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Issue Da	Issue Date: Page No.:			
1.0	PURPOSE			
	To define a procedure for Status labeling	<u>;</u> .		
2.0	SCOPE			
2.1	This procedure applies to labels used at .			
2.2	Specific departments under the scope of	f this SOP are "Quality Assurance, Quality Control, Production,		
	Warehouse, Engineering, Environment, l	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 (I	Raw/ Packing material)		
3.2.2	Attachment-II: Sampled Label (Raw/pac	king/ In-process material)		
3.2.3	Attachment-III: Under test label (Raw/pa	acking/ In-process material/ Finished Product)		
3.2.4	Attachment-IV: Sample for Analysis (Ra	aw/packing/ In-process material/ Finished Product)		
3.2.5	Attachment-V: Passed Label Analysis (R	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 Ma	aterial)		
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 Ma	aintenance Label		
3.2.18	8 Attachment-XVIII: Area Status Label			
3.2.19	Attachment-XIX: Online Rejection Labe	1		

III XXX	CELAND AND OPEN A SENIC PRO CEDANDE			
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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	Attachment-XXII: Calibration Status Label		
3.2.23	Attachment-XXIII: Out of Calibration Status Lab	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	er 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 Te	st		
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 Chambe	er		
3.2.47	Attachment-XLVII: Specimen Label for Bulk Fir	nished Placebo		
3.2.48	Attachment-XLVIII: Specimen Label for Placebo	o 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



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- III. Ware house
- 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.
- 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.
- 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 material from 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.



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- 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.



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- 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.



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- 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: N	ew SOP Prepared		



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Attachment-I

QUARANTINE STATUS LABEL (RAW/PACKING MATERIAL)

	QUARANTINE			
Material/ Item Name:				
Item Code	:			
Vendor Batch/ Lot	Vendor Batch/ Lot No.:			
Mfg. Date	:	Exp. Date:		
Total Quantity	:			
Total Packs/ Conta	iners (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/ Container	s (Nos.):	Container/ Pack No.: of	·
Quantity/ Pack or Cont	tainer:		
Manufacturer/ Supplie	r 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/Su	ıpp	lier Name:		
Sampled By Sign / Date		Sampled at Time		
		<u>'</u>	Format No	



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Attachment-V

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

		PASSED	
Product/ ItemNa	me:		
Batch/ Lot No.	:		
Item Code	:		
A.R. No.	:		
Mfg. Date	:	Exp. Date:	
Stage	:		
GR No.	:		
Total Quantity	:		
Total Packs/ Con	tainers (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 N	lame:		
Batch/ Lot No.	:		
Item Code	:		
Mfg. Date	:		Exp. Date:
Stage	:		
Total Quantity	:		
Total Packs/ Co	ntainers (N	os.): Co	ontainer/ Pack No.: of
Gross Wt.:	T	Tare Wt.:	Net Wt.:
GR No.	:	A.R. No.:	
Supplier/ Manu	facturer Na	ame:	
Reason for Reje	ection:		
Prepar	red by (Sign	n/ 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	Pack No.:	
Product Name	:			
B. No.	:	Lot	Lot No.:	
Gross Wt.	:			
Tare Wt.	:			
Net Wt./ Nos.	:			
Dispensed 1 (Sign/ Dat		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

		PACKING LABEL W/PACKING MATERIAL)
Item Name :		
Item Code :		
Batch No. :		
Mfg. Date :		Exp. Date:
Manufacturer/ Supp	lier Name:	
No. of Containers/ Pa	acks:	of
Gross Wt.:	Tare Wt.:	Net Wt.:
Reason :		
Prepared by (Sign/		Checked By Quality Assurance (Sign/ Date)
		Format No



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Attachment-X

CONTROL SAMPLE LABEL (RAW MATERIAL)

		CONTROL SAM (RAW MATERIAL)	
Item Name	:		
Item Code	:		
Batch/ Lot No.	:		
A.R. No.	:		
Mfg. Date	:	Exp. Date:	
Quantity of samp	le:		
Prepared By Sign / Date		Disposal due On (one year after expiry)	
			t No

Color of Shading: ORANGE

Format No.....



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Attachment-XI

CONTROL SAMPLE LABEL (FINISHED PRODUCT)



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.: Quantity in Nos.: Department :	Tare Wt.:	Net Wt.:
Prepared 1	By/ Date	Checked By/ Date
		Format No



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Attachment-XIV

TO BE CLEANED LABEL

,	TO BE CLEANED	
Area:		
Equipment/ Accessory Cod	le 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/ Accesso	ry 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/ Instru	
Code No.	:
Nature of Breakdo	wn :
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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PREVENTIVE MAINTENANCE STATUS LABEL

	PREVENTIVE MAINTENANCE STATUS	
Equipment/ Instrumen	t 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



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Attachment-XXII

CALIBRATION STATUS LABEL

	CALIBRATION STATUS	
Department: Equipment/Instrumen	t Name:	
Code No.:		
Calibrated On:		
Calibration Due On:		
Calibrated By (Sign/Date):		
	Format No	



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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



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Attachment-XXIV

FOR ETP LABEL

	FOR ETP
Material/Produ	ict:
Quantity (Weig	ght / Nos.):
Department :	
Checked By :	Date :
	Format No



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Attachment-XXV

LOOSE SHIPPER LABEL

	LO	OSE SHIPPER
Product Name	:	
B. No.	:	
Mfg. Date	:	
Exp. Date	:	
Quantity	:	
Pro	oduction	QA
Sig	gn/ Date	Sign/ Date
_		Format No

Color of Shading: Red



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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	e):		

Format No.....

