



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Status Labeling	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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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**.

**6.1.5** Label shall contain the following details:



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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).

**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.



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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.

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.



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**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 (Warehouse/Production, Executive/Officer), Verified By & Date (QA Executive/Officer)	12 Font Running & Bold
Format No.	09 Font Normal & Capital



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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.

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).



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**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 (Kg)’, Checked By & Date (Operator), Verified By & Date (Production Exec. / Officer)	12 Running & Bold
Format No.	09 Normal & Capital



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### 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**.

**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





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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
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:

**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).





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**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, <b>Stage</b> , 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 & Date (Operator), Verified By & Date (Production Exec./ Officer)	12 Running & Bold
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.



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**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.

**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:



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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

### 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.



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**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.

**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:



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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, Checked By Date	12 Running & Bold
Format No.	09 Capital & Normal



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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.

**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:



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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

### 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.





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**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”
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**.



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### 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**.

### 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:



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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
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**.



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### 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).

**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	11 Font Running & Normal



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CONTENT OF LABEL	FONT SIZE & LETTER STYLE
(Sign & Date)	
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**.

### 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 :



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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:

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



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### 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:

Annexure No.	Title of Annexure	Format No.
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

### 9.0 DISTRIBUTION:



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- 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, 2<sup>nd</sup> 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		

ANNEXURE-I





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6.0 cm

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):	

8.5 cm



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**SAMPLED**

Sampled By:                      Date:



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<b>6 cm</b>	<b>UNDER TEST</b>
	Material Name : _____
	GRN No. : _____
	Vendor Batch No.: _____
	Insp. Lot No. : _____
	Container No. : _____
	Store Loc. : _____
Sampled By : _____ Date: _____	
	<b>7.5 cm</b>



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**6.0 cm**

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





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## LINE CLEARANCE

<b>Room No.</b>		<b>Equipment</b>	
<b>Area</b>		<b>Department</b>	
<b>Last Product Processed</b>			
<b>Batch No.</b>			
<b>Product to be Processed</b>			
<b>Batch No.</b>			
<b>Checked By &amp; Date</b>		<b>Verified By &amp; Date</b>	
<b>(Warehouse/Production, Executive/Officer)</b>		<b>(QA Executive/Officer)</b>	



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### TO BE INSPECTED

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Batch Size</b>	
<b>Mfg. Date</b>	
<b>Exp. Date</b>	
<b>Container No.</b>	
<b>Quantity</b>	
<b>Checked By &amp; Date (Production Exec./Officer)</b>	<b>Verified By &amp; Date (QA Exec./Officer)</b>



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### INSPECTED

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Batch Size</b>	
<b>Mfg. Date</b>	
<b>Exp. Date</b>	
<b>Container No.</b>	
<b>Quantity</b>	
<b>Checked By &amp; Date (Production Exec./ Officer)</b>	<b>Verified By &amp; Date (QA Exec./Officer)</b>



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### BIN STATUS

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



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### TO BE CLEANED

<b>Previous Product</b>	
<b>Batch No.</b>	
<b>Date</b>	
<b>Checked By &amp; Date</b> <b>(Operator)</b>	<b>Verified By &amp; Date</b> <b>(Production Exec./Officer)</b>



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department:** Quality Assurance

**SOP No.:**

**Title:** Status Labeling

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### CONTAINER STATUS

<b>Product Name</b>					
<b>Batch No.</b>					
<b>Batch Size</b>					
<b>Mfg. Date</b>		<b>Exp. Date</b>			
<b>Container No.</b>					
<b>G. Wt. (Kg)</b>		<b>Tare Wt.(Kg)</b>		<b>Net Wt. (Kg)</b>	
<b>Checked By &amp; Date</b>			<b>Verified By &amp; Date</b>		
<b>(Production Exec. / Officer)</b>			<b>(QA Exec. / Officer)</b>		



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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### INPROCESS STATUS

<b>Product Name</b>			
<b>Batch No.</b>			
<b>Batch Size</b>			
<b>Mfg. Date</b>		<b>Exp. Date</b>	
<b>Stage</b>			
<b>Use Before</b>			
<b>Checked By &amp; Date</b>	<b>Verified By &amp; Date</b>		
<b>(Production Exec./Officer)</b>	<b>(QA Exec./Officer)</b>		



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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### STATUS LABEL

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Batch Size</b>	
<b>Mfg. Date</b>	
<b>Exp. Date</b>	
<b>Stage</b>	
<b>Checked By &amp; Date</b> <b>(Production Exec./Officer)</b>	<b>Verified By &amp; Date</b> <b>(QA Exec./Officer)</b>





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Page No.:**

**CLEANED**

**Bin / Container No. / Accessories**

**Last Product  
Used**

**Batch No.**

**Cleaned By**

**Date of Cleaning**

**Used Before Date**

**Checked By & Date**

**Verified By & Date**

**(Operator)**

**(Production Exec./ Officer)**



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Review Date:**

**Issue Date:**

**Page No.:**

### EQUIPMENT STATUS

**Equipment Name  
& ID No.**

**Location**

**Product Name**

**Batch No.**

**Batch Size**

**Stage**

**Checked By & Date  
(Operator)**

**Verified By & Date  
(Production Exec./Officer)**



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Issue Date:**

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### LOOSE BOX

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Batch Size</b>	
<b>Mfg. Date</b>	
<b>Exp. Date</b>	
<b>Quantity</b>	
<b>Checked By &amp; Date</b> (Production Exec./Officer)	<b>Verified By &amp; Date</b> (QA Exec./Officer)



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

UNDER MAINTENANCE	
<b>Equipment/ Machine Name</b>	
<b>Date</b>	
<b>Remarks</b>	
<b>Observed By &amp; Date</b> <b>(Production Exec./Officer)</b>	



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

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



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### ON-LINE REJECTION

<b>Material Name</b>	
<b>A.R. No.</b>	
<b>Qty. Returned</b>	
<b>Product &amp; Batch No.</b>	
<b>Date</b>	
<b>Checked By &amp; Date</b> (Production Exec./Officer)	<b>Verified By &amp; Date</b> (QA Exec./Officer)



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Review Date:**

**Issue Date:**

**Page No.:**

### EXPIRED MATERIAL

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



# DECODING PHARMA

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<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

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





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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### WEIGHT RANGE

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Packing Style</b>	
<b>Weight Range</b>	<b>To</b>
<b>Checked By &amp; Date (Production Exec./Officer)</b>	<b>Verified By &amp; Date (QA Exec./Officer)</b>



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### INPROCESS SAMPLE

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Batch Size</b>	
<b>Mfg. Date</b>	
<b>Exp. Date</b>	
<b>Quantity</b>	
<b>Date:</b>	<b>Sampled By:</b> (QA Exec./Officer)



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Review Date:**

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### VALIDATION SAMPLE

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



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

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**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### FINISHED SAMPLE

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



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department:** Quality Assurance

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**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

**REJECTED**

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Batch Size</b>	
<b>Mfg. Date</b>	
<b>Exp. Date</b>	
<b>Quantity</b>	
<b>Checked By &amp; Date</b> (Production Exec./Officer)	<b>Verified By &amp; Date</b> (QA Exec./Officer)



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Review Date:**

**Issue Date:**

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



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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<b>Title:</b> Status Labeling	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**OUT OF ORDER**

**M/c / Instrument Name:**

**ID No.:**

**Remarks:**

**Observed By :**  
**(Sign &Date)**



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Review Date:**

**Issue Date:**

**Page No.:**

### CALIBRATED

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





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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### 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



# DECODING PHARMA

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**Review Date:**

**Issue Date:**

**Page No.:**

**UNDER RETEST**

Material Name:

GRN No.:

A.R. No. :

Vendor Batch No.:

Insp. Lot No. :

Container No.:

Store Loc. :

Sampled By :



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### 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)



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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**Review Date:**

**Issue Date:**

**Page No.:**

### ANNEXURE-XXXIII

#### RINSE WATER/SWAB SAMPLE

**Previous Product:** \_\_\_\_\_

**Batch No.:** \_\_\_\_\_

**Equipment Name:** \_\_\_\_\_

**EQ.ID. No.:** \_\_\_\_\_ **Quantity Sampled:** \_\_\_\_\_

**Sampled By QA:** \_\_\_\_\_

(Sign/Date)