



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

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

### 1.0 OBJECTIVE:

To lay down a procedure for inspection of punches and dies.

### 2.0 SCOPE:

This procedure is applicable to inspection of punches and dies with the help of punch inspection kit used in production department.

### 3.0 RESPONSIBILITY:

Technical Associate, Officer, Executive – Production Department  
Head Production – SOP Compliance

### 4.0 DEFINITION(S):

NA

### 5.0 PROCEDURE:

#### 5.1 Tip diameter of punches

5.1.1 Check the tip diameter with the help of a micrometer.

5.1.2 Check the zero error of the micrometer.

5.1.3 Place the punch tip in a vertical position in between the micrometer jaws.

5.1.4 Turn the micrometer knob in such a way that at one point the micrometer stops moving further and only the knob rotates to give a sound.

5.1.5 Check the fine setting of the micrometer and record the reading in the Annexure- I.

5.1.6 The readings should be within  $\pm 0.1$  mm

#### 5.2 Difference in height of the punches

5.2.1 Set the dial gauge of the inspection kit at zero position with the help of the standard punch.

5.2.2 Keep the punches in 'Head up ' and ' tip down ' position one by one inside the punch holder over the metal pad of the inspection kit and check the difference in deflection from the zero position.

5.2.3 Record the difference in Annexure-I.

5.2.4 The difference should not be more than  $\pm 0.08$  mm.

#### 5.3 Body diameter of punches

5.3.1 The body diameter of the punches shall be checked with the help of calibrated micrometer.

5.3.2 Check the zero error of the micrometer.

5.3.3 Place the punch body in a horizontal position in between the micrometer jaws.



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5.3.4 Turn the micrometer knob in such a way that at one point the micrometer stop moving further and only the knob rotates to give a sound.

5.3.5 Check the fine setting of the micrometer and record the reading in Annexure-I.

5.3.6 The readings should be within  $\pm 0.1$  mm.

5.3.7 The standard dimensions are as given below

D tooling - 25.35 mm

B tooling - 19.0 mm

BB tooling - 19.0 mm

**5.4 Embossing of punches**

5.4.1 Visually check the embossing and enter the remarks in the Annexure- I.

**5.5 Difference in concentricity of punches**

5.5.1 Keep the punch over a 'V' block pad horizontally and set the dial gauge at zero position over the punch body.

5.5.2 Rotate the punch in the clockwise direction, take two readings each from the punch (one from the top and one from the bottom of the punch body) and record the observations in Annexure- I.

5.5.3 The deflection should be within  $\pm 0.05$  mm.

**5.6 Head go and no-go of punches**

5.6.1 Move the punch heads between the standards of GO and NO-GO.

5.6.2 The punch head should pass through GO but not through NO-GO.

5.6.3 Record the observations in the Annexure- I.

**5.7 Outer diameter of dies**

5.7.1 Check the outer diameter of the die with the help of a micrometer/ vernier caliper.

5.7.2 Check the zero error of the micrometer/ vernier caliper.

5.7.3 Place the die in a horizontal position in between the micrometer/ vernier caliper jaws.

5.7.4 Record the reading in the Annexure –II and the readings should be within  $\pm 0.05$  mm that of the standard.

The standard dimensions are as follows:

