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1.0 PURPOSE

To define a procedure for Status labeling.

2.0 SCOPE

2.1 This procedure applies to labels used at …….

2.2 Specific departments under the scope of this SOP are "Quality Assurance, Quality Control, Production, Warehouse, Engineering, Environment, Health and safety, Human Resource and Administration".

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-House

3.2 Attachments

3.2.1 Attachment- I: Quarantine Status label (Raw/ Packing material)

3.2.2 Attachment-II: Sampled Label (Raw/packing/ In-process material)

3.2.3 Attachment-III: Under test label (Raw/packing/ In-process material/ Finished Product)

3.2.4 Attachment-IV: Sample for Analysis (Raw/packing/ In-process material/ Finished Product)

3.2.5 Attachment-V: Passed Label Analysis (Raw/packing/ In-process material/ Finished Product)

3.2.6 Attachment-VI: Rejected Label Analysis (Raw/packing/ In-process material/ Finished Product)

3.2.7 Attachment-VII: Dispensing Label (raw/packing material)

3.2.8 Attachment-VIII: Loose Pack Label (raw/packing material)

3.2.9 Attachment-IX: Repacking Label (raw/packing material)

3.2.10 Attachment-X: Control Sample (Raw Material)

3.2.11 Attachment-XI: Control Sample (Finished Product)

3.2.12 Attachment-XII: Under hold (In-process Material/ Finished Product)

3.2.13 Attachment-XIII: Scrap material label

3.2.14 Attachment-XIV: To be cleaned Label

3.2.15 Attachment-XV: Cleaned Label

3.2.16 Attachment-XVI: Material Return Label

3.2.17 Attachment-XVII: Under Breakdown Maintenance Label

3.2.18 Attachment-XVIII: Area Status Label

3.2.19 Attachment-XIX: Online Rejection Label

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3.2.20 Attachment-XX: Preventive Maintenance Status Label

3.2.21 Attachment-XXI: Under Preventive Maintenance Status Label

3.2.22 Attachment-XXII: Calibration Status Label

3.2.23 Attachment-XXIII: Out of Calibration Status Label

3.2.24 Attachment-XXIV: For ETP label

3.2.25 Attachment-XXV: Loose Shipper Label

3.2.26 Attachment-XXVI: Market returned product under hold label

3.2.27 Attachment-XXVII: Specimen issuance label for log

3.2.28 Attachment-XXVIII: Validation sample label

3.2.29 Attachment-XXIX: Label for swab/ rinse sample

3.2.30 Attachment-XXX: Daily verification Status for Weighing Balance

3.2.31 Attachment-XXXI: Filter cleaning status label

3.2.32 Attachment-XXXII: Disinfectant/ Detergent/ Deactivating/ Sanitizing solution Label

3.2.33 Attachment-XXXIII: Label of Stock / Stability Solution

3.2.34 Attachment-XXXIV: Label of Reference / Impurity Standard

3.2.35 Attachment-XXXV: Label of Working Standard

3.2.36 Attachment-XXXVI: Label for Instrument/ Equipment (In-house Code)

3.2.37 Attachment-XXXVII: Label for Restricted entry (Quality Control Department)

3.2.38 Attachment-XXXVIII: Label for Glassware in Use

3.2.39 Attachment-XXXIX: Label for Column/Syringe/Plunger Flushing

3.2.40 Attachment-XL: Status Label for HPLC/GC Analysis

3.2.41 Attachment-XLI: Status Label for Dissolution Test

3.2.42 Attachment-XLII: Status Label for Analysis (Other than HPLC/GC & Dissolution)

3.2.43 Attachment-XLIII: Label for Karl Fisher Reagent

3.2.44 Attachment-XLIV: Label Methanol for Karl Fisher Reagent

3.2.45 Attachment-XLV: Status Label for Mobile Phase

3.2.46 Attachment-XLVI: Status Label for TLC Chamber

3.2.47 Attachment-XLVII: Specimen Label for Bulk Finished Placebo

3.2.48 Attachment-XLVIII: Specimen Label for Placebo for Analytical Purpose

3.2.49 Attachment-XLIX: Isopropyl alcohol (IPA) 70% (v/v) Solution Label

3.2.50 Attachment-XLX: Material for Destruction Label

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4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Nil