Color of Shading: Yellow



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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		Received by	
(Sign / Date):		(Sign / Date):	
Completed Log Submitted by		Completed Log Retrieved by	
(Sign / Date):		QA(Sign / Date):	
		Format No	



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Attachment-XXVIII

VALIDATION SAMPLE LABEL

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



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Attachment-XXIX

LABEL FOR SWAB/RINSE SAMPLE

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



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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



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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	



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Attachment-XXXII

DISINFECTANT/DETERGENT/DEACTIVATING/SANITIZING SOLUTION LABEL

	DISINFECTANT/DETERGENT/ DEACTIVATING/SANITIZING SOLUTION			
Block Name:		Department/Area N	lame:	
Disinfectant/Detergent	/Deactivating/S	Sanitizing agent :		
Prepared on :	Prepared on:			
Valid up to:				
Prepared 1	By	Checke	ed By	
(Sign/ Dat	(e)	(Sign/	Date)	
]	Format No	



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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	



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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



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Attachment-XXXV

LABEL OF WORKING STANDARD

	WORKING STANDAR	RD	
Name			nth
W.S. No.	Effective Date		e month
Assay (as is)	Vial No. / No. of vial.	of	r the
Water content/LOD	Use Before		 Vial for
Prepared By/Date	Checked By / Date		
Storage Condition	1		
_		Format No	••••



QUALITY ASSURANCE DEPARTMENT

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Attachment-XXXVI

LABEL FOR INSTRUMENT/EQUIPMENT (IN-HOUSE CODE)

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



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Attachment-XXXVII

LABEL FOR RESTRICTED ENTRY (QUALITY CONTROL DEPARTMENT)

QUALITY CONTROL DEPARTMENT

RESTRICTED ENTRY ONLY FOR AUTHORIZED PERSONNEL

Format No....



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Attachment-XXXVIII

LABEL FOR GLASSWARE IN USE

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



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Attachment-XXXIX

LABEL FOR COLUMN/SYRINGE/PLUNGER FLUSHING

	COLUMN/SYRINGE/	
	PLUNGER FLUSHING	r T
Solvent:		
Date of Dispensing/Preparation:		
Valid Up to:		
Sign:	Date:	
	Format No	



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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	



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Attachment-XLI

STATUS LABEL FOR DISSOLUTION TEST

	DISSOLUTION A STATU	
Product Name:		
Batch No./A.R. No.:		
Medium:		
RPM:		
Test:		
Sign:	Date:	
	Fo	ormat No



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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	



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Attachment-XLIII

LABEL FOR KARL FISCHER REAGENT

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



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Attachment-XLIV

LABEL FOR METHANOL FOR KARL FISHER REAGENT

	METHANOL FOR KARL FISHER REAGENT
Batch No.:	
Manufactu	irer:
Valid Up t	0:
Sign:	Date:
	Format No



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Attachment-XLV

STATUS LABEL FOR MOBILE PHASE

	MOBILE PHA	SE STATUS
Product	Name:	
Batch No	o./A.R. No.:	
Composi	ition:	
Test:		
Prepare	d on:	
Valid Up	to:	
Sign:	Date:	
		Format No



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Attachment-XLVI

STATUS LABEL FOR TLC CHAMBER

	TLC CHAMBE STA	
Product Na	me:	
Batch No./A.R. No.:		
Start Time:		
Test:		
Sign:	Date:	
		Format No



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Attachment-XLVII

SPECIMEN LABEL OF BULK FINISHED PLACEBO

	BULK FINISHED PLACEBO
Product Name:	
Component Exclu	ided:
Batch No.:	
Mfg. date :	
Valid Up to:	
Signature :	
Date:	
	Format No



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Attachment-XLVIII

SPECIMEN LABEL OF PLACEBO FOR ANALYTICAL PURPOSE

		_
	PLACEBO FOR ANALYTICAL PURPOSE	
Product Name:		
Component Exclude	ed:	
Batch No.:		
Mfg. date :		
Valid Up to:		
Signature :		
Date:		
	Format No	



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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	Checked By	
(Sign/ Date)	(Sign/ Date)	
	Format No	



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Attachment-XLX

MATERIAL FOR DESTRUCTION LABEL

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