PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for sampling, testing, release & reject of Packaging Materials.

2.0 SCOPE:

This procedure is applicable for sampling, testing, release & reject of Packaging Materials.

3.0 RESPONSIBILITY:

Executive, Officer- Quality Control

Head -Quality Control

4.0 PROCEDURE:

4.1 Sampling of Packaging Materials:

4.1.1 Packaging material sampling shall be initiated after receiving the "Goods Receipt Note" from Packaging Material Store.

4.1.2 QC officer shall enter the material details in ''Packing Material Inward Record'' as per Annexure-I and shall assign A. R. No. for each batch /lot of packaging material.

4.1.3 QC officer shall generate the "QC UNDER TEST" labels from the ERP by using their login as per below procedure on receipt of GRN for each container one additional label shall be generated for affixing the same on the back side of QC GRN copy. (Refer Annexure-II).

4.1.3.1 QC officer shall login in ERP as per SOP No.: ……...

4.1.3.2 ERP Related Process for Generating Under test Label.

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

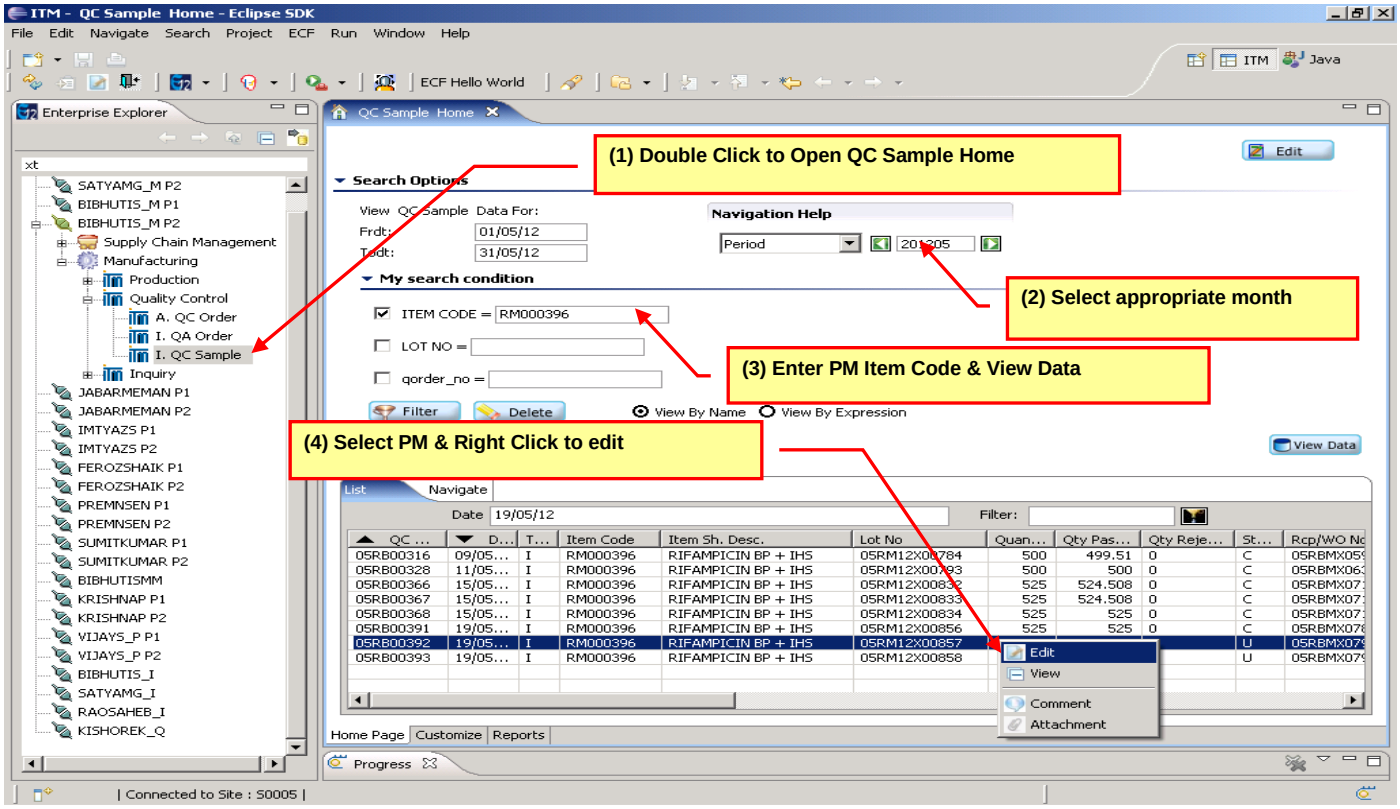

Fig. 1

1 Double click QC Sample to Open QC Sample Home Screen.

2 Select Appropriate month.

3 Enter Item Code for Packing Material.

