DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Assigning Retest/Expiry period of Raw materials, Packing materials, Intermediates and Finished products	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for assigning the retest/expiry date for Raw materials, Packing materials, Intermediates and Finished products.

2.0 SCOPE:

This SOP is applicable to all the raw materials, intermediates and finished products used in …….

3.0 RESPONSIBILITY:

Head – Quality Control

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1. Assign retest/Expiry date for the product, raw material and packing materials as given below.

S.No.	Stage/Material	Retest date	Expiry Date
1.	Raw Material (Active)	6 months	As per manufacturer's COA
2.	Raw Material (Inactive/excipient) For biological origin material	12 months 6 months	As per manufacturer's instructions COA
3.	Primary packing material - Foils etc.	12 months	--------
4.	Secondary Packing materials e.g. adhesive rolls, labels etc, which are stored at ambient temperature	12 months	-------
5.	Dispensed Raw materials	7 days	-----
6.	Blend granules	7 days	As per product Specification
7.	Core tablets / Capsules	14 days	As per product specification
8.	Coated tablets	21 days	As per product specification

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6.0 ABBREVIATION(S):

COA : Certificate Of Analysis

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Nil

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION