



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Status Labeling	Effective Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Status Labeling.

2.0 SCOPE:

This SOP shall be applicable to Status Labeling for all Department of

3.0 RESPONSIBILITY:

QA (Officer/Executive): Preparation, Distribution (to Respective Departments), Revision, Retrieval & Destruction of this SOP.

QA Manager: Review, Approval, Training Effective implementation of this SOP in all the applicable areas.

Concern Departments: To follow Status Labeling in respective Areas.

4.0 ACCOUNTABILITY:

Head QA: Authorization of this SOP & ensure Training and effective Implementation of SOP. Training and Effective Implementation of this SOP.

5.0 DEFINITIONS:

Status Labeling is a stage where different types of Labels are affixed at various stages of Operations on Containers, Samples, Areas, Equipment's/Instruments and Bins. Different Color code is given to various Labels for proper identification.

6.0 PROCEDURE:

6.1 "QUARANTINE" LABEL:

6.1.1 'QUARANTINE' Label shall be affixed on the received Raw and Packaging Material in Warehouse by Warehouse person.

6.1.2 Specification of Label shall be 8.5 cm (L) X 6.0 cm (W)

6.1.3 Quarantine Label shall contain white background with text in Black.

6.1.4 Specimen of 'QUARANTINE' Label is as shown in **Annexure-I**.



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6.1.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
Name of Organization	08 Font Capital & Bold
Quarantine	14 Font Capital & Bold
Material Name, Item Code, GRN No., Date, Vendor Batch No., Manufacturing Date, Expiry Date, Total Qty., Date of Receipt, Container No., Manufacturer, Supplier, Stor. Loc., Prepared By (Sign / Date)	08 Font Running & Normal
Format No.	09 Font Capital & Normal

6.2 “SAMPLED” LABEL:

6.2.1 ‘SAMPLED’ Label shall be affixed on Sampled Container by QC Officer/Executive on the Right Upper Corner of the Quarantine Label.

6.2.2 Specification of the Label shall be 6.0 cm (L) X 3.0 cm (W). ‘Sampled Label’ shall be of White Color with logo on left side and printed ‘SAMPLED’ in Black Color.

6.2.3 Label shall contain the following details :

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
Sampled	28 Font Capital & Bold
Sampled By & Date	14 Font Running & Normal
Format No.	09 Font Capital & Normal

6.2.4 Specimen of ‘SAMPLED’ Label is as shown in **Annexure-II**.

6.3 “UNDER TEST” LABEL:

6.3.1 After sampling from the consignment QC Officer shall sample and affix ‘UNDER TEST’ Label on the ‘QUARANTINE LABEL’, by overlapping the part where ‘QUARANTINE’ word is written.

6.3.2 Specification of the Label shall be 7.5 cm (L) X 6.0 cm (W).



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6.3.3 Under Test Label contain Yellow Color Band with white background having logo on left side and printed 'UNDER TEST' in Black Color.

6.3.4 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width-0.27"
Under Test	24 Font Capital & Bold
Material Name, GRN No., Vendor Batch No., Insp. Lot. No., Container No., Stor. Loc., Sampled By, Date:	08 Running & Normal
Format No.	09 Font Capital & Normal

6.3.5 Specimen of 'UNDER TEST' Label is as shown in **Annexure-III**.

6.4 "APPROVED" LABEL:

6.4.1 'APPROVED' Label shall be affixed on the Raw and Packaging Material approved by QC, by overlapping the Under Test Label.

6.4.2 Specification of the Label shall be 7.5 cm (L) X 6.0 cm (W).

6.4.3 Approved Label shall contain Green Color Band with logo on left side and printed 'APPROVED' in Black Color.

6.4.4 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width-0.27"
Approved	26 Font Capital & Bold
Material Name, Vendor Batch No., ERP Batch No., GRN No., A.R. No., Assay, LOD: Water, Qty. Approved, Approval Date, Retesting Date, Approved By (Sign & Date)	08 Font Running & Normal
Format No.	09 Font Capital & Normal

6.4.5 Specimen of 'APPROVED' Label is as shown in **Annexure-IV**.

6.5 "REJECTED" LABEL:

6.5.1 'REJECTED' Label shall be affixed on the Raw and Packaging Material Rejected by QC.



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6.5.2 Specification of the Label shall be 7.5 cm (L) X 6.0 cm (W).

6.5.3 Rejected Label shall contain **Red Color Band** with white background having logo on left side and printed '**REJECTED**' in Black Color.

6.5.4 Label shall contain the following details :

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
Rejected	26 Font Capital & Bold
Material Name, Batch No., GRN No., A.R. No., Date of Analysis, Qty. Rejected, Rejection Reason, Checked By (Sign & Date)	08 Font Running & Normal
Format No.	09 Font Capital & Normal

6.5.5 Specimen of '**REJECTED**' Label is as shown in **Annexure-V**.

6.6 “LINE CLEARANCE” LABEL

6.6.1 '**LINE CLEARANCE**' Label shall be affixed on the Equipments, Machines and areas after taking the Line Clearance by Warehouse/Production, Executive/Officer form Quality Assurance Department before start of the Activity.