4 Select desired PM and right click mouse to go into Edit mode.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

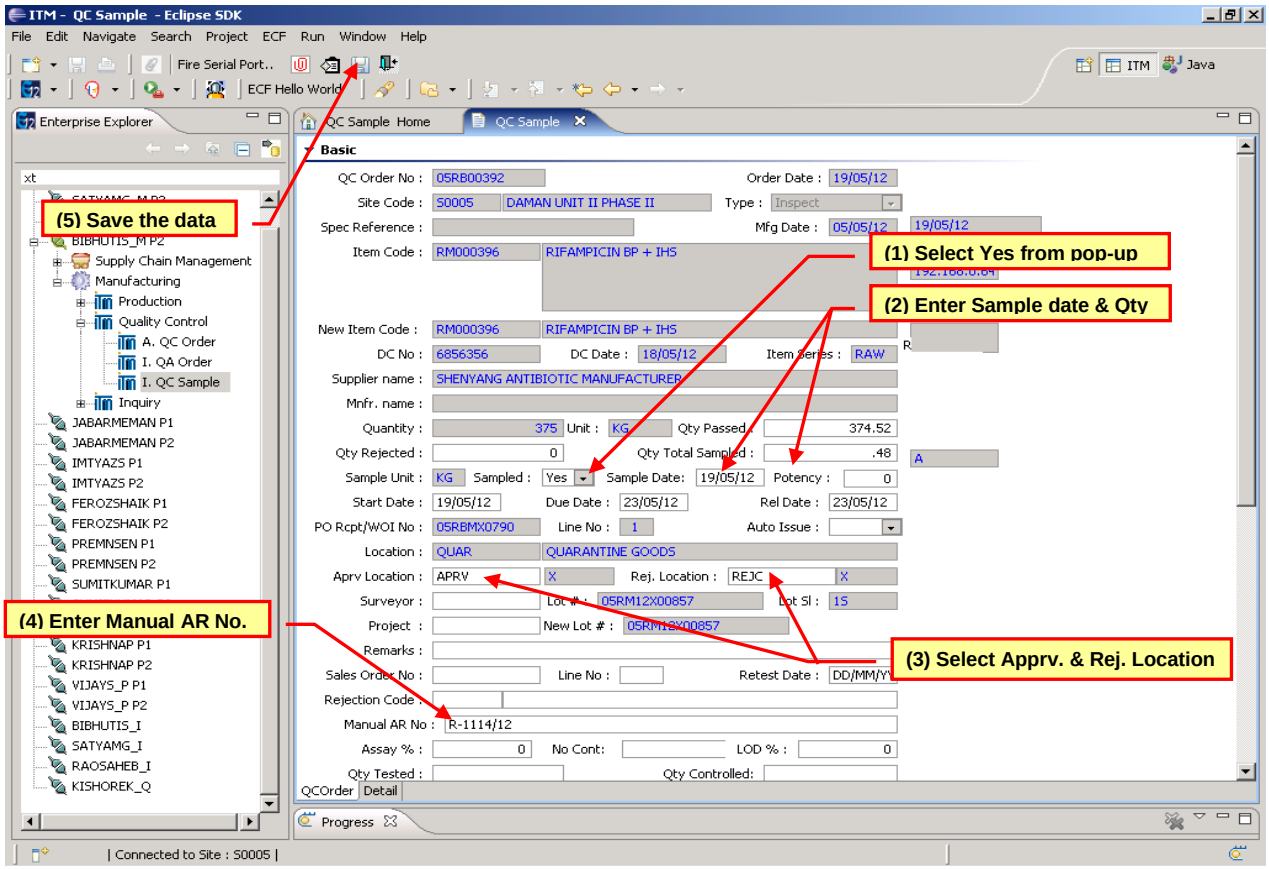

Fig. 2

1 Select Yes from the pop-up.

2 Enter Sample date & Quantity.

3 Select Approved (APRV) & Rejection (REJC) from pop-up.

4 Enter Manual AR No.

5 Save the above entered data.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

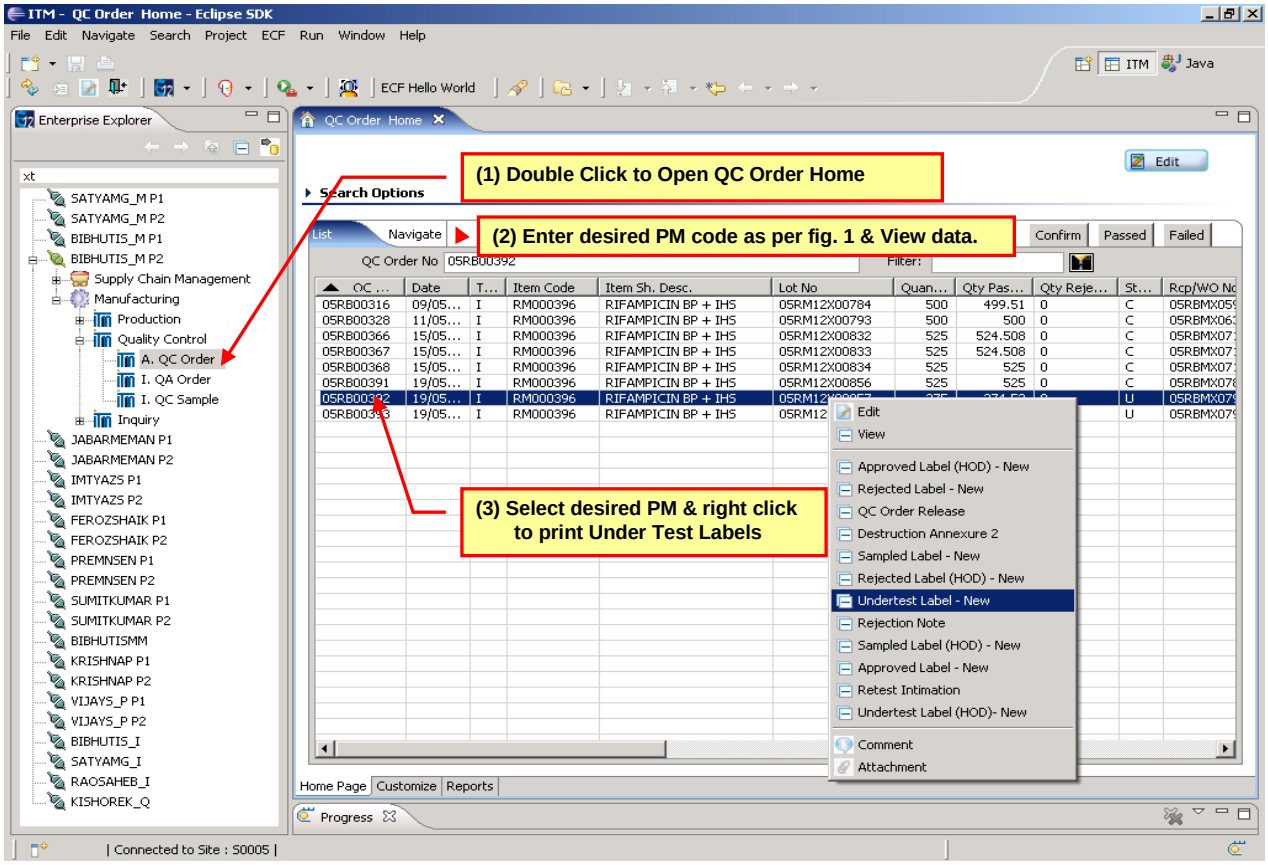

Fig. 3

1 Double Click to Open QC Order Home

2 Enter Item Code for Packing Material as per Fig. 1

Select desired PM and right click mouse to go into Label printing mode.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

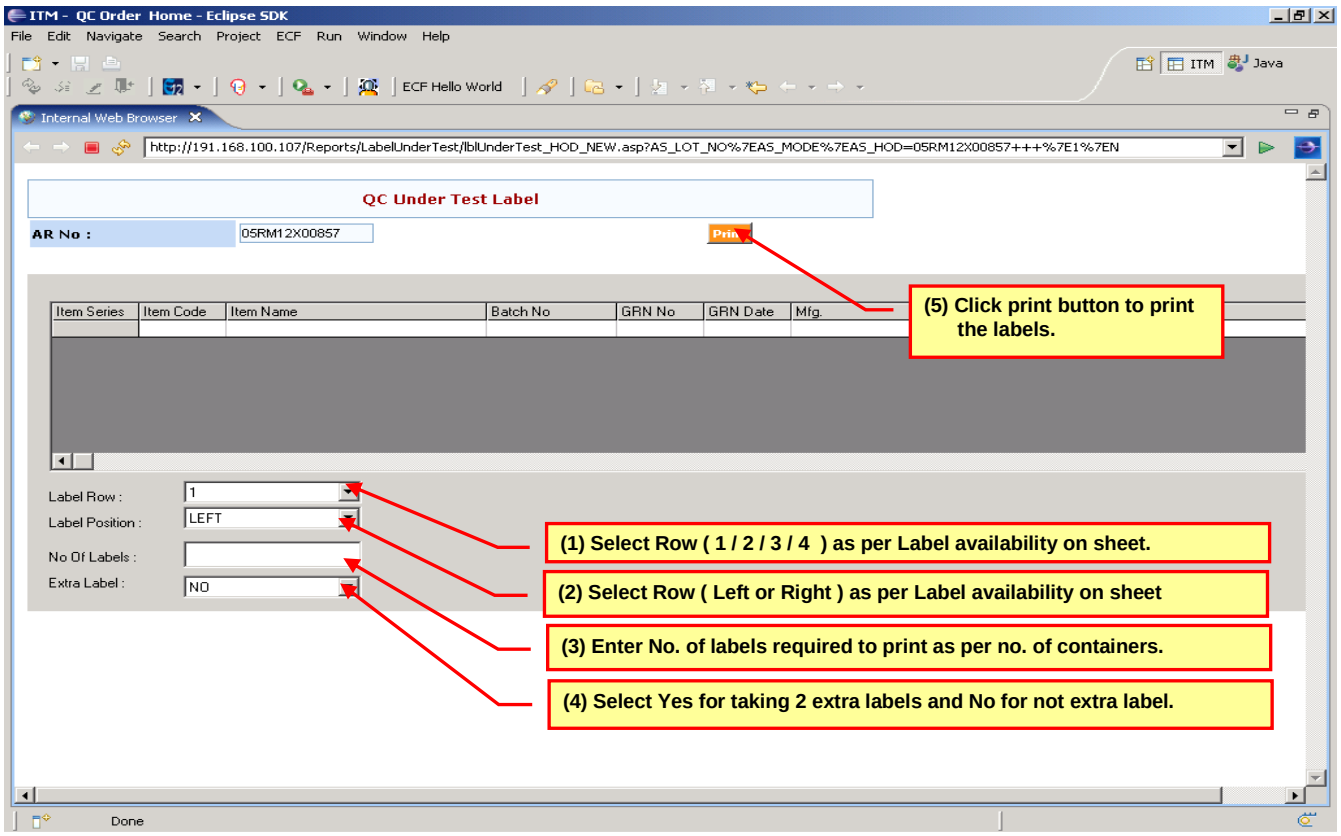

Fig. 4

1 Select Row (1 / 2 / 3 / 4) as per Label availability on sheet.

2 Select Row (Left or Right) as per Label availability on sheet

3 Enter No. of labels required to print as per no. of containers.

4 Select Yes for taking 2 extra labels and No for not extra label.

5 Click print button to print the labels.

4.1.4 The QC officer shall also generate "QC SAMPLED" labels (Annexure–III) as per sampling plan table. The generation of "QC SAMPLED" from ERP has to follow similarly as described above at point no. 4.1.3.2.

Note: PVC & PVC-PVDC, Aluminum foil (printed & plain) two label shall be generate and affix one on core (Inner side of roll) and other on polythene bag of foil for every pack.

4.1.5 QC officer shall go in the Stores area along with GRN and sampler's remark sheets,

sampling kit with calibrated S.S. scale, calibrated vernier caliper, marker pen, duly printed "Under Test labels", "QC sampled label", BOPP tape, hand gloves etc. to Packaging material store for sampling and on the spot-checking.

4.1.6 For Printed packing material QC officer shall collect the full web sheet/card (that contains all the ups or replicates of the individual sample) to ensure that the consignment is printed from the single plate or positive. In case if the consignment is printed from more than one positive or plate then the web card or sheet for all should be available.

4.1.7 The requirement of full web card/sheet shall not be applicable for roll labels, cut labels and printed foils.

4.1.8 QC officer shall always wear the hand gloves during sampling of primary packaging material. Sampling of foils (Aluminum, PVC & PVC-PVDC type) shall be carried out under RLAF located in sampling area of Stores. Secondary and Tertiary packaging materials sampling shall be carried out under sampling area located separately in stores.

4.1.9 In case of foil or films; Inspect the core of each roll while pasting the "UNDER TEST LABLE".

4.1.10 For the number of cases, packs, containers, rolls, or boxes shall be sampled as per sampling plan given in a tablet 1a (US Military Standard 105-E).

4.1.11 Sample quantity of the material/ consignment shall be collected as per table 1b (Normal inspection level II) and same shall be record in the sample remark sheet.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Sampling plan Table 1a
(US Military Standard 105-E: Single sampling plan)
(For Packs / Containers / Boxes to be sampled in a lot)

Number of pack / roll / container Received	Number of packs selected for sampling
2 - 8	2
9 - 15	3
16 - 25	5
26 - 50	8
51 - 90	13
91 - 150	20
151 - 280	32
281 - 500	50
501 - 1200	80
1201 - 3200	125
3201 - 10000	200
10001 - 35000	315
35001 - 150000	500
150001 - 500000	800
500001 and over	1250

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Inspection Level Table 1b
US Military Standard 105-E: Single sampling plan,
Normal inspection level-II

Sample size Code letter	Sample size	Acceptance Quality Limit in non conforming items					
		Critical (0.65 %)		Major (1.0 %)		Minor (2.5 %)	
		Ac	Re	Ac	Re	Ac	Re
2 - 8	2	0	1	0	1	0	1
9 - 15	3	0	1	0	1	0	1
16 - 25	5	0	1	0	1	0	1
26 - 50	8	0	1	0	1	0	1
51 - 90	13	0	1	0	1	1	2
91 - 150	20	0	1	0	1	1	2
151 - 280	32	0	1	1	2	2	3
281 - 500	50	1	2	1	2	3	4
501 - 1200	80	1	2	2	3	5	6
1201 - 3200	125	2	3	3	4	7	8
3201 - 10000	200	3	4	5	6	10	11
10001 - 35000	315	5	6	7	8	14	15
35001 - 150000	500	7	8	10	11	21	22
150001 - 500000	800	10	11	14	15	21	22
500001 and over	1250	14	15	21	22	21	22
Ac: Acceptance; Re : Rejected							

4.1.12 In case of only one container received; in such case sample shall be taken from same; without considering Sampling plan Table 1a. Normal inspection sample quantity of the individual material shall be collect as per table 1b.

