



# PHARMA DEVILS

PHARMACOVIGILANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Qualification and Requalification of Dies and Punches	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

- 1.1 To lay down Standard Operating Procedure for the qualification and requalification of dies and punches.

### 2.0 SCOPE:

- 2.1 This SOP is applicable to all the sets of dies and punches used in Production Department.

### 3.0 RESPONSIBILITY:

- 3.1 Officer/Sr. Officer of production department shall be responsible for qualification and requalification of dies and punches.
- 3.2 Executive/Sr. Executive shall be responsible for execute this SOP.
- 3.3 Head of production department shall be ensure the compliance of this SOP.

### 4.0 ACCOUNTIBILITY:

- 4.1 Department Head.

### 5.0 PROCEDURE:

#### 5.1 Procedure for Qualification (Checks at the Time of Receiving of Dies and Punches):

##### 5.1.1 Check the received dies and punches for

- Type of Tooling
- Description
- Dimensions
- Embossing

as per Challan sent by the manufacturer and verified with purchase order raised.

##### 5.1.2 Check that MOC Certificate, inspection report and drawing are received from the manufacturer.

##### 5.1.3 Check that the numbers of dies and punches received are as per the purchase order raised.

##### 5.1.4 Check that all the units have engraved with following details on them

- Serial Number



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➤ Size in mm

5.1.5 Record the observations as per **Format**, “Qualification & Requalification of Dies & Punches”.

**5.2 Checks for Upper Punches and Lower Punches:**

5.2.1 Check the tip dimensions using vernier caliper.

5.2.2 Tip dimensions should be in between the +0.00 mm to -0.04 mm of standard dimensions of that punch.

5.2.3 Check tip surfaces for absence of scratches, damages, cracks, pits and spots using magnifying glass.

5.2.4 Check body surface for absence of scratches, damages, cracks, pits and spots using magnifying glass.

5.2.5 Check chamfer for proper angle and uniformity using magnifying glass.

5.2.6 Check tip edge for damage, cracks and absence of burr using magnifying glass.

5.2.7 Check embossing for absence of flattening of letters and roughness using magnifying glass and mirror.

5.2.8 Check central break line or deep score for absence of flattening and roughness using magnifying glass.

5.2.9 Check head flat for uniformity using magnifying glass.

5.2.10 Use “**GO**” and “**NO GO**” gauges to check punch head.

5.2.11 Allow the punch head to pass through “**NO GO**” side of gauge. Punch should not pass.

5.2.12 Allow the punch head to pass through “**GO**” side of gauge and punch should pass.

5.2.13 Check height of all punches using vernier caliper.

5.2.14 Height of all punches should be within limit of  $133.60 \pm 0.02$  mm.

5.2.15 Record the observations as per **Format**, “Qualification & Requalification of Dies & Punches”.

**5.3 Checks For Dies:**

5.3.1 Check bore dimensions with the help of vernier caliper.

5.3.2 Bore dimensions should be in between the 0.03 mm to -0.00 mm of Standard dimensions of that die.



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- 5.3.3 Check the inner die surface for absence of scratches, damages, cracks, pits and spots using magnifying glass.
- 5.3.4 Check the outer die surface for smooth surface finish, level uniformity and edges using magnifying glass.
- 5.3.5 Check chamfer for uniformity using magnifying glass.
- 5.3.6 Check free movement of upper punch and lower punch by into the die bore.
- 5.3.7 Record the observations as per **Format**, “Qualification & Requalification of Dies & Punches”.
- 5.3.8 If any odd observation found during the checks intimate it to Production Head.

**5.4 Procedure for Requalification:**

**5.4.1 Checks for Dies and Punches:**

- 5.4.1.1 Requalification of dies and punches to be carried out after compression of 2 million (20 Lacs) tablets on one unit.
- 5.4.1.2 Check the dies and punches for
  - Type of Tooling
  - Description
  - Dimensions
  - Embossing
- 5.4.1.3 Ensure the availability of MOC Certificate, inspection report and drawing.
- 5.4.1.4 Record the number of dies and punches available.
- 5.4.1.5 Record the observations as per **Format**, “Qualification & Requalification of Dies & Punches”.

