



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Procurement, Inspection, Utilization and Destruction of Dies and Punches	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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**1.0 OBJECTIVE:**

To lay down the procedure for procurement, inspection, utilization and destruction of dies and punches.

**2.0 SCOPE:**

This procedure is applicable for procurement, inspection, utilization and destruction of dies and punches.

**3.0 RESPONSIBILITY:**

Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance

**4.0 Procedure:**

**4.1 Procurement of dies and punches:**

4.1.1 For ordering a new set, raise a requisition to Purchase Department with the required specifications in the purchase indent.

4.1.2 Get the indent approved by the department head and forward it to purchase department at head office.

4.1.3 On receipt of the proper drawing from supplier, the same is to be approved by QA and Production.

4.1.4 Send the approved drawing to the supplier for manufacturing.

**4.2 Receipt of punches & dies:**

4.2.1 On receipt of intimation from stores, collect the punch set.

4.2.2 On receipt of the consignment, party report & diagram shall be reviewed and verified for meeting the dies and punches acceptance criteria. Party report & diagram shall be signed & dated by the reviewer.

4.2.3 Verify the quantity received against the Purchase Order.



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- 4.2.4 Check physically the Dies and Punches for quantity and for any physical defects at the time of receipt of the set.
- 4.2.5 In case of receipt of part quantity of particular punch set, the punches shall be inspected against the diagram supplied initially.
- 4.2.6 Upon receipt of the consignment, excessive oil/ grease on the Punches and Dies shall be wiped by using a clean dry cloth followed by cleaning with Isopropyl alcohol and then with clean, dry, lint free cloth.
- 4.2.7 File the inspection report of Die-punch set and supplier inspection report and keep it in the Die-Punch History record. If there is any difference in inspection report of supplier and user, then user report shall be considered as final.
- 4.2.8 After the completion of inspection assign the set identification number and enter the same in Die-punch Stock Statement.
- 4.2.9 Apply a thin layer of food grade oil/lubricant on the surface of punches and dies.
- 4.2.10 In case of rejection of dies or punches, inform the purchase department and return the punches to stores for further action.
- 4.2.11 Label the punch set with the identification number and the quantity.  
Apply suitable food grade oil on all the surfaces of dies and punches.  
Give set number as T/XXX.  
Where :  
T - Tool set  
XXX –Serial Number of set starts from 001.
- 4.2.12 Enter the details of new die punch set in the format of 'Die-punch Stock Statement' as per **Annexure –I.**
- 4.3 Inspection (Height and depth of the punches):**
- 4.3.1 Set the dial gauge of the inspection kit at zero position with the help of the standard punch.
- 4.3.2 Keep the punches one by one inside the punch holder over the metal pad of the inspection kit in such a way that the punch head is on the upper position and check the difference in deflection from the zero position.



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4.3.3 If the deflection is in (+ve) then add the numeric value on the standard length of the punch. If the deflection is in (- ve) then subtract the numeric value from the standard length. Record the total length in the column given in **Annexure-II**.

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

4.3.5 Keep the punches one by one inside the punch holder over the metal pad of the inspection kit in such a way that the punch tip is on the upper position and check the difference in deflection from the zero position.

4.3.6 Record the deflection value as cup depth in the column given in **Annexure-II**.

4.3.7 If the deflection is in - ve then subtract the numeric value from the standard length and record the working length in the column given in **Annexure-II**.

4.3.8 If the punch having embossing measure the working length from the top of the embossing.

4.3.9 The difference should not be more than  $\pm 0.05$  mm.

#### **4.4 Inspection:(Tip diameter of punches)**

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

4.4.2 Check the zero error of the micrometer.

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

4.4.4 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.

4.4.5 Check the fine setting of the micrometer and record the reading in the **Annexure- II**.

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

#### **4.5 Body diameter of punches:**

4.5.1 Check the body diameter with the help of a micrometer.

4.5.2 Check the zero error of the micrometer.

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

4.5.4 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.

4.5.5 Check the fine setting of the micrometer and record the reading in **Annexure-II**.

4.5.6 The readings should be within  $\pm 0.15$  mm.



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4.5.7 The standard dimensions are as given below-

D tooling - 25.4mm

B tooling - 19.0mm

BB tooling - 19.0mm

**4.6 Embossing of punches:**

4.6.1 Visually check the embossing and enter the remarks in the **Annexure- II**.

**4.7 Difference in concentricity of punches:**

4.7.1 Keep the punch over a 'V' blocks pads horizontally and set the dial gauge at zero position over the punch body.

4.7.2 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-II**.

