STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Core Tablet & Capsule Defect Album	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Purpose: The purpose of this SOP is to describe the action to be taken for defects observed at Core Tablets & Capsules.

2.0 Scope: This SOP is applicable for the action to be taken for defects observed at Core tablet & Capsules at ……...

3.0 References, Attachments and Annexures:

3.1 References:

3.1.1 In House

3.1.2 SOP: Acceptable Quality Level

3.2 Attachments: NA

3.3 Annexures:

3.2.1 Annexure – 1: List of Defects of Core Tablet and their recommended action

3.2.2 Annexure – 2: Defect Album for Core Tablet

3.2.3 Annexure – 3: List of defects of Capsule & their Recommended Action

3.2.4 Annexure – 4: Defect Album for Capsules

4.0 Responsibilities:

4.1 Quality Assurance:

4.1.1 To ensure for the action to be taken for defects observed at Core tablet & Capsules.

4.1.1 To ensure implementation of SOP.

4.1.2 Concerned department Head or Designee shall be responsible for the action to be taken for defects observed at Core tablet & Capsules.

4.2 Regulatory Affairs, Quality Head and Plant Head:

4.2.1 To review and approve the SOP.

5.0 Distribution:

5.1 Quality Assurance

5.2 Production

6.0 Abbreviations & Definition of terms:

6.1 **Abbreviations:**

6.1.1 CC No. : Change Control Number

6.1.2 NA. : Not Applicable

6.1.3 SOP : Standard Operating Procedure

6.1.4 MCS : Mini Capsule Sorter

6.1.5 DP : De-dusting and Polishing

6.2 **Definition of terms:** NA

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7.0 Procedure:

7.1 Action Plan to be taken for Defects Observed at Core tablet & Capsules:

1.1.1. Carryout the compression & capsulation as per instruction and parameters given in the BMR.
1.1.2. Check physical appearance of tablets & capsules during compression & capsulation process.
1.1.3. If defects are observed at physical appearance of the tablet & capsule during compression & capsulation, take the corrective action, by controlling the compression & capsulation process parameters and keep the minimum number of defective tablet/capsules.
1.1.4. Defect Album shall be maintained as per Annexure-2 & 4.
1.1.5. Defect should be identified during AQL Procedure.
1.1.6. Critical and Major defects should be considered for preparation of defect album.
1.1.7. Collect sample of 04 to 10 tablet/capsule from whole of the batch.
1.1.8. The below mentioned list of the Core Tablets/Capsule defects which are observed during Compression/Capsulation activity.

Note:

1. **If the Problem is persisting and repetitive for 03 batches then investigate the cause and to resolve the problem and review the formulation and process in consultation with F & D.**

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Annexure – 1
Tablet Defects and Recommendations

S.No.	Defects	Recommended Action
1.	**Sticking**	❖ Maintain temperature and RH. ❖ Punches and dies need polishing. ❖ Decrease LOD of granules.
2.	**Capping**	❖ Increase LOD of granules. ❖ Remove damage punches and dies. ❖ Decrease machine speed.
3.	**Chipping**	❖ Decrease the friability ❖ Remove damage punches or dies. ❖ Increase hardness. ❖ Handling of the tablets must be proper.
4.	**Weight variation**	❖ Decrease machine RPM ❖ Granules must be uniform. ❖ Check granules flow parameters
5.	**Soft tablet**	❖ Decrease machine speed ❖ Check granules flow property. ❖ Increase compressibility.
6.	**Oil spot**	❖ Clean the punches properly.
7.	**Black Particle**	❖ Clean the Machine. ❖ Check the lubricated granules.
8.	**Wrong Embossing**	❖ Check the punches properly.
9.	**Picking**	❖ Maintain temperature and RH. ❖ Decrease LOD of granule. ❖ Punches need polishing.

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Annexure – 2

Album for Tablet defects

Product:_____ **Batch No._____**

Type of Defect _____	Type of Defect _____

Prepared By **Checked By QA** **Review By**

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Annexure – 3

Capsule Defects & Recommendation

S.No	Defects	Recommended Action
1.	**Denting**	❖ Ensure Proper setting of Body & Cap Bush ❖ Ensure Proper Setting of Locking Length of capsule. ❖ Ensure Proper Setting of Ejection Locking Pin.
2.	**Telescopic/V notch**	❖ Ensure Proper setting of Body & Cap Bush.
3.	**Shade Variation/Misprint capsule**	❖ Ensure the color of Empty Capsule Shells ❖ Ensure the printing on Empty Capsule Shell
4.	**Double Cap**	❖ Ensure the cleaning of DP100 & MCS.
5.	**Locking Length**	❖ Ensure proper setting of machine as per BMR.
6.	**Half Filled Capsule**	❖ Ensure the Air Supply in Pneumatic cylinder. ❖ Ensure that there is no filling Hole Jamming Problem.
7.	**Pin Hole**	❖ Ensure the Quality of Empty Capsule Shell

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Annexure – 4

Album for Capsule Defects

Product:_____ **Batch No._____**

Type of Defect _____	Type of Defect _____

Prepared By **Checked By QA (Section Head)** **Review By QA Head**

6.0 History:

Version No.	NA	**Effective Date**	NA
New SOP			