



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Procedure to Control Status label and to maintain its stock	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for control of the status label and maintain its stock.

2.0 SCOPE:

This SOP is applicable for all Under test, Approved, Rejected, and Retest labels .

3.0 RESPONSIBILITY – Execution – Executive QC.

Checking - Assistant Manager QC .

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 The Under test label shall be as per Annexure-I.

5.2 The Approved label shall be as per Annexure-II.

5.3 The Rejected label shall be as per Annexure-III.

5.4 The under Retest label shall be as per Annexure-IV.

5.5 Receive the labels from PM store and enter the details as shown in Annexure-V to VIII.

5.6 Store the issued quantity of labels for Raw material / Packaging material area with sign of Q.C.

In-charge for daily use and enter the detail of same as mentioned as in Annexure-V to VIII.

5.7 Use the label as per requirement and maintain the stock of labels and record it daily as shown in

Annexure-V to VIII.

6.0 SAFETY & PRECAUTIONS:

Not Applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date



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8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

PM : Packaging Material

Annexure-I : Specimen of Under Test Label

Annexure -II : Specimen of Approved Label

Annexure -III : Specimen of Rejected Label

Annexure -IV : Specimen of Retest Label

Annexure -V : Record of Under Test Label

Annexure -VI : Record of Approved Label

Annexure -VII : Record of Rejected Label

Annexure -VIII : Record of Retest Label



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ANNEXURE-I

SPECIMEN OF UNDER TEST LABEL

NAME OF MATERIAL :
A.R. NO.
SAMPLED BY : _____ DATE : _____
UNDER TEST

Specification of Label	
Total label dimension	Length :108 mm , Width : 80 mm
Shaded area of label	Length : 108 mm , Width :35 mm.
Color of Shaded area	Yellow
Color of printed matter	Black
Size and color of logo	As per specimen



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ANNEXURE-II

SPECIMEN OF APPROVED LABEL

APPROVED			
A.R. NO.	:		
APPROVED BY	:	DATE	:
RETEST DUE DATE	:		

Specification of Label	
Total label dimension	Length :108 mm , Width : 40 mm
Shaded area of label	15 mm
Color of Shaded area	Green
Color of printed matter	White
Size and color of logo	As per specimen



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ANNEXURE-III

SPECIMEN OF REJECTED LABEL

REJECTED	
A.R. NO. :	
REJECTED BY:	DATE :
REASON :	

Specification of Label	
Total label dimension	Length :108 mm , Width : 40 mm
Shaded area of label	15 mm
Color of Shaded area	Red
Color of printed matter	White
Size and color of logo	As per specimen



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ANNEXURE-IV

SPECIMEN OF RETEST LABEL

NAME OF MATERIAL :	
A.R. NO.	
SAMPLED BY :	DATE :
UNDER RETEST	

Specification of label	
Total label dimension	Length :108 mm , Width : 80 mm
Shaded area of label	Length : 108 mm , Width :35 mm.
Color of Shaded area	Blue
Color of printed matter	Black
Size and color of logo	As per specimen



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ANNEXURE-VIII

RECORD OF RETEST LABEL RETEST LABELS STOCK

DATE OF ISSUE	QUANTITY ISSUED	NAME OF MATERIAL	A.R. NO.	NO. OF CONTAINER	LABEL USED	DATE FOR LABEL USED	NO.OF LABEL DESTROY	LABEL BALANCE	SIGN

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