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

**4.8 Head go and no-go of punches:**

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

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

4.8.3 Record the observations in the **Annexure-II**.

**4.9 Outer diameter of dies:**

4.9.1 Check the outer diameter of the die with the help of a Vernier Caliper.

4.9.2 Check the zero error of the Vernier Caliper.

4.9.3 Place the die in a horizontal position in between the Vernier Caliper jaws.

4.9.4 Record the reading in the **Annexure -III**.

The readings should be within  $\pm 0.05$  mm that of the standard. The standard dimensions are as follows:-

D tooling - 38.10 mm

B tooling - 30.15 mm

BB tooling - 24.00 mm

**4.10 Height of the die:**

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



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- 4.10.2 Check the zero error of the micrometer.
- 4.10.3 Place the die in a vertical position in between the micrometer jaws.
- 4.10.4 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.
- 4.10.5 Check the fine setting of the micrometer and record the reading in the **Annexure III**.
- 4.10.6 The readings should be within  $\pm 0.1$  mm of that of the standard.
- 4.10.7 Standard dimensions are as follows:
  - D tooling - 23.82 mm
  - B tooling - 22.22 mm
  - BB tooling - 22.22 mm

**4.11 Difference in concentricity of dies:**

- 4.11.1 Keep the die over a 'V' block pad horizontally and set the dial gauge at zero position over the die body.
- 4.11.2 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-III.
- 4.11.3 The deflection should be within  $\pm 0.05$  mm.
- 4.11.4 **Note:** 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 carry out the inspection by using a micrometer, dial gauge or Vernier caliper which is due for calibration.

**4.12 Frequency:**

- 4.12.1 Inspection of punches and dies to be done after receiving of a new punch set.  
1<sup>st</sup> re-inspection to be done after compression of 2-million of tablets per punch sub-set and 2<sup>nd</sup> re-inspection to be done after compression of 4-million of tablets per punch sub-set.

**4.13 STORAGE:**

- 4.13.1 For the storage of dies and Punches, storage drawer/Box shall be used.
- 4.13.2 Store all the die-punch sets as per their size, shape and design in drawer/Box located at Die Punch Storage Room.
- 4.13.3 Store one set only in one drawer/Box with proper lubrication using suitable food grade oil.
- 4.13.4 Affix the label in each Drawer/Box as per **Annexure-IV**.



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- 4.13.5 Use dies and punches as a set. Avoid mixing among the sets.
- 4.13.6 Maintain the label as per **Annexure – IV** indicating drawer/Box numbers For easy location and identity of die-punch set in storage area. Drawer/box numbering as drawer /box No.-xxx (xxx-denotes as serial no. starts from 001).
- 4.13.7 After inspection of die-punch sets on receipt or its use during process, place upper punches lower punches and dies in a drawer of a drawer/Box in Die-Punch Storage Room.

**4.14 HANDLING AND CLEANING:**

- 4.14.1 Take out required die-punch set from its assigned drawer in rotation depending upon the number of station of machine.
- 4.14.2 Document the details of die/punch issue and return slip in the format as per **Annexure-VI**.
- 4.14.3 Transfer the die-punch set in compression machine cubicle using portable trolley and document the details of issuing/returning of die-punch set in the format as per **Annexure-V**.
- 4.14.4 After completion of compression, remove dies and punches from the Compression machine. Clean the upper punches and dies with dry lint free duster.
- 4.14.5 Clean the dies and punches with IPA using nylon brush having bristles or with dry lint free cloth.
- 4.14.7 Transfer the die punch set to Die-Punch storage area using die punch trolley.
- 4.14.8 Inspect the dies and punches for their apparent defects and arrange for destruction of rejected dies and punches and record in **Annexure VII**.
- 4.14.9 Apply little suitable food grade oil on punches and dies covering all surfaces. Document the details of die/punch issue and return slip in the format as per **Annexure-VI** and also with in format in **Annexure –V**.



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**4.14.10 Precaution:-**

- While inserting or removing punches, check that edges of the tip is not touching with the edges of other punches or with the tablet press turret.
- While inserting or removing the punches avoid collision of punch tip with guide hole.
- Remove the punches from tablet press one at a time,
- While cleaning of punch and die ensure that it is being cleaned one by one and not together.