6.6.2 Line Clearance Label shall be filled by Warehouse/Production, Executive/Officer and cross verified by QA Executive/Officer and shall be signed along with Date.

6.6.3 Specification of the Label shall be 16.5 cm (L) x 9.0 cm (W).

6.6.4 Line Clearance Label shall contain **Green Color Band** with white background having logo on left side and printed '**LINE CLEARANCE**' in Black Color.

6.6.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
Line Clearance	18 Font Capital & Bold
Room No., Equipment Area, Department, Last Product Processed, Batch No., Product to Be Proceeded, Batch No., Checked By & Date	12 Font Running & Bold



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
(Warehouse/Production, Executive/Officer), Verified By & Date (QA Executive/Officer)	
Format No.	09 Font Normal & Capital

6.6.6 Specimen of ‘LINE CLEARANCE’ Label is as shown in **Annexure-VI**.

6.7 “TO BE INSPECTED” LABEL:

6.7.1 ‘TO BE INSPECTED’ Status Label shall be affixed on the container which contains materials ready for inspection. Container shall contain Status Label on both side.

6.7.2 To be Inspected Label shall contain **Yellow Color Band** with white background having logo on left side and printed ‘TO BE INSPECTED’ in Black Color.

6.7.3 To be Inspected Status Label shall be filled by Production Executive / Officer and cross verified by QA Executive / Officer and shall be signed along with Date.

6.7.4 Specification of the Label shall be 13.0 cm (L) X 8.2 cm (W).

6.7.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
To Be Inspected,	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Container No., Quantity, Checked By & Date (Production Executive/Officer), Verified By & Date (QA Executive / Officer)	12 Running & Bold
Format No.	09 Normal & Capital

6.7.6 Specimen of ‘TO BE INSPECTED’ Label is as shown in **Annexure-IX**.

6.8 “INSPECTED” LABEL:

6.8.1 ‘INSPECTED’ Status Label shall be affixed on the container which contains Inspected Material.



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6.8.2 Inspected Label shall contain **Green Color Band** with white background having Logo on left side and printed '**INSPECTED**' in Black Color.

6.8.3 Inspected Label shall be filled by Production Executive/Officer and cross verified by QA Executive / Officer and shall be signed along with Date.

6.8.4 Specification of the Label shall be 13.0 cm (L) x 8.2 cm (W).

6.8.5 Label shall contain the following details :

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width-0.27"
Inspected	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Container No., Quantity, Checked By & Date (Production Executive/Officer), Verified By & Date (QA Executive/Officer)	12 Running & Bold
Format No.	09 Normal & Capital

6.8.6 Specimen of '**INSPECTED**' Label is as shown in **Annexure-X**.

6.9 "BIN STATUS" LABEL:

6.9.1 '**BIN STATUS**' shall be affixed on IPCs/Bins used for storage of the In -process Semi Finished Product.

6.9.2 Bin Status Label shall be of **White Color Band** with white background having logo on left side and printed '**BIN STATUS**' in Black Color.

6.9.3 Bin Status Label shall be filled by Operator and verified by Production Executive / Officer and shall be signed along with Date.

6.9.4 Label Specification shall be 13.0 cm (L) X 8.2 cm (W).

6.9.5 Specimen of '**BIN STATUS**' Label is as shown in **Annexure-XI**.

6.9.6 Label shall contain the following details :

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width-0.27"
Bin Status	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Bin No., Container No., G. wt (Kg), 'Tare Wt (Kg), Net Wt	12 Running & Bold



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(Kg)', Checked By & Date (Operator), Verified By & Date (Production Exec. / Officer)	
Format No.	09 Normal & Capital

6.10 "TO BE CLEANED" LABEL:

6.10.1 'TO BE CLEANED' Label shall be affixed on the Containers, Equipments, Utensils, Machines and areas which are to be cleaned.

6.10.2 To be Cleaned Label shall contain **Yellow Color Band** with white background having Logo on left side and printed 'TO BE CLEANED' in Black Color.

6.10.3 To Be Cleaned Status Label shall be filled by Operator and verified by Production Executive/ Officer and shall be signed along with Date.

6.10.4 Specification of the Label to be Cleaned shall be 13.0 cm (L) X 8.2 cm (W).

6.10.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width-0.27"
To Be Cleaned	18 Capital & Bold
Previous Product, Batch No., Date, Checked By & Date (Operator), Verified By & Date (Production Exec. / Officer)	12 Running & Bold
Format No.	09 Normal & Capital

6.10.6 Specimen of 'TO BE CLEANED' Label is as shown in **Annexure-XII**.

6.11 "CONTAINER STATUS" LABEL:

6.11.1 'CONTAINER STATUS' Label shall be affixed on the containers which contains Semi Finished / Finished and Packaging Materials.

6.11.2 Status Label shall contain **White Color Band** with white background having Logo on left side and printed 'CONTAINER STATUS' in Black Color.

6.11.3 Container Status Label shall be filled by Production Executive / Officer and cross verified by QA Executive / Officer and shall be signed along with Date.

6.11.4 Specification of the Label Container Status shall be 13.0 cm (L) X 8.2 cm (W).

6.11.5 Specimen of 'CONTAINER STATUS' Label is as shown in **Annexure-XIII**.



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6.11.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
Container Status	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, ‘G. Wt (Kg), Tare Wt (Kg), Net Wt (Kg)’, Checked By & Date (Production Exec. / Officer), Verified By & Date (QA Exec. / Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.12 “INPROCESS STATUS” LABEL:

6.12.1 ‘INPROCESS STATUS’ Label shall be affixed on the Containers / Vessels / Equipment which contains Semi Finished or Finished Materials during operations.

6.12.2 In process Status Label shall contain **Yellow Color Band** having logo on left side and printed ‘INPRECESS STATUS’ in Black Color.

6.12.3 In process Status Label shall be filled by Production Executive / Officer and cross verified by QA Executive / Officer and shall be signed along with Date.

6.12.4 Specification of the In process Status Label shall be 13.0 cm (L) X 8.2 cm (W).

6.12.5 Specimen of ‘INPROCESS STATUS’ Label is as shown in **Annexure-XIV**.

6.12.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width-0.27”
Inprocess Status	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Stage, Checked By & Date (Production Exec. / Officer), Verified By & Date (QA Exec. / Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.13 STATUS LABEL:



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6.13.1 ‘STATUS LABEL’ shall be affixed for showing the status of Equipments, IPCs, Bins, Machines, Materials Status and Rooms / Areas status etc.

6.13.2 Status Label shall contain White Color Band with white background having Logo on left side and printed ‘STATUS LABEL’ in Black Color.

6.13.3 Specification of Status Label shall be 13.0 cm (L) X 8.2 cm (W).

6.13.4 Specimen of ‘STATUS LABEL’ is as shown in **Annexure-XV**.

6.13.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Status Label	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Stage , Checked By & Date (Production Exec. / Officer), Verified By & Date (QA Exec. / Officer)	12 Running & Bold
Format No.	9 Capital & Normal

6.14 “CLEANED” LABEL:

6.14.1 ‘CLEANED’ Status Label shall be affixed on the Containers, Equipments, Utensils, Machines, Bins, IPCs and Areas to indicate status of cleaning.

6.14.2 Status Label shall contain **Green Color Band** with white background having Logo on left side and printed ‘CLEANED’ in Black Color.

6.14.3 Cleaned Label shall be filled by operator and verified by Production Executive/Officer and shall be signed along with Date.

6.14.4 Specification of Cleaned Status Label shall be 13.0 cm (L) x 8.2 cm (W).

6.14.5 Specimen of ‘CLEANED’ Label is as shown in **Annexure-XVI**.

6.14.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Cleaned	18 Capital & Bold
Bin / Container No. / Accessories, Last Product Used, Batch No., Cleaned By, Date of Cleaning, Used Before Date, Checked By &	12 Running & Bold



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Date (Operator), Verified By & Date (Production Exec./ Officer)	
Format No.	09 Normal & Capital

6.15 “EQUIPMENT STATUS” LABEL:

6.15.1 ‘EQUIPMENT STATUS’ Label shall be affixed on the machine during operation time of the machine to indicate the stage of product.

6.15.2 Status Label shall contain **Blue Color Band** with white background having Logo on left side and printed ‘EQUIPMENT STATUS’ in Black Color.

6.15.3 Equipment Status Label shall be filled by operator and verified by Production Executive / Officer and shall be signed along with Date.

6.15.4 Specification of Equipment Status Label shall be 13.0 cm (L) X 8.2 cm (W).

6.15.5 Specimen of ‘EQUIPMENT STATUS’ Label is as shown in **Annexure-XVII**.

6.15.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Equipment Status	18 Capital & Bold
Equipment Name & ID No., Location, Product Name, Batch No., Batch Size, Stage, Checked By & Date (Operator), Verified By & Date (Production Exec./ Officer)	12 Running & Bold
Format No.	09Capital & Normal

6.16 “LOOSE BOX” LABEL:

6.16.1 ‘LOOSE BOX’ Status Label shall be affixed on the box which contains loose Semi Finished or Finished Materials.

6.16.2 Loose Box Label shall contain **Red Color Band** with white background having Logo on left side and printed ‘LOOSE BOX’ in Black Color.



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6.16.3 Loose Box Status Label shall be filled by Production Executive/Officer and Verified By QA Executive/Officer and affixed on the Loose Box and shall be signed along with Date.

6.16.4 Specification of Loose Box Label shall be 13.0 cm (L) X 8.2 cm (W).

6.16.5 Specimen of 'LOOSE BOX' Label is as shown in **Annexure-XVIII**.

6.16.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Loose Box	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Quantity, Checked By & Date (Production Exec./ Officer), Verified By & Date (QA Exec./ Officer)	12 Running & Bold
Format No.	09 Normal & Capital

6.17 "UNDER MAINTENANCE" LABEL:

6.17.1 'UNDER MAINTENANCE' Status Label shall be affixed on Machines/Equipments/ Instruments which are under maintenance.

6.17.2 Under Maintenance Label shall contain **Blue Color Band** with white background having Logo on left side and printed 'UNDERMAINTENANCE' in Black Color.

6.17.3 Under Maintenance Status Label shall be filled by Production Executive/Officer and affixed on that Machine/Equipment/Instrument which is under maintenance and shall be signed along with Date.

6.17.4 Specification of Under Maintenance Label shall be 13.0 cm (L) x 8.2 cm (W).

6.17.5 Specimen of 'UNDERMAINTENANCE' Label is as shown in **Annexure-XIX**.

6.17.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Under Maintenance	18 Capital & Bold
Equipment/Machine Name, Date, Remarks, Observed By & Date (Production Exec./Officer)	12 Running & Bold
Format No.	09 Capital & Normal



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6.18 “EXCESS MATERIAL RETURN” LABEL:

6.18.1 ‘EXCESS MATERIAL RETURN’ Status Label shall be affixed on the unused material which is excess after completion of the process (In case of Packaging Material only).

6.18.2 Coded material can not be returned.

6.18.3 Excess Material Return Label shall contain **Pink Color Band** with white background having Logo on left side and printed ‘EXCESS MATERIAL RETURN’ in Black Color.

6.18.4 Excess Material Return Status Label shall be filled by Production Executive/Officer and verified by QA Executive/Officer and affixed on the excess material to be return to store on Material Return Note Slip/Material Return Note.

6.18.5 Specification of Excess Material Return Label shall be 13.0 cm (L) x 8.2 cm (W).

6.18.6 Specimen of ‘EXCESSMATERIALRETURN’ Label is as shown in **Annexure-XX**.

6.18.7 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Excess Material Return	18 Capital & Bold
Material Name, A.R. No., Qty. Required, No. of Packs, Used For (Product & Batch No.), Date, Checked By & Date (Production Executive/Officer), Verified By & Date (QA Executive/Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.19 “ON-LINE REJECTION” LABEL:

6.19.1 ‘ON-LINE REJECTION’ Status Label shall be affixed on the material which is rejected during the Process/Packing Activity.

6.19.2 For Example: Cartons were rejected during packing process due to improper pasting, any raw material during Process/Shifting.

6.19.3 On-Line Rejection Label shall contain **Red Color Band** with white background having Logo on left side and printed ‘ON-LINE REJECTION’ in Black Color.

6.19.4 On-Line Rejection Label shall be filled by Production Executive/Officer and verified by QA Executive/Officer and affixed on On-Line Rejected Material to be return to store on On-Line Rejection Note.



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6.19.5 Specification of On-Line Rejection Label shall be 13.0 cm (L) X 8.2 cm (W).

6.19.6 Specimen of 'ON-LINEREJECTION' Label is as shown in **Annexure-XXI**.

6.19.7 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
On-Line Rejection	18 Capital & Bold
Material Name, A.R. No., Qty. Returned, Product & Batch No., Date, Checked By & Date (Production Executive/Officer), Verified By & Date (QA Executive / Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.20 EXPIRED MATERIAL (CHEMICAL/REAGENT):

6.20.1 'EXPIRED MATERIAL' Status Label shall be affixed on the material (Chemical/Reagent) which is expired.

6.20.2 Expired Material Label shall contain **Red Color Band** with white background having Logo on left side and printed 'EXPIRED MATERIAL' in Black Color.

6.20.3 Expired Material Label shall be filled by Executive/Officer of respective Department and shall be signed along with Date.

6.20.4 For Nature of material (Acid/Base/Corrosive/Hazardous) shall be marked as (√).

6.20.5 Specification of the Label shall be 13.0 cm (L) X 8.2 cm (W).

6.20.6 Specimen of 'EXPIREDMATERIAL' Label is as shown in **Annexure-XXII**.

6.20.7 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Expired Material	18 Capital & Bold
Material Name, Nature : Acid / Base / Corrosive / Hazardous, A.R. No., Mfg. Date, Exp. Date, Quantity, Department,	12 Running & Bold



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Checked By Date	
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6.21 “HOLD” LABEL:

6.21.1 ‘HOLD’ Status Label shall be affixed on the Material (Raw material/Chemical/Reagent /Packaging Material), Semi Finished/Finished Product which is hold due to some reason for further investigation.

6.21.2 Hold Status Label shall contain **Red Color Band** with white background having Logo on left side and printed ‘**HOLD**’ in Black Color.

6.21.3 Hold Label shall be filled by QA Executive/Officer and shall be signed along with Date with reason for Hold.

6.21.4 Specification of the Label shall be 13.0 cm (L) x 8.2 cm (W).

6.21.5 Specimen of ‘**HOLD**’ Label is as shown in **Annexure-XXIII**.

6.21.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Hold	18 Capital & Bold
Product Name, Batch No., Batch Size, Hold Quantity, Stage, Area, Reason for Hold, Sign & Date (QA Exec. / Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.22 “WEIGHT RANGE” LABEL:

6.22.1 ‘WEIGHT RANGE’ Status Label shall be affixed on the balance at the time of weighing operation.

6.22.2 Weight Range Label shall contain Yellow Color Band with white background having logo on left side and printed ‘**WEIGHT RANGE**’ in Black Color.



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6.22.3 Weight Range Label shall be filled by Production Executive/Officer and Verified By QA Executive / Officer and shall be signed along with Date.

6.22.4 Specification of the Label shall be 13.0 cm (L) X 8.2 cm (W).

6.22.5 Specimen of 'WEIGHT RANGE' Label is as shown in **Annexure-XXIV**.

6.22.6 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Weight Range	18 Capital & Bold
Product Name, Batch No., Packing Style, Weight Range, To, Checked By & Date (Production Exec./ Officer), Verified By & Date (QA Exec./ Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.23 "INPROCESS SAMPLE" LABEL (FOR QA USE) :

6.23.1 'INPROCESS SAMPLE' Label shall be affixed on Semi Finished Sampled material which is for QC testing.

6.23.2 In process sample Label shall contain **Yellow Color Band** with white background having Logo on left side and printed 'INPROCESS SAMPLE' in Black Color.

6.23.3 In process sample Label shall be filled by QA Executive / Officer and shall be signed along with Date.

6.23.4 Specification of the Label shall be 9.0 cm (L) X 8.0 cm (W).

6.23.5 Specimen of 'INPROCESSSAMPLE' Label is as shown in **Annexure-XXV**.

6.23.6 Label shall contain following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
In process Sample	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Quantity, Date, Sampled By (QA Exec. / Officer)	12 Running & Bold
Format No.	09 Capital & Normal



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6.24 “VALIDATION SAMPLE” LABEL:

6.24.1 ‘VALIDATION SAMPLE’ Status Label shall be affixed on the validation samples of each stage of the product as per protocol.

6.24.2 Validation Sample Label shall contain Green Color Band with white background having logo on left side and printed ‘VALIDATION SAMPLE’ in Black Color.

6.24.3 Validation Sample Label shall be filled by QA Executive / Officer and shall be signed along with Date.

6.24.4 Specification of the Label shall be 9.0 cm (L) X 8.0 cm (W).

6.24.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Validation Sample	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Stage, Quantity, Date, Sampled By (QA Exec. / Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.24.6 Specimen of ‘VALIDATION SAMPLE’ Label is as shown in **Annexure–XXIX**.

6.25 “FINISHED SAMPLE” LABEL:

6.25.1 ‘FINISHED SAMPLE’ Status Label shall be affixed on the Finished Sample which is to be QC Analysis.

6.25.2 Finished Sample Label shall contain **Green Color Band** with white background having Logo on left side and printed ‘FINISHED SAMPLE’ in Black Color.

6.25.3 Finished Sample Label shall be filled by QA Executive/Officer and shall be signed along with Date.

6.25.4 Specification of the Label shall be 9.0 cm (L) x 8.0 cm (W).

6.25.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Finished Sample	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Stage, Quantity, Date, Sampled By (QA Exec./ Officer)	12 Running & Bold
Format No.	09 Capital & Normal

6.25.6 Specimen of 'FINISHED SAMPLE' Label is as shown in **Annexure-XXX**.

6.26 "REJECTED" LABEL (FOR INPROCESS MATERIAL):

6.26.1 'REJECTED' Status Label shall be affixed on the container which contain materials generated during manufacturing and packing activities and can not be reuse.

6.26.2 **For Example:** Broken & Sealing Rejected Vials after Filling & Sealing operation, Broken Glass Bottles (After filled bottle inspection), Vials, Rejected Ampoules after inspection, rejection generated during Granulation / Compression stage etc.

6.26.3 'NON-RECOVERABLE' Label can also be used if 'REJECTED' Label is not available.

6.26.4 Rejected Label shall contain **Red Color Band** with white background having Logo on left side and printed 'REJECTED' in Black Color.

6.26.5 Rejected Status Label shall be filled by Production Executive / Officer and cross verified by QA Executive / Officer and shall be signed along with Date.

6.26.6 Specification of the Label shall be 13.0 cm (L) X 8.2 cm (W).

6.26.7 Label shall contain the following details

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Rejected	18 Capital & Bold
Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Quantity, Checked By & Date (Production Executive / Officer), Verified By & Date (QA Executive / Officer)	12 Running & Bold
Format No.	09 Normal & Capital

6.26.8 Specimen of 'REJECTED' Label is as shown in **Annexure-XXXI**.



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6.27 PREVENTIVE MAINTENANCE CARD:

6.27.1 'PREVENTIVE MAINTENANCE CARD' shall be hanged with Card Holder on the Machine /Equipment after Preventive Maintenance work by Engineering Officer/Executive, after completing the details along with Done By and Checked By Sign.

6.27.2 Specification of the Label shall be 9.0 cm (L) X 5.0 cm (W).

6.27.3 Preventive Maintenance Card shall be of **Light Blue color** with text printed in black.

6.27.4 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Organization Name	12 Capital & Bold
Plant-III, Haridwar, Engineering Department, Preventive Maintenance Card	10 Capital & Bold
Equipment Name, Equipment ID No., Maintenance Done On, Done By, Next Due On, Checked By	09 Capital & Bold
Format No.	09 Capital & Normal

6.27.5 Specimen of 'PREVENTIVE MAINTENANCE CARD' is as shown in **Annexure-XXXII**.

6.28 "OUT OF ORDER" LABEL :

6.28.1 'OUT OF ORDER' Status Label shall be affixed on the Machine/Instrument to show its status for not in working condition.

6.28.2 Out of Order Label shall contain **Red Color Band** with white background having Logo on left side and printed 'OUT OF ORDER' in Black Color.

6.28.3 Out Of Order Label shall be filled by Officer/Executive of the respective Department along with Sign and Date.

6.28.4 Specification of the Label shall be 13.0 cm (L) x 8.2 cm (W).

6.28.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
-------------------------	-------------------------------------



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Out of Order	18 Capital & Bold
M/c/Instrument Name, ID No., Remarks, Observed By (Sign & Date)	12 Running & Bold
Format No.	09 Capital & Normal

6.28.6 Specimen of ‘OUT OF ORDER’ Label is as shown in **Annexure-XXXIII**.

6.29 “CALIBRATED” LABEL:

6.29.1 ‘CALIBRATED’ Status Label shall be affixed on the instruments which are calibrated.

6.29.2 Calibrated Label shall contain **Sky Blue Color Band** with white background having Logo on left side and printed ‘CALIBRATED’ in Black Color.

6.29.3 Calibrated Label shall be filled by Officer / Executive of the respective Department.

6.29.4 Specification of the Label shall be 8.0 cm (L) X 7.0 cm (W).

6.29.5 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Calibrated	18 Capital & Bold
Instrument Name, ID No., Date of Calibration, Calibration Due On, Done By (Sign & Date), Checked By (Sign & Date)	12 Running & Bold
Format No.	09 Normal & Capital

6.29.6 Specimen of ‘CALIBRATED’ Label is as shown in **Annexure-XXXIV**.

6.30 “QUARANTINE RETEST” LABEL:

6.30.1 ‘QUARANTINE RETEST’ Label shall be affixed on the retest Raw and Packaging Material in Warehouse by Warehouse person.

6.30.2 Specification of Label shall be 8.5 cm (L) X 6.0 cm (W).



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6.30.3 Quarantine Retest Label shall contain white background with text in Black.

6.30.4 Specimen of 'QUARANTINE RETEST' Label is as shown in **Annexure-XXXV**.

6.30.5 Label shall contain the following details :

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Name of Organization	08 Font Capital & Bold
Quarantine Retest	14 Font Capital & Bold
Material Name, Manufacturer, Supplier, Date of Receipt, Item Code, Batch No., Mfg. Date, Exp. Date, 'Total Qty Received. Kg / Nos.', GRN No., Date, Container / Box No., Prepared By (Sign & Date)	11 Font Running & Normal
Format No.	09 Font Running & Capital

6.31 "UNDER RETEST" LABEL:

6.31.1 After sampling from the Quarantine Retest Material QC Officer shall sample and affix 'UNDER RETEST' Label on the 'QUARANTINE RETEST LABEL', by overlapping the part where 'QUARANTINE RETEST' word is written.

6.31.2 Specification of the Label shall be 7.5 cm (L) x 6.0 cm (W).

6.31.3 Under Retest Label shall be contain **Yellow Color Band** with white background having Logo on left side and printed 'UNDER RETEST' in Black Color.

6.31.4 Label shall contain the following details:

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31" & Width 0.27"
Under Retest	24 Font Capital & Bold
Material Name, GRN No., A.R. No., Vendor Batch No., Insp. Lot. No., Container No., Storage Location , Sampled By	12 Font Running & Normal
Format No.	09 Font Capital & Bold

6.31.5 Specimen of 'UNDER RETEST' Label is as shown in **Annexure-XXXVI**.



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6.32 “IDENTIFICATION SLIP” LABEL:

6.32.1 ‘IDENTIFICATION SLIP’ Label shall be affixed on the Dispensed Raw & Packaging Material Containers/Poly Bags in Warehouse by Warehouse Person.

6.32.2 Specification of Label shall be 9.0 cm (L) x 6.0 cm (W).

6.32.3 ‘IDENTIFICATION SLIP’ shall contain white background with text in Black.

6.32.4 Specimen of ‘IDENTIFICATION SLIP’ Label is as shown in **Annexure-XXXVII**.

6.32.5 Label shall contain the following details :

CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Identification Slip	14 Font Capital & Bold
Issue No., Serial No., Item Name, For Product, FG/SFG Batch No., Batch Size, Mat. Batch No., Qty., Out of Qty., Tare Wt., Gross Qty., Container, Mat. Mfg. Date, Issued By :____ (Sign & Date), Checked By:____ (Sign & Date)	08 Font Capital
Format No.	09 Font Running & Capital

6.33 “RINSE WATER/SWAB SAMPLE” LABEL:

6.33.1 “RINSE WATER/SWAB SAMPLE” Status Label shall be affixed on the Equipment’s, Mixing tank & Holding tank of Aseptic Areas to indicate status of Sampling.

6.33.2 Status Label shall contain white of white background having Logo on left side and printed “RINSE WATER/SWAB SAMPLE in Black Color.

6.33.3 “Rinse Water/Swab Sample” Label shall be filled by QA Executive/Officer and shall be signed along with Date.

6.33.4 Specification of “Rinse Water/Swab Sample” Status Label shall be 13.0 cm (L) x 8.2 cm (W).

6.33.5 Specimen of “Rinse Water/Swab Sample” Label is as shown in **Annexure-XXXIII**.

6.33.6 Label shall contain the following details:



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
Logo	Height-0.31” & Width 0.27”
Rinse Water /Swab Sample	18 Capital & Bold
Previous Product, Batch No, Equipment Name, EQ.ID. No., Quantity Sampled, Sampled By QA (Sign/Date)	12 Running & Bold
Format No.	09 Normal & Capital

7.0 ABBREVIATIONS:

A.R. No. :	Analytical Report Number
Exec. :	Executive
Exp. :	Expiry
G. Wt. :	Gross Weight
GRN No. :	Goods Receipt Note Number
ID No. :	Identification Number
IPCs :	In-Process Containers
L :	Length
LOD :	Loss on Drying
Ltd. :	Limited
Mfg. :	Manufacturing
QA :	Quality Assurance
QC :	Quality Control
Regular :	Running
SOP:	Standard Operating Procedure
w:	Width
No. :	Number



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8.0 ANNEXURES:

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Annexure-I	Quarantine	F01-00
Annexure-II	Sampled	F02-00
Annexure-III	Under Test	F03-00
Annexure-IV	Approved	F04-00
Annexure-V	Rejected	F05-00
Annexure-VI	Line clearance	F06-00
Annexure-VII	To Be Inspected	F07-00
Annexure-VIII	Inspected	F08-00
Annexure-IX	Bin Status	F09-00
Annexure-X	To be Cleaned	F10-00
Annexure-XI	Container Status	F11-00
Annexure-XII	In process Status	F12-00
Annexure-XIII	Status Label	F13-00
Annexure-XIV	Cleaned	F14-00
Annexure-XV	Equipment Status	F15-00
Annexure-XVI	Loose Box	F16-00
Annexure-XVII	Under Maintenance	F17-00
Annexure-XVIII	Excess Material Return	F18-00
Annexure-XIX	On-Line Rejection	F19-00
Annexure-XX	Expired Material	F20-00
Annexure-XXI	Hold	F21-00
Annexure-XXII	Weight Range	F22-00
Annexure-XXIII	In process Sample	F23-00
Annexure-XXIV	Validation Sample	F24-00
Annexure-XXV	Finished Sample	F25-00
Annexure-XXVI	Rejected (For In process Material)	F26-00
Annexure-XXVII	Preventive Maintenance Card	F27-00
Annexure-XXVIII	Out of Order	F28-00
Annexure-XXIX	Calibrated	F29-00
Annexure-XXX	Quarantine Retest	F30-00
Annexure-XXXI	Under Retest	F31-00
Annexure-XXXII	Identification Slip	F32-00
Annexure-XXXIII	Rinse Water/Swab Sample	F33-00



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9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 04 Human Resource Department (HR).
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No. 07 Information Technology Department.

10.0 REFERENCES:

- Quality Assurance of Pharmaceuticals, 2nd Edition, Volume- 2, 2007 (WHO).
- WHO TRS 961
- National Sanitary Surveillance Agency (ANVISA-Brazil) Resolution - RDC No. 210, August 4, 2003
- Quality Manual

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE-I

QUARANTINE	
Material Name:	
Item Code:	
GRN No.:	Date:
Vendor Batch No.:	
Manufacturing Date:	
Expiry Date:	
Total Qty.:	
Date of Receipt:	
Container No.:	
Manufacturer:	
Supplier:	
Stor. Loc.:	
Prepared By (Sign & Date):	

6.0 cm

8.5 cm



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ANNEXURE – II

SAMPLED

Sampled By:

Date:



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ANNEXURE – IV

6.0 cm	APPROVED
	Material Name: Vendor Batch No. : ERP Batch No.: GRN No. : A.R. No. : Assay : LOD: Water: Qty. Approved: Approval Date : Retesting Date: Approved By (Sign & Date):
	7.5 cm



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ANNEXURE – V

6.0 cm	REJECTED
	Material Name: Batch No. : GRN No.: A.R. No.: Date of Analysis : Quantity Rejected : Rejection Reason : Checked By (Sign & Date):
	7.5 cm



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ANNEXURE – VI

LINE CLEARANCE			
Room No.		Equipment	
Area		Department	
Last Product Processed			
Batch No.			
Product to be Processed			
Batch No.			
Checked By & Date		Verified By & Date	
(Warehouse/Production, Executive/Officer)		(QA Executive/Officer)	



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ANNEXURE - VII

TO BE INSPECTED

TO BE INSPECTED	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Container No.	
Quantity	
Checked By & Date (Production Exec./Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE - VIII

INSPECTED	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Container No.	
Quantity	
Checked By & Date (Production Exec./ Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE - IX

BIN STATUS

Product Name		
Batch No.		
Batch Size		
Mfg. Date		
Exp. Date		
Bin No.		
Container No.		
G. Wt. (Kg)	Tare Wt.(Kg)	Net Wt. (Kg)
Checked By & Date		Verified By & Date
(Operator)		(Production Exec./Officer)



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ANNEXURE -X

TO BE CLEANED

Previous Product		
Batch No.		
Date		
Checked By & Date (Operator)	Verified By & Date (Production Exec./Officer)	



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ANNEXURE – XI

CONTAINER STATUS

CONTAINER STATUS			
Product Name			
Batch No.			
Batch Size			
Mfg. Date		Exp. Date	
Container No.			
G. Wt. (Kg)	Tare Wt.(Kg)	Net Wt. (Kg)	
Checked By & Date		Verified By & Date	
(Production Exec. / Officer)		(QA Exec. / Officer)	



