



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Issuance, Usage and Retrieval of Punches and Dies	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for issuance, use and retrieval of the Punches and Dies.

2.0 SCOPE:

This procedure is applicable to issuance, use and retrieval of the Punches and Dies used in production department.

3.0 RESPONSIBILITY:

Technical Associate : Operation

Officer/ Executive Production : Supervision

Head Production : SOP Compliance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Issuance of dies and punches:

5.1.1 Issue required number of dies and punches for a particular product as specified in the respective BMR.

5.1.2 All tooling to be checked for any damage before assemble. In case of any deviation, report to the department head and QA.

5.1.3 Record the details in Puches and dies utilization record (Refer in Annexure- I).

5.2 Use of dies and punches:

5.2.1 Clean the lubricating oil on dies and punches by dipping in to 70% v/v IPA, wipe the dies and punches with lint free cloth and record the activity in Annexure –II.



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5.2.2.1 For 37 Station compression machine:

Use 1 to 37 number of sub sets on the first issue. The punches and dies are to be issued in rotation so as to ensure that all the spare sub sets of a particular set are being utilized uniformly.

For example, if a set of 40 nos. of punches & dies, then

-1st issue – sub set no.1 to 37

-2nd issue – sub set no.4 to 40 and so on.

For 55 Station compression machine:

5.2.2.2 Use 1 to 55 number of sub sets on the first issue. The punches and dies are to be issued in rotation so as to ensure that all the spare sub sets of a particular set are being utilized uniformly.

For example, if a set of 60 nos. of punches & dies, then

-1st issue – sub set no.1 to 55

-2nd issue – sub set no.5 to 59 and so on.

5.2.2.3 For 35 Station Compression machine:

Use 1 to 35 number of sub sets on the first issue. The punches and dies are to be issued in rotation so as to ensure that all the spare sub sets of a particular set are being utilized uniformly.

5.2.2.4 For 20 Station Compression machine:

Use 1 to 20 number of sub sets on the first issue. The punches and dies are to be issued in rotation so as to ensure that all the spare sub sets of a particular set are being utilized uniformly.

5.2.2.5 For 27 Station Compression machine:

Use 1 to 27 number of sub sets on the first issue. The punches and dies are to be issued in rotation so as to ensure that all the spare sub sets of a particular set are being utilized uniformly.

5.2.2.6 For 51 Station Compression machine:

Use 1 to 51 number of sub sets on the first issue. The punches and dies are to be issued in rotation so as to ensure that all the spare sub sets of a particular set are being utilized uniformly.

NOTE: If B or D Tooling set already utilized in other machine, rotation will be Continue according to type of tooling.

5.3 Retrieval of dies and punches:

5.3.1 After completion of the batches, remove the dies and punches from the compression machine.

5.3.2 Clean the punches and die after completion of operation with lint free cloth for the batch to batch change over (Type-A), and by wiping with 70% v/v IPA using lint free cloth (Type-B cleaning) and record in annexure –II.



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- 5.3.3 Transfer the cleaned punch set to the spare part room and checks the dies and punches for any defects as per SOP.
- 5.3.4 Retrieve the dies and punches and make the entries in Annexure-I.
- 5.3.5 If any abnormality is found, isolate the product and punch set, keep it under hold till the completion of investigation of incident and action plan.
- 5.3.6 Inform to the Production and head QA.
- 5.3.7 Investigate the cause of incidence and action plan to be prepared for further processing.
- 5.3.8 Keep the good punches and dies at its designated rack after smearing of thin layer of food grade oil.
- 5.3.9 Reject the punch set after the compression of five million tablets per each sub set.

6.0 ABBREVIATION (S):

- BMR : Batch Manufacturing Record
QA : Quality Assurance
SOP : Standard Operating Procedure

7.0 REFERENCE(S):

SOP - Indent, inspection and maintenance of punches and Dies

8.0 ANNEXURE(S):

- ANNEXURE– I : Puches and Dies Utilization Record
ANNEXURE– II : Dies and Punches cleaning Record

9.0 DISTRIBUTION

- Master Copy** : Quality Assurance
Controlled Copy(s) : Production department , Quality Assurance
Reference Copy (s) : Production department



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ANNEXURE I

Department: _____

Die Punch Set Box No.: _____

Die punches Set Cumulative Life: _____

Punch Set Nos.: _____

Specification: _____

Product	Issued Sub set No.		Punches & Dies Issued			Isu. By / Date	Used for B. No.		No. of Batch es	B. Size (Lacs)	Total Tablets Comp. (Lacs)	Cumulative Qty. (Lacs)	Punches & Dies Returned			Rtr. By /Date	Rec By / Date	Remarks
	From	To	U/P	L/P	Dies		From	To					U/P	L/P	Dies			

Checked By/Date: _____