4.14.11 Unused punches and dies shall be cleaned after every six months  $\pm 15$  days as punches in use are cleaned before & after use.

4.14.12 Once in a six months  $\pm 15$  day's Plastic holder of Cabinet/Drawer /Box and all Punches and dies shall be cleaned.

4.14.13 Clean the punches and dies with 70% IPA dipped in a lint free cloth.

4.14.14 Always apply a thin film of food grade oil on the tool before store.

4.14.15 Place the die-punch set into its respective drawer/box.

4.14.16 Record the cleaning activity in **Annexure-VIII**.

**4.15 Utilization of Dies and punches:**

4.15.1 On receipt of the die/punch issue and return slip, record the same in 'Dies/punch Utilization Record' as per **Annexure-V**.

4.15.2 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 50 nos. of punches & dies, then a 45 station compression machine

1st issue – sub set no.1 to 45

2nd issue – sub set no.4 to 48

3rd issue – sub set no.7 to 50 and 1, and so on.

4.15.3 Accordingly rotate the punches and dies for 55 stations, 75 stations and in such a way that all the subsets are being used uniformly to utilize the spare subsets of a particular punch set.

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

4.15.5 Clean the punches and dies and transfer the cleaned punch set to the Die-Punch room and check the dies and punches for any defects. Retrieve the good dies and punches and make the entries.



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**4.16 Destruction of Dies And Punches :**

4.16.1 Collect the rejected dies and punches observed during routine inspection of the die-punch set or damaged due to any accident on compression machine or mishandling.

**4.16.2 Destroy the dies or punches in following cases-**

- Punch having total length difference more than  $\pm 0.08$ mm against standard. Punch having total working length difference more than  $\pm 0.05$  mm against standard.
- Punch having damaged tip. Punch having continuous sticking even after polishing.
- Die with damaged die bore.
- Die with heavy ring formation. Any other apparent defects.
- After 5.0 Million tablets compressed with each sub-set or every ten years whichever is earlier.

4.16.3 In case of rejection of punches, utilization record to be updated & cumulative quantity per punch shall be calculated by dividing the cumulative quantity with the remaining quantity of the punches available e.g., If a punch is broken of a tool set with 55 no. of punches and number of available punches reduced to 54, then cumulative per punch set shall be calculated by dividing cumulative quantity with 54.

4.16.4 After rejection maintain the record of die punch stock statement.

4.16.5 Die and punch set shall be discarded by sending to engineering department through die punch Destruction Scrap Note.

4.16.6 The Engineering department shall destroy the Punches (especially tips) and Dies by de-shaping them after making the entry in Punch and die Destruction Scrap Note and then shall return the scrap note to the Production department.

4.16.7 In case of rejected punches of what so ever reason, the rejected punch no. to be recorded in **Annexure-VI** and **Annexure-IX** .e.g. If in a tool set with 55 no. of punches, punch No 07 is rejected and tool set is reduced to 54, the last punch of the tool set with punch No. 55 will be renumbered as punch No 07 by engraving no. 07 on neck of the Punch along with the die and defacing the existing no. 55 on the punch with the mark of Cross (X).





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**5.0 ANNEXURE (S):**

- Annexure-I: Die Punch Stock Statement.
- Annexure -II: Punch Inspection Report (Upper/Lower).
- Annexure -III: Die Inspection Report.
- Annexure -IV: Specimen label for Die Punch Drawer/Box.
- Annexure -V: Die Punch Utilization Record.
- Annexure -VI: Die Punch issue/return slip.
- Annexure -VII: Die Punch Destruction Record.
- Annexure -VIII: Die Punch Drawer/Box Cleaning Record.
- Annexure -IX: Die Punch Destruction Scrap Note.

**6.0 REFERENCE (S) :**

SOP: Preparation, Approval, Distribution Control, Revision and Destruction of Standard Operating Procedure(SOP).

**7.0 ABBREVIATION (S) /DEFINITION (S) :**

- BMR: Batch Manufacturing Record.
- QA : Quality Assurance
- S.No. : Serial Number
- U/P : Upper Punch
- L/P : Lower Punch
- STN. : Station
- No. : Number

**REVISION CARD**

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---