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ANNEXURE – XII

INPROCESS STATUS			
Product Name			
Batch No.			
Batch Size			
Mfg. Date		Exp. Date	
Stage			
Use Before			
Checked By & Date		Verified By & Date	
(Production Exec./Officer)		(QA Exec./Officer)	



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ANNEXURE – XIII

STATUS LABEL	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Stage	
Checked By & Date (Production Exec./Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE – XIV

CLEANED			
Bin / Container No. / Accessories			
Last Product Used			
Batch No.			
Cleaned By			
Date of Cleaning		Used Before Date	
Checked By & Date (Operator)		Verified By & Date (Production Exec./ Officer)	



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ANNEXURE – XV

EQUIPMENT STATUS	
Equipment Name & ID No.	
Location	
Product Name	
Batch No.	
Batch Size	
Stage	
Checked By & Date (Operator)	Verified By & Date (Production Exec./Officer)



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ANNEXURE – XVI

LOOSE BOX	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Quantity	
Checked By & Date (Production Exec./Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE - XVII

UNDER MAINTENANCE	
Equipment/ Machine Name	
Date	
Remarks	
Observed By & Date (Production Exec./Officer)	



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ANNEXURE - XVIII

EXCESS MATERIAL RETURN			
Material Name			
A.R. No.			
Qty. Returned		No. of Packs	
Used for (Product & Batch No.)			
Date			
Checked By & Date	Verified By & Date		
(Production Exec./ Officer)	(QA Exec./Officer)		



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ANNEXURE – XIX

ON-LINE REJECTION

ON-LINE REJECTION	
Material Name	
A.R. No.	
Qty. Returned	
Product & Batch No.	
Date	
Checked By & Date (Production Exec./Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE - XXX

EXPIRED MATERIAL

Material Name			
Nature	Acid/Base/Corrosive/Hazardous		
	Format No: SOP/QA/030/F22-00		
A.R. No.			
Mfg. Date			
Exp. Date			
Quantity			
Department			
Checked By		Date	



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ANNEXURE – XXI

HOLD	
Product Name	
Batch No.	
Batch size	
Hold Quantity	
Stage	
Area	
Reason for Hold	
Sign & Date (QA Officer/Executive)	



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ANNEXURE - XXII

WEIGHT RANGE	
Product Name	
Batch No.	
Packing Style	
Weight Range	To
Checked By & Date (Production Exec./Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE - XXIII

INPROCESS SAMPLE	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Quantity	
Date:	Sampled By: (QA Exec./Officer)



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ANNEXURE – XXIV

VALIDATION SAMPLE

VALIDATION SAMPLE	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Stage	
Quantity	
Date:	Sampled By: (QA Exec./Officer)



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ANNEXURE – XXV

FINISHED SAMPLE	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Stage	
Quantity	
Date:	Sampled By: (QA Exec./Officer)



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ANNEXURE – XXVI

REJECTED	
Product Name	
Batch No.	
Batch Size	
Mfg. Date	
Exp. Date	
Quantity	
Checked By & Date (Production Exec./Officer)	Verified By & Date (QA Exec./Officer)



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ANNEXURE - XXVII

PREVENTIVE MAINTENANCE CARD			
EQUIPMENT NAME		EQUIPMENT ID No.	
MAINTENANCE DONE ON		DONE BY	
NEXT DUE ON		CHECKED BY	



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Status Labeling

Effective Date:

Supersedes: Nil

Review Date:

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ANNEXURE - XXVIII

OUT OF ORDER

M/c / Instrument Name:

ID No.:

Remarks:

Observed By :
(Sign & Date)



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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

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ANNEXURE - XXIX

CALIBRATED	
Instrument Name	
ID No.	
Date of Calibration	
Calibration Due Date	
Calibration Done By (Sign & Date)	Checked By Sign & Date



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ANNEXURE – XXX

QUARANTINE RETEST

6.0 cm

Material Name:
Manufacturer:
Supplier:
Date of Receipt:
Item Code:
Batch No.:
Mfg. Date:
Exp. Date:
Total Qty Received.: Kg / Nos.
GRN No.: Date:
Container / Box No.:
Prepared By (Sign & Date):

8.5 cm



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ANNEXURE – XXXI

UNDER RETEST

Material Name:

GRN No.:

A.R. No. :

Vendor Batch No.:

Insp. Lot No. :

Container No.:

Store Loc. :

Sampled By :



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ANNEXURE-XXXII

IDENTIFICATION SLIP	
Issue No.:	Serial No.:
Item Name:	
For Product:	
FG/SFG Batch No.:	
Batch Size:	
Mat. Batch No.:	
Qty.:	Out of Qty.:
Tare Wt.: _____	Gross Qty.: _____
Container :	
Mat. Mfg. Date:	Mat. Exp. Date:
Issued By: _____ (Sign & Date)	Checked By: _____ (Sign & Date)



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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE-XXXIII

RINSE WATER/SWAB SAMPLE

Previous Product: _____

Batch No.: _____

Equipment Name: _____

EQ.ID. No.: _____ **Quantity Sampled:** _____

Sampled By QA: _____

(Sign/Date)