D tooling - 38.1 mm

B tooling - 30.15 mm

BB tooling - 24.0 mm

**5.8 Height of the die**

5.8.1 Check the height of the die with the help of a micrometer.

5.8.2 Check the zero error of the micrometer.



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- 5.8.3 Place the die in a vertical position in between the micrometer jaws.
- 5.8.4 Turn the micrometer knob in such a way that at one point the micrometer stop moving further and only the knob rotates to give a sound.
- 5.8.5 Check the fine setting of the micrometer and record the reading in the Annexure II.
- 5.8.6 The readings should be within  $\pm 0.1$  mm of that of the standard.
- 5.8.9 Standard dimensions are as follows:
- D tooling - 23.82 mm
  - B tooling - 22.22 mm
  - BB tooling - 22.22 mm
- 5.9 Difference in concentricity of dies**
- 5.9.1 Keep the die over a 'V' block pad horizontally and set the dial gauge at zero position over the die body.
- 5.9.2 Rotate the die in the clockwise direction, take two readings each from the die (one from the top and one from the bottom of the die body) and record the observations in Annexure-I.
- 5.9.3 The deflection should be within  $\pm 0.05$  mm.
- 5.10** Check the calibration status of dial gauge, micrometer and vernier caliper before use and record the same as O.K./NOT O.K. in the respective annexure. Do not carryout the inspection by using a micrometer, dial gauge or vernier caliper which is due for calibration.
- 5.11 Frequency**
- Inspection of punches and dies to be done after receiving of a new punch set and after compression of two million tablets per punch sub-set.

**6.0 ABBREVIATION(S):**

QA : Quality Assurance  
SOP : Standard operating procedure

**7.0 REFERENCE(S):**

NA



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### 8.0 ANNEXURE(S):

- Annexure –I : Inspection of Upper Punches
- Annexure – II : Inspection of Lower Punches
- Annexure- III : Inspection of Dies
- Annexure–IV : Inspection of Upper Punches (Multitip)
- Annexure–V : Inspection of Lower Punches (Multitip)

### 9.0 DISTRIBUTION:

- 9.1 **Master copy** : Quality Assurance
- 9.2 **Controlled copy( S)** : Production department, Quality Assurance
- 9.3 **Reference copy (s)** : Production department



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### Annexure -I

#### Inspection of Upper Punches

**Department:** \_\_\_\_\_ **Punch Set No.:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Description:** \_\_\_\_\_

#### Calibration Status of:

S.No.	Instrument	Instrument ID No.	Status (OK/not OK)
1.	Micrometer		
2.	Vernier Calipers		
3.	Dial Gauge		
4.	Go-NO-GO		

S.No.	Tip Dia. (mm)	Diff. in Punch Height (mm)	Body Dia. (mm)	Embossing	Difference In Concentricity		Head GO / NO-GO	Remarks
					I	II		

**Done by:** \_\_\_\_\_

**Checked by:** \_\_\_\_\_



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### Annexure – II Inspection of Lower Punches

**DEPARTMENT:** \_\_\_\_\_ **Punch Set No.:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Description:** \_\_\_\_\_

**Calibration Status of:**

S.No.	Instrument	Instrument ID No.	Status ( OK/not OK)
1.	Micrometer		
2.	Vernier Calipers		
3.	Dial Gauge		
4.	Go-NO-GO		

S.No.	Tip Dia. (mm)	Diff. in Punch Height (mm)	Body Dia. (mm)	Embossing	Difference In Concentricity		Head GO / NO-GO	Remarks
					I	II		

**Done by:** \_\_\_\_\_

**Checked by:** \_\_\_\_\_



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### Annexure- III

#### Inspection of Dies

**DEPARTMENT:** \_\_\_\_\_ **Punch Set No.:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Description:** \_\_\_\_\_

#### Calibration Status of:

S.No.	Instrument	Instrument ID No.	Status (OK/not OK)
1.	Micrometer		
2.	Vernier Calipers		
3.	Dial Gauge		

S.No.	OUTER DIAMETER (mm)	DIFFERENCE IN CONCENTRICITY OF DIE		HEIGHT OF DIE (mm)	REMARKS
		I	II		

**Done by:** \_\_\_\_\_

**Checked by:** \_\_\_\_\_



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### Annexure-IV

#### Inspection of Upper Punches (Multi-tip)

**DEPARTMENT:** \_\_\_\_\_ **Punch Set No.:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Description:** \_\_\_\_\_

**Calibration Status of:**

S.No.	Instrument	Instrument ID No.	Status (OK/not OK)
1.	Micrometer		
2.	Vernier Calipers		
3.	Dial Gauge		
4.	Go-NO-GO		

S.No.	Tip Dia. (mm)			Diff. in Punch Height (mm)	Body Dia. (mm)	Embossing	Difference In Concentricity		Head GO / NO-GO	Remarks
	I	II	III				I	II		

**Done by:** \_\_\_\_\_ **Checked by:** \_\_\_\_\_