**5.4.2 Checks for Upper Punches and Lower Punches:**

- 5.4.2.1 Check the upper punches and lower punches for following checks as per step 5.2.1 to 5.2.15.
  - Tip Dimensions
  - Tip Surface
  - Body Surface
  - Chamfer
  - Tip Edge



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- Embossing
- Central Break line or Deep Score
- Head Flat
- “GO” and “NO GO”
- Height of Punches

### 5.4.3 Checks For Dies:

5.4.3.1 Check the dies for following checks as per step 5.3.1 to 5.3.8.

- Bore Dimensions
- Inner Surface
- Die Surface
- Chamfer
- Punch Movement in Die

5.4.3.2 If any odd observation found during the checks intimate it to Production Head.

### 5.4.4 Requalification Certification:

5.4.1 Ensure that all the checks performed are meeting the Specified Criteria.

“No. of Tablet Compressed on One Unit = Cumulative No. of Tablets Compressed on Set”

Total No. of Available Unit

## 6.0 RELATED DOCUMENTS:

6.1 Nil

## 7.0 REFERENCES:

7.1 In-house.

## 8.0 FORMATS:

8.1 : Qualification & Requalification of Dies & Punches.



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### 9.0 ABBREVIATIONS:

- 9.1 SOP : Standard Operating Procedure  
9.2 QA : Quality Assurance  
9.3 HOD : Head Of Department  
9.4 MOC : Material of Construction

### 10. REVISION HISTORY:

Version	Reason for Revision	Effective Date
00	New SOP	



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**ANNEXURE I**

**Checking of Dies & Punches**

- 1 Rec : **Qualification / Requalification**  
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- 2 Set : \_\_\_\_\_  
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er

Pun  
ches

Dies : \_\_\_\_\_

1 **Engraving Details:**

3 Serial Number : Available

. Size in mm : Available / Not Available



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### Checks for Upper & Lower Punches

Items	Description	Remarks	Verified By
Tip Dimension	Absence of Scratches, Damages and Cracks	Ok/Not Ok	
Tip Surface	Absence of Scratches, Damages, Cracks, Pits and Spots	Ok/Not Ok	
Body Surface	Absence of scratches, Damages, Cracks, Pits and Spots	Ok/Not Ok	
Chamfer	Presence of Proper Angle and Uniformity	Ok/Not Ok	
Tip Edge	Absence of Damages, Cracks and Burr	Ok/Not Ok	
Embossing	Absence of Flattening of Letters and Roughness	Ok/Not Ok	
Central Break line or Deep Score	Absence of Flattening of Line and Roughness	Ok/Not Ok	
Head Flat	Presence of Uniformity	Ok/Not Ok	
Head	Pass through the GO Side of Gauge and not pass through the NO GO Side of Gauge	Ok/Not Ok	
Height of Punches	Height of all Punches should be within $133.6 \pm 0.02$ mm	Ok/Not Ok	

### Checks for Dies

Items	Description	Remarks	Verified By
Bore Dimension	Absence of scratches, Damages and Cracks	Ok/Not Ok	
Inner Die Surface	Absence of scratches, Damages, Cracks, Pits and Spots	Ok/Not Ok	
Outer Die Surface	Presence of Smooth Surface Finish, Level Uniformity and Edges	Ok/Not Ok	
Chamfer	Presence of Uniformity	Ok/Not Ok	
Punch movement in Die	Presence of free movement of individual Upper Punch and Lower Punch by inserting into the Die.	Ok/Not Ok	









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### Dies Checks

Die No.	Bore Dimension (in mm)	Inner Surface	Die Surface		Chamfer	Free Movement of Punches in to Die Bore
			Upper	Lower		
1						
2						
3						
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### Observation

1. No. of Upper Punches Rejected :  
(if any)
2. No. of Lower Punches Rejected :  
(if any)
3. No. of Dies Rejected :  
(if any)

### Conclusion

The Set Complies / Does Not Complies as per Specification

It can be used for Compression / cannot be used for Compression.

**Checked By**  
**(Office/Executive Production)**

**Approved By**  
**(Officer/Executive QA)**