



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Handling of Encapsulation Dies and Segment	Effective Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Handling of Encapsulation Dies and Segment.

2.0 SCOPE:

This SOP is applicable for Handling of Encapsulation Dies and Segment in Soft Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 ISSUANCE, USAGE, CLEANING AND RETRIEVAL:

- 6.1.1 Officer/Executive Production shall prepare the list of Dies & Segment as per Annexure-II.
- 6.1.2 When Dies & Segment are required for use in production, Officer / Executive Production shall issue the dies and segment to the concerned operator and make entry in Dies Utilization Record as per Annexure – III.
- 6.1.3 Operator shall check the condition of LHS and RHS Dies and enter the details in **Annexure – III**.
- 6.1.4 Transfer the Dies & Segment to respective Encapsulation area by trolley.
- 6.1.5 Set up and fix Dies & Segment on the machine as per the specification in respective BMR.
- 6.1.6 Remove the Dies and Segment after completion of encapsulation.
- 6.1.7 After removing dies from the machine clean the dies and segment with 70% Isopropyl Alcohol and mop with dry lint free cloth.
- 6.1.8 Check the Dies visually for any kind of damages during handling, if damages are observed, inform immediately to Officer / Executive Production and matter shall be brought to the notice of department head.



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- 6.1.9** Make necessary entry in the Dies Utilization Record and sign. Put status label as “REJECTED DIES DO NOT USE” for the damaged dies, and keep in separate box until next course of action is decided.
- 6.1.10** Log Incident Report, Investigate the cause of damages to the Dies and suggest CAPA to avoid the re-occurrence in future.
- 6.1.11** If it is decided to destroy the damage Dies, approval shall be taken from appropriate authority for destruction as per Annexure-IV.
- 6.1.12** After approval for destruction, rejected dies shall be sent to engineering department for destruction and record shall be maintained as per **Annexure-IV**.
- 6.1.13** Apply the light liquid paraffin on good Dies & Segment and put into the box.
- 6.1.14** Transfer the Dies & Segment to the respective SS cabinet by trolley, lock the cabinet and make entry in Dies Utilization Record as per **Annexure-III**.
- 6.1.15** Get “Dies Utilization Record” signed in returned by the concerned operator and checked by Officer / Executive Production.

6.2 PROCEDURE FOR DIES INTEGRITY TEST (Carbon Impression Test) :

- 6.2.1** Get issued Dies to be intended from Dies store for integrity test, Officer/Executive Production shall issue the dies to the concerned operator and make necessary entry in Dies Utilization Record as per **Annexure – III**.
- 6.2.2** Visually check the condition of LHS and RHS Dies for any physical abnormality in presence of officer / Executive.
- 6.2.3** Transfer the Dies to respective Encapsulation area by trolley.
- 6.2.4** Fix the L.H.S and R.H.S Dies on machine appropriately.
- 6.2.5** Set the papers with carbon sheet between L.H.S and R.H.S Dies precisely on which impressions of Dies cavities to be taken.
- 6.2.6** Switch on the main supply of Encapsulation machine and apply the suitable pressure on Dies to get the impressions of Dies cavities on Paper.
- 6.2.7** Ensure that impression of Dies cavities on paper should be clearly visible and containing all the impressions of Dies cavities of entire round.
- 6.2.8** Collect the paper containing impressions of Dies cavities appropriately from the encapsulation machine and visually check the impressions of cavities carefully for any damages.
- 6.2.9** Record the Dies Integrity test as per **Annexure –I**.



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6.2.10 Maintain the impression record with signature and date as 'Done By', 'Checked By' and 'Verified By'.

6.2.11 If damages are observed, inform immediately to Officer / Executive Production and matter shall be brought to the notice of department head.

6.2.12 Make necessary entry in the Dies Utilization Record and sign. Put status label as "REJECTED DIES DO NOT USE" for the damaged dies, and keep in separate box until next course of action is decided.

6.2.13 Log Incident Report, Investigate the cause of damages to the Dies and suggest CAPA to avoid the re-occurrence in future.

6.2.14 If required the matter shall be brought to the notice of concerned vendor for necessary actions.

6.2.15 If it is decided to destroy the damage Dies, approval shall be taken from appropriate authority for destruction as per **Annexure-IV**.

6.2.16 After approval for destruction, rejected damaged dies shall be sent to engineering department for destruction and record shall be maintained as per **Annexure-IV**.

6.2.17 Frequency of Dies Integrity Test:

6.2.17.1 After 10 million encapsulation on particular Dies or after six month or whichever is earlier.

6.3 DESTRUCTION OF DIES:

6.3.1 Rejected damaged dies shall be destroyed by Engineering Department after approval for destruction.

6.3.2 After approval for destruction, send the rejected damaged Dies to engineering department for destruction.

6.3.3 After receiving damaged Dies from production, engineering department has to deface the Dies by grinding machine and record the same in **Annexure-IV**.

6.3.4 The defaced Dies shall be handled as a scrap as per SOP.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Dies Integrity Record	
Annexure-II	List of Dies	
Annexure-III	Die Utilization Record	
Annexure-IV	Destruction of Dies	



PHARMA DEVILS

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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:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE-II LIST OF DIES

Box No.	Size	Description	LHS Die	RHS Die	Segment

	Prepared By Operating Executive	Checked By Operating Manager	Approved By Head QA
Sign			
Date			



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ANNEXURE – IV DESTRUCTION OF DIES

SUPPLIER:

DESCRIPTION:

SIZE:

DATE OF RECEIPT:

S.No	Date	No. of Left Dies	No. of Right Dies	No. Of Dies	Checked by Production Officer / Executive	Received by Engineering	Destroyed by Engineering	Remarks

Verified By:
(Head Operation)

Approved By:
(Head QA)

Note: Approval shall be taken before destruction.