP Training Record

8.0 **DISTRIBUTION:**

• Controlled Copy No. 01 Quality Assurance Department

• Controlled Copy No. 02 Production Department

Master Copy
 Quality Assurance Department

9.0 **REFERENCES:**

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By
02	CC/H - G/PROD/18/0228	Up gradation as per SOP-QAH/0119	Periodic Review		Sushant Dwivedi



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ANNEXURE – I LOG FOR DISPOSAL OF REJECTED SOFT GELATIN CAPSULES

Date	Product Name	B. No.	B. Size	Mfg. Date	Exp. Date	Rejected Capsules (Qty.)	Done By Sign/Date	Checked By Sign/Date	Verified By