4.2 Abbreviations

4.2.1 etc.: Etcetera

4.2.2 QA: Quality Assurance

4.2.3 A.R. No.: Analytical Reference Number

4.2.4 B. No.: Batch Number

4.2.5 No.: Number

4.2.6 Wt.: Weight

4.2.7 QC: Quality Control

4.2.8 IPA: Iso Propyl Alcohol

4.2.9 V/V: Volume by Volume

4.2.10 SOP: Standard operating procedure

4.2.11 Qty.: Quantity

4.2.12 GR No.: Goods receipt number

4.2.13 Avg.: Average

5.0 RESPONSIBILITY

5.1 Applicable Departments

5.1.1 To prepare and display proper labels at appropriate stages/activity/times.

5.2 Applicable Department Heads

5.2.1 To check whether the labels are properly affixed as per SOP.

5.3 Quality Assurance Head:

5.3.1 To ensure implementation of system as per defined procedure.

5.4 Plant Head:

5.4.1 To ensure implementation of system as per defined procedure.

6.0 Distribution:

I. Quality Assurance

II. Production

III. Ware house

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IV. Engineering
V. Human resource and Administration
VI. Environment, Health and safety
VII. Quality Control

7.0 PROCEDURE:

7.1 Concern department will prepare the specimen for label by following the attachments of this standard operating procedure.

7.2 Head of concern department will approve the label.

7.3 Approved format will send to QA department for approval. After QA approval specimen will be sent to purchase department for printing of the label.

7.4 Purchase department will receive the approved specimen of label and proceed for final printing of labels as per the requirement.

7.5 Any printed labels left after updation in label format shall be destroyed.

7.6 All equipments, in-process material, finished product, containers etc. shall be labeled appropriately and at all times. No unlabeled equipment, in-process material, finished product etc., shall be taken / used for processing:

7.7 All equipment containers, area, pack and in-process shall be labeled before the start of the activity to clearly depict their status and identification.

7.8 Labels shall be attached in a manner that they are clearly visible.

7.9 Text of the label shall be in clear and legible language.

7.10 Concerned persons shall sign with date on labels properly.

7.11 **Quarantine Status Label (Raw/ Packing Material):** This label shall be affixed by warehouse person on consignment of raw or packaging materials received from manufacturer /supplier as per Attachment-I.

7.12 **Sampled**: After sampling of raw material/ packing materialfrom the received consignment from manufacturer /supplieror after sampling of in-process material, affix the sampled label as per Attachment-II on the container/ bag/ unit from which the sampling is done.

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7.13 **Under Test**:This label is affixed after taking sample of raw /packing material from the received consignment from manufacturer /supplier, on in-process material and finished product which is under analysis. Affix the labels on each container/ bag/ unit as per Attachment-III near the Sampled Label.

7.14 **Sample for Analysis (Raw/ Packing/ In-Process Material/ Finished Product)**:This label is affixed on sample poly bag/ bottle/ poly bag containing raw material/ packing material/ in-process/ finished product sample for analysis purpose as per Attachment-IV.

7.15 **Passed Label (Raw/ Packing/ In-Process Material/ Finished Product)**: After Approval of batches affix passed label on the container/bag/unit as per Attachment-V over under test label in such a way that the passed label shall completely hide the "UNDER TEST" label.

7.16 **Rejected Label (Raw/ Packing/ In-Process Material/ Finished Product)**: This label is affixed on Raw /Packing/ In-process Material/ Finished Product as per Attachment-VI when material does not comply the specifications of Pharmacopoeia or In-House specifications. It shall be affixed on the "UNDER TEST" label by completely hiding the "UNDER TEST" label.

7.17 **Dispensing label**: This label is affixed on raw and packing material after dispensing from warehouse as per Attachment-VII.

7.18 **Loose Pack label (Raw/Packing Material)**: This label is affixed on loose container of raw/ packing material as per Attachment-VIII.

7.19 **Repacking label (Raw/Packing material)**: This label is affixed on repacking of Raw/ Packing material as per Attachment-IX.

7.20 **Control sample Label (Raw material)**: This label is affixed on the container/poly bag containing control sample of raw materials as per Attachment-X. This label shall be prepared and affixed by Quality Control person.

7.21 **Control Sample label (Finished Product)**: This label is affixed on the container such as cartons/poly bag containing finished product as per Attachment-XI.

7.22 **Under Hold Label (In-process material/ Finished Product)**:If at any stage during manufacturing / packing operation, process is stopped or not continued due to reasons, which require investigation, etc., then "HOLD" label shall be pasted as per Attachment-XII.

7.23 **Scrap Material label**: This label is affixed on container/ polybag of Scrap as Attachment-XIII.

7.24 **To be cleaned label**: All equipment/accessory to be cleaned shall bear a status label "TO BE CLEANED" as per Attachment-XIV. Details of previous product shall be given on the label per Attachment-XIV.

7.25 **Cleaned label**: After cleaning, the equipment shall bear status label as "CLEANED" (as per Attachment-XV). Cleaning shall be done by user department. If after cleaning, equipment is not used within 07 days, re-cleaning shall be carried out (as per Attachment-XV).

7.26 **Material return label**: This label is affixed on those containers of excess material which are returned from production to ware house, as per Attachment-XVI.

7.27 **Under breakdown maintenance label:** When Instrument/equipment under maintenance due to breakdown of the equipment/instrument, then affix the label "UNDER BREAKDOWN MAINTENANCE" as per Attachment-XVII.

7.28 **Area status label**: Area in which the dispensing/ manufacturing/ packing is being done shall bear the "AREA STATUS" label that gives the details of product under process as per Attachment-XVIII.

7.29 **On line rejection label**: This label is affixed on containers/materials which are rejected at the time of manufacturing / packing stage, as per Attachment-XIX.

7.30 **Preventive maintenance status label**: This label is affixed after preventive maintenance of equipments is completed as per Attachment-XX.

7.31 **Under Preventive Maintenance Status Label:** This label is affixed during preventive maintenance of equipments as per Attachment- XXI.

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7.32 **Calibration Status label**: When instrument /equipment is calibrated in-house then this label affixed on the calibrated instrument/equipment as per Attachment-XXII.

7.33 **Out of Calibration Status Label:** If calibration of instrument has expired/or failed then user department shall affix "OUT OF CALIBRATION" label as per Attachment-XXIII.

7.34 **FOR ETP**: This label is affixed on container containing material or product for disposition in ETP as per Attachment- XXIV.

7.35 **Loose Shipper Label**: "LOOSE SHIPPER" label shall be affixed on the shipper having less than the standard quantity bearing all the details related to product as per Attachment-XXV. The original stamped /labeled quantity on the shipper shall be appropriately modified with sign and date by Production personnel.

7.36 **Market return product under hold label:** When material is returned from market then affix the label "UNDER HOLD (MARKET RETURNED) as per Attachment-XXVI.

7.37 **Specimen Issuance Label for Log:** This label is affixed on the log as per Attachment-XXVII at the time of issuance to user department by QA person.

7.38 **ValidationSample**: This label is affixed on the validation samples which shall be sent to QC for analysis purpose as per Attachment – XXVIII.

7.39 **Label for Swab/ Rinse Sample**: "SWAB/ RINSE SAMPLE" label shall be affixed on the test tube stand or on the wrapper containing the swab samples and on the container of rinse sample as per Attachment-XXIX.

7.40 **Daily verification status for weighing balance:** This label shall be affixed on the weighing balance for daily verification status as per Attachment-XXX.

7.41 **Filter cleaning Status Label:** This label is used for filter cleaning status of AHU as per Attachment – XXXI.

7.42 **Disinfectant/ Detergent/Deactivating/Sanitizing solution Label**: This label shall be on the containers in which Cleaning agents/ deactivating/ disinfectant/ sanitizing solutions shall be stored in the designated areas as per Attachment- XXXII.

7.43 **Label of Stock/Stability Solution:** This label shall be affixed on Stock/ Stability solution as per Attachment-XXXIII.

7.44 **Label of Reference / Impurity Standard:** This label shall be affixed on Reference / Impurity Standard as per Attachment-XXXIV.

7.45 **Label of Working Standard:** This label shall be affixed on Reference / Impurity Standard as per Attachment-XXXV.

7.46 **Label for Instrument/ Equipment (In-House Code):** This label shall be affixed on Instrument/ Equipment in Quality Control department as per Attachment-XXXVI.

7.47 **Label for Restricted Entry (Quality Control Department):** This label shall be used for Restricted Entry in Quality Control department as per Attachment-XXXVII.

7.48 **Label for Glassware in Use:** This label shall be affixed on the glassware in use in Quality Control department as per Attachment-XXXVIII.

7.49 **Label for Column/Syringe/Plunger Flushing:** This label shall be affixed on the solvent used for Column/Syringe/Plunger Flushing in Quality Control department as per Attachment-XXXIX.

7.50 **Status Label for HPLC/GC Analysis:** This label shall be affixed on HPLC/ GC used for analysis in Quality Control department as per Attachment-XL.

7.51 **Status Label for Dissolution Test:** This label shall be affixed on Dissolution Apparatus used for analysis in Quality Control department as per Attachment-XLI.

7.52 **Status Label for Analysis (Other than HPLC/ GC& Dissolution):** This label shall be affixed on equipment/ instrument used for analysis other than HPLC/ GC and Dissolution Apparatus in Quality Control department as per Attachment-XLII.

7.53 **Label for Karl Fischer Reagent:** This label shall be used for Karl Fischer Reagent in Quality Control department as per Attachment-XLIII.

7.54 **Label for Methanol for Karl Fischer Reagent:** This label shall be used for methanol for Karl Fisher Reagent in Quality Control department as per Attachment-XLIV.

7.55 **Status Label for Mobile Phase:** This label shall be used for mobile phase in Quality Control department as per Attachment-XLV.

7.56 **Status Label for TLC Chamber:** This label shall be used for TLC Chamber in Quality Control department as per Attachment-XLVI.

7.57 **Specimen Label for Bulk Finished Placebo:** This label shall be affixed on the bulk finished placebo after completion of batch manufacturing and before start of packing activity as per Attachment-XLVII.

7.58 **Specimen Label for Placebo for Analytical Purpose:** This label shall be affixed on the bulk finished placebo after completion of manufacturing of a placebo batch required for analytical purpose as per Attachment-XLVIII.

7.59 **Isopropyl Alcohol (IPA) 70% V/V Solution label**: This label is affixed on the container of disinfectant solution as per Attachment-XLIX.

7.60 **Material for Destruction Label:** This label is affixed on the container of material to be destroyed as per Attachment-XLX.

NOTE: Put (-) mark or 'NA' in the provided space of label which is not required or not applicable.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

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Attachment-I

QUARANTINE STATUS LABEL
(RAW/PACKING MATERIAL)

	QUARANTINE
Material/ Item Name:	
Item Code :	
Vendor Batch/ Lot No.:	
Mfg. Date :	**Exp. Date:**
Total Quantity :	
Total Packs/ Containers (Nos.): _____	**Container/ Pack No.: ____ of ____**
Signature :	**Date:**
Format No……..	

Color of Shading: Yellow

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Attachment-II

SAMPLED LABEL
(RAW/ PACKING/ IN-PROCESS MATERIAL)

	SAMPLED
Sampled By: **Sign/ Date**	
Format No…….	

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Attachment-III

UNDER TEST LABEL
(RAW/PACKING/ IN-PROCESS MATERIAL/FINISHED PRODUCT)

	UNDER TEST
Product/ Item Name :	
Batch / Lot No. :	
Item Code :	
A.R. No. :	
Mfg. Date :	**Exp. Date:**
Stage :	
GR No. :	**GR Date:**
Total Quantity :	
Total Packs/ Containers (Nos.): _____	**Container/ Pack No.: ____ of ____**
Quantity/ Pack or Container: _____	
Manufacturer/ Supplier Name:	
Signature :	**Date:**
	Format No……

Color of Shading: Yellow

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Attachment-IV

SAMPLE FOR ANALYSIS
(RAW/ PACKING/IN-PROCESS MATERIAL/FINISHED PRODUCT)

	SAMPLE FOR ANALYSIS		
Type of Sample :		**Sampling Stage:**	
Name of Sample:			
Batch No. :		**Lot No.:**	
Item Code :		**Qty. Sampled:**	
Mfg. date :		**Expiry date:**	
A.R. No. :		**GR No.:**	
Manufacturer/Supplier Name:			
Sampled By Sign / Date		**Sampled at Time**	
			Format No……..

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Attachment-V

PASSED LABEL
(RAW/PACKING/ IN-PROCESS MATERIAL/ FINISHED PRODUCT)

	PASSED
Product/ ItemName:	
Batch/ Lot No. :	
Item Code :	
A.R. No. :	
Mfg. Date :	**Exp. Date:**
Stage :	
GR No. :	
Total Quantity :	
Total Packs/ Containers (Nos.): _____	**Container/ Pack No.: ____ of ____**
Signature :	**Date:**
	Format No……

Color of Shading: Light Green

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Attachment-VI

REJECTED LABEL
(RAW/PACKING/ IN-PROCESS MATERIAL/ FINISHED PRODUCT)

	REJECTED

Product/ Item Name:
Batch/ Lot No. :
Item Code :
Mfg. Date : **Exp. Date :**
Stage :
Total Quantity :
Total Packs/ Containers (Nos.): _____ **Container/ Pack No.: ____ of ____**
Gross Wt.: **Tare Wt.:** **Net Wt.:**
GR No. : **A.R. No.:**
Supplier/ Manufacturer Name:
Reason for Rejection:

Prepared by (Sign/ Date)	**Checked by QA (Sign/ Date)**

Format No……..

Color of Shading: RED

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Attachment-VII

DISPENSING LABEL (RAW/PACKING MATERIAL)

	DISPENSING LABEL	
Item Name : **Item Code :** **A.R. No. :** **Pack No.:** **Product Name :** **B. No. :** **Lot No.:** **Gross Wt. :** **Tare Wt. :** **Net Wt./ Nos. :**		
Dispensed By (Sign/ Date)	**Checked By (Sign/ Date)**	**Verified By (Sign/ Date)**
Format No……..		

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Attachment-VIII

LOOSE PACK LABEL (RAW/PACKING MATERIAL)

	LOOSE PACK LABEL **(RAW / PACKING MATERIAL)**
Item Name :	
Item Code :	
Batch No. :	
A.R. No. :	
Net Quantity :	
Signature / Date :	
	Format No……..

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Attachment-IX

REPACKING LABEL FOR RAW / PACKING MATERIAL

	REPACKING LABEL **(RAW/PACKING MATERIAL)**
Item Name : **Item Code :** **Batch No. :** **Mfg. Date :** **Exp. Date:** **Manufacturer/ Supplier Name:** **No. of Containers/ Packs: _____ of _____** **Gross Wt.:** **Tare Wt.:** **Net Wt.:** **Reason :**	
Prepared by Warehouse **(Sign/ Date)**	**Checked By Quality Assurance** **(Sign/ Date)**
Format No……	

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Attachment-X

CONTROL SAMPLE LABEL
(RAW MATERIAL)

	CONTROL SAMPLE **(RAW MATERIAL)**		
Item Name :			
Item Code :			
Batch/ Lot No. :			
A.R. No. :			
Mfg. Date :		**Exp. Date:**	
Quantity of sample:			
Prepared By Sign / Date		**Disposal due On (one year after expiry)**	
			Format No……..

Color of Shading: ORANGE

Format No……

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Attachment-XI

CONTROL SAMPLE LABEL
(FINISHED PRODUCT)

	CONTROL SAMPLE **(FINISHED PRODUCT)**
Format No……	

Color of Shading: ORANGE

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Attachment-XII

UNDER HOLD LABEL
(IN-PROCESS MATERIAL/FINISHED GOOD)

	UNDER HOLD **(IN-PROCESS MATERIAL / FINISHED PRODUCT)**
Product Name	**:**
Batch/ Lot No.	**:**
Batch Size	**:**
Mfg. Date	**:** **Exp. Date:**
Container No.	**: _____ of _____**
Reason for Hold	**:**
QA (Sign/Date)	**:**
	Format No……

Color of Shading: Yellow

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Attachment-XIII

SCRAP MATERIAL LABEL

	SCRAP MATERIAL
Type of Scrap : **Gross Wt.:** **Tare Wt.:** **Net Wt.:** **Quantity in Nos.:** **Department :**	
Prepared By/ Date	**Checked By/ Date**
Format No. ……..	

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Attachment-XIV

TO BE CLEANED LABEL

	TO BE CLEANED
Area:	
Equipment/ Accessory Code No.:	
Previous Product	**:**
Previous Batch No.	**:**
Prepared by (Sign / Date)	**:**
	Format No……..

Color of Shading: Red

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Attachment-XV

CLEANED LABEL

	CLEANED
Equipment/ Accessory Name:	
Code No./ Area	**:**
Previous Product	**:**
Previous Batch No.	**:**
Cleaned By/Date	**:**
Use Before	**:**
Checked By/Date	**:**
Note: If not used within 07 days from date of cleaning, then re-clean before use	
Format No. ……..	

Color of Shading: Light Green

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Attachment-XVI

MATERIAL RETURN LABEL

	MATERIAL RETURN	
Material Name: **Item Code:** **A.R. No.:** **Product Name:** **Batch No.:** **Gross Wt. (kg):** **Quantity (in Nos.):** **Tare Wt. (kg):** **Net Wt. (kg):**		
Prepared by Production (Sign/Date)	**Checked By QA (Sign/Date)**	**Received By Warehouse (Sign/Date)**
		Format No…….

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Attachment-XVII

UNDER BREAKDOWN MAINTENANCE LABEL

	UNDER BREAKDOWN MAINTENANCE
Equipment/ Instrument Name:	
Code No.	**:**
Nature of Breakdown	**:**
Sign/Date	**:**
	Format No. ……

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Attachment-XVIII

AREA STATUS LABEL

	AREA STATUS
Product/ Item :	
Batch/ A.R. No. :	**Lot No.** :
Batch Size :	
Mfg. Date :	**Exp. Date** :
Status/ Stage :	
M.R.P. :	
Signature :	
Date :	
Format No……	

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Attachment-XIX

ON LINE REJECTION LABEL

	ON LINE REJECTION
Material Name: **Item Code:** **A.R. No.:** **Product Name:** **Batch No.:** **Gross Wt. (kg):** **Tare Wt. (kg):** **Net Wt. (kg):** **Quantity (Nos.):**	
Reason for Rejection:	
Prepared By User (Sign/Date)	
Checked By QA (Sign/Date)	
Format No……..	

Color of Shading: Red

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Attachment-XX

PREVENTIVE MAINTENANCE STATUS LABEL

	PREVENTIVE MAINTENANCE STATUS
Equipment/ Instrument Name: **Code No. :** **Done on :** **Due on :** **Done By (Sign/ Date):**	
Format No……	

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Attachment-XXI

UNDER PREVESNTIVE MAINTENANCE STATUS LABEL

	UNDER PREVENTIVE MAINTENANCE
SIGN : _____ **DATE : _____**	
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXII

CALIBRATION STATUS LABEL

	CALIBRATION STATUS

Department:

Equipment/Instrument Name:

Code No.:

Calibrated On :

Calibration Due On :

Calibrated By (Sign/Date):

Format No……..

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXIII

OUT OF CALIBRATION STATUS LABEL

	OUT OF CALIBRATION
Department: **Equipment / Instrument Name:** **Code No.:** **Sign / Date:**	
Format No……	

Color of Shading: Red

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXIV

FOR ETP LABEL

	FOR ETP
Material/Product :	
Quantity (Weight / Nos.) :	
Department :	
Checked By :	**Date :**
	Format No……

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XXV

LOOSE SHIPPER LABEL

	LOOSE SHIPPER
Product Name : **B. No. :** **Mfg. Date :** **Exp. Date :** **Quantity :**	
Production **Sign/ Date**	**QA** **Sign/ Date**
Format No……	

Color of Shading: Red

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXVI

MARKET RETURNED PRODUCT UNDER HOLD LABEL

	UNDER HOLD (MARKET RETURNED)
Product Name :	
Batch No. :	
Mfg. Date :	**Exp. Date:**
Total No. of Shippers :	
Total Qty. (Unit Packs) :	
Reason :	
Date of Receipt :	
Received By Name :	
Prepared By (Sign/Date):	
Format No…….	

Color of Shading: Yellow

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXVII

SPECIMEN ISSUANCE LABEL FOR LOG

	ISSUANCE LABEL FOR LOG
Year:	**Department:**
Log Title:	
Format No.:	**Reference SOP No.:**
Log book/ Register Serial No. particular to that area/ equipment:	**Total No. of Page(s):**
Area Name:	**Area Code No.:**
Equipment Name:	**Equipment Code No.:**
Date of Issue:	**Log book/ Register Usage Period (Date):** **_____ to _____**
Issued by QA **(Sign / Date):**	**Received by** **(Sign / Date):**
Completed Log Submitted by **(Sign / Date):**	**Completed Log Retrieved by** **QA(Sign / Date):**
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XXVIII

VALIDATION SAMPLE LABEL

	VALIDATION SAMPLE
Product Name:	
Batch No.:	**Batch Size:**
Stage:	**Avg. Weight:**
Sampled Qty.:	
Sampled By QA (Sign):	
Date/Time:	
Format No……..	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XXIX

LABEL FOR SWAB/RINSE SAMPLE

	SWAB/RINSE SAMPLE
Equipment Name: **Code No.:** **Previous Product Name:** **Previous B. No.:** **Purpose of Sample: Chemical/ Microbial** **Sample No.: _____ of _____** **Sampled By QA (Sign):** **Date/Time:**	
Format No…….	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXX

DAILY VERIFICATION STATUS LABEL FOR WEIGHING BALANCE

	DAILY VERIFICATION STATUS (WEIGHING BALANCE)
Department:	**Date:**
Code No.: _____ **Capacity: _____** **Least Count: _____** **Operating Range: Min.: _____** **Max.: _____** **Verification Done On : _____** **Verification Done By (Sign / Date): _____**	
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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Attachment-XXXI

FILTER CLEANING STATUS LABEL

	FILTER CLEANING STATUS
AHU Code No.:	
Pre Filter Size:	**Code No.:**
HEPA Filter Size:	**Code No.:**
Return Filter Size:	**Code No.:**
Done Date:	**Due Date:**
Checked by (Sign/ Date):	
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XXXII

DISINFECTANT/DETERGENT/DEACTIVATING/SANITIZING SOLUTION LABEL

	DISINFECTANT/DETERGENT/ DEACTIVATING/SANITIZING SOLUTION
Block Name:	**Department/Area Name:**
Disinfectant/Detergent/Deactivating/Sanitizing agent : **Prepared on :** **Valid up to :**	
Prepared By (Sign/ Date)	**Checked By (Sign/ Date)**
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXXIII

LABEL OF STOCK/STABILITY SOLUTION

	STOCK/STABILITY SOLUTION		
Name			
Preparation date			
Solution for		**For product**	
Prepared By		**Checked By**	
Storage condition			
			Format No……

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXXIV

LABEL OF REFERENCE/IMPURITY STANDARD

	REFERENCE/IMPURITY STANDARD		
Name			
Identification / Code No.		**Purity (as specified)**	
Validity of use		**For purpose**	
Labeled by		**Checked By**	
Storage Condition			
			Format No……

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXXV

LABEL OF WORKING STANDARD

	WORKING STANDARD			**Vial for the month**
Name				
W.S. No.		**Effective Date**		
Assay (as is)		**Vial No. / No. of vial.**	**___ of____**	
Water content/LOD		**Use Before**		
Prepared By/Date		**Checked By / Date**		
Storage Condition				
			Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXXVI

LABEL FOR INSTRUMENT/EQUIPMENT (IN-HOUSE CODE)

	INSTRUMENT/EQUIPMENT (In-house Code)
Name: …….. **ID No. :** ……..	
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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Attachment-XXXVII

LABEL FOR RESTRICTED ENTRY

(QUALITY CONTROL DEPARTMENT)

	QUALITY CONTROL DEPARTMENT
RESTRICTED ENTRY **ONLY FOR AUTHORIZED PERSONNEL**	
Format No…….	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXXVIII

LABEL FOR GLASSWARE IN USE

Name:
A.R. No.:
Test/Dilution:
Sign: **Date:**
Format No. ……

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XXXIX

LABEL FOR COLUMN/SYRINGE/PLUNGER FLUSHING

	COLUMN/SYRINGE/ PLUNGER FLUSHING
Solvent: **Date of Dispensing/Preparation:** **Valid Up to:** **Sign:** **Date:**	
Format No……..	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XL

STATUS LABEL FOR HPLC/GC ANALYSIS

	HPLC/GC ANALYSIS STATUS
Product Name:	
Batch No./A.R. No.:	
Mobile Phase:	
Column No.:	
Test:	
Sign:	**Date:**
	Format No……

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLI

STATUS LABEL FOR DISSOLUTION TEST

	DISSOLUTION ANALYSIS STATUS
Product Name:	
Batch No./A.R. No.:	
Medium:	
RPM:	
Test:	
Sign:	**Date:**
	Format No……..

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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Attachment-XLII

STATUS LABEL FOR INSTRUMENT ANALYSIS (OTHER THAN HPLC/GC & DISSOLUTION)

	INSTRUMENT ANALYSIS STATUS
Product Name:	
Batch No./A.R. No.:	
Test:	
Sign:	**Date:**
	Format No……..

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLIII

LABEL FOR KARL FISCHER REAGENT

	KARL FISCHER REAGENT
Batch No.: **Valid Up to:** **Sign:** **Date:**	
Format No.	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLIV

LABEL FOR METHANOL FOR KARL FISHER REAGENT

	METHANOL FOR KARL FISHER REAGENT
Batch No.:	
Manufacturer:	
Valid Up to:	
Sign:	**Date:**
	Format No……..

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLV

STATUS LABEL FOR MOBILE PHASE

	MOBILE PHASE STATUS
Product Name:	
Batch No./A.R. No.:	
Composition:	
Test:	
Prepared on:	
Valid Up to:	
Sign:	**Date:**
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLVI

STATUS LABEL FOR TLC CHAMBER

	TLC CHAMBER ANALYSIS STATUS
Product Name:	
Batch No./A.R. No.:	
Start Time:	
Test:	
Sign:	**Date:**
	Format No……..

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLVII

SPECIMEN LABEL OF BULK FINISHED PLACEBO

	BULK FINISHED PLACEBO
Product Name : **Component Excluded :** **Batch No.:** **Mfg. date :** **Valid Up to:** **Signature :** **Date:**	
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLVIII

SPECIMEN LABEL OF PLACEBO FOR ANALYTICAL PURPOSE

	PLACEBO FOR ANALYTICAL PURPOSE
Product Name : **Component Excluded :** **Batch No.:** **Mfg. date :** **Valid Up to:** **Signature :** **Date:**	
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment-XLIX

ISOPROPYL ALCOHOL (IPA) 70% (V/V) SOLUTION LABEL

	ISOPROPYL ALCOHOL (IPA) 70% v/v
Date of Preparation : **Use Before :**	
Prepared By **(Sign/ Date)**	**Checked By** **(Sign/ Date)**
Format No……	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Status Labeling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XLX

MATERIAL FOR DESTRUCTION LABEL

	MATERIAL FOR DESTRUCTION
Material/Product :	
Quantity (Weight / Nos.) :	
Department :	
Prepared By : **(Sign/ Date)**	**Checked By :** **(Sign/ Date)**
Format No……	