



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Album for Progress of Coating Process	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 1. Purpose:** The purpose of this SOP is to describe the procedure to make an album of tablet samples for monitoring the coating process.
- 2. Scope:** This SOP is applicable to make an album of samples for monitoring the coating process.
- 3. Reference, Attachment and Annexure:**
 - 3.1. Reference:**
 - 3.1.1. In-House
 - 3.2. Attachment:**
 - 3.2.1. Attachment-1 : Album for Progress of Coating Process
 - 3.3. Annexure:** NA
- 4. Responsibilities:**
 - 4.1. User Department Head or Designee:**
 - 4.1.1. Concerned department Head or Designee shall be responsible for maintaining an album of tablet of coating process.
 - 4.2. Quality Assurance:**
 - 4.2.1. To ensure for the making of coating process progress album.
 - 4.2.2. To review, approve and implementation of SOP.
 - 4.3. Regulatory Affairs, Quality Head and Plant Head:**
 - 4.2.3 To review and approve the SOP.
- 5. Distribution:**
 - 5.1. Quality Assurance
 - 5.2. Production (Coating Section)
- 6. Abbreviations & Definition of terms:**
 - 6.1 Abbreviations:**
 - 6.1.1: CC No.: Change Control Number
 - 6.1.2: SOP : Standard Operating Procedure
 - 6.2 Definition of terms:** NA
- 7. Procedure:**
 - 7.1 Collection of Sample & Preparation of Coating album:**
 - 7.1.1. Collect the samples after various intervals depending on the total spraying time as coating process progresses.
 - 7.1.2. Collect the samples of each relevant stage (Minimum 4 to 10 tablets) in sample bags.
 - 7.1.3. Staple the sample bags on the format attached (Attachment-1).
 - 7.1.4. This album is to be used as a guideline for comparing the in-process coated tablets during the coating process.
 - 7.1.5. The samples used for coating album should be replaced in the first quarter of every year with fresh batch. (If batch is not manufactured, then it should be continued till the manufacturing of the next batch).



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Attachment – 1

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Product: _____

Batch No. _____

Uncoated Tablet	After _____ Hours
After _____ Hours	After _____ Hours

Prepared By/Date	Checked By QA/Date	Review By QA Head/Date

8. History

Version No.	Effective Date