Note:

- *In case Aluminum foil/PVC/PVC-PVDC films up to five rolls, all are to be sampled; Incase of more than 5 rolls received; select sample quantity number as per the "Inspection Level Table".*

- *For printed foil roll, the joints shall not be more than three. Same shall be verified during sampling.*

4.1.13 In case of Aluminum foil/PVC/PVC-PVDC films take minimum 3 meters of length per roll for visual inspection and analysis.

4.1.14 After visual inspection, for Poly bags 5 nos. and Corrugated box 3 nos. sample shall be collect for analysis.

4.1.15 Record the quantity of samples collected for analysis in the "Packing material sampler's remark sheet" as per annexure - VIII.

4.1.16 QC officer shall paste "Packing material sample slip" on each sampled pack as per Annexure - IV.

4.1.17 **Visual Inspection:**

4.1.17.1 The visual observations of the packaging materials shall be carried in packing QC Lab. Details are given below:

4.1.17.2 For visual inspection carry out the sample quantity as per given in a sampling plan table 1b; record the observation in analytical raw data sheets.

4.1.17.3 Check the samples for defects. Classify the defects as critical, major, and minor as categorized in the individual specification and indicate the same in the analytical raw data sheets.

4.1.17.4 Confirm the number of defects of each category found, against the AQL chart for acceptance / rejection of material.

4.1.17.5 In case of consignment with minor / major defects (exceeding the acceptance quality levels), where inspection of entire consignment is possible e.g. rolls, inspect entire consignment. Reject the defective units and accept the remaining units.

4.1.17.6 Remaining quantity of consignment shall be sampled and check against AQL.

4.2 After sampling, reseal the boxes of the packaging material and "QC UNDER TEST" status labels shall be affixed on every pack received in a lot & "QC SAMPLED" labels shall be affixed on the packs which are sampled near the under test label. "QC UNDER TEST" label shall be affixed in such a manner that the word "QUARANTINED" of Quarantined

label is completely covered & text of Quarantined label is visible. Ensure that the sampled boxes are closed.

Note: PVC & PVC-PVDC, Aluminum foil (printed & plain) two label shall be generate and affix one on core (Inner side of roll) and other on polythene bag of foil for every pack.

4.3 Documentation for sampling:

4.3.1 Sampler shall record his observation during sampling in "sampler's remark sheet" as given in Annexure -VIII.

4.3.2 **Precautions:**

Before sampling of foil, QC officer shall take the following precautions:

a) Always wear the hand gloves during sampling.
b) RLAF of sampling booth should be switched on 15 minutes before starting the sampling activity.
c) Only one batch/Lot shall be sampled at one time and sampled roll or box shall be closed properly with Polybags.
d) Sampling activities/documentation shall be done as per Ref.SOP No. ……...

4.4 Testing of Packaging Materials:

4.4.1 QC officer shall perform the tests as per respective specification and standard test procedure.

4.4.2 Packaging data shall be recorded in the respective analytical raw data sheet.

4.4.3 Approved artwork/shade card shall be tested for text matter and colour shade.

4.4.4 QC officer shall check the web sheet for text and colour of each up's with sampled material.

4.4.5 After completion of analysis, all data shall be reviewed and certificates of analysis for each batch shall be prepared.

4.4.6 Attach a specimen of packing material in the data sheet wherever possible.

4.5 Release / Reject of Packaging material:

4.5.1 The defects if observed in the sample as critical, major and minor. Refer Annexure –IX.

4.5.2 AQL for critical defects shall be 0.65%, for Major defects 1.0% and for Minor defects 2.5%. A consignment shall be accepted if the number of defectives at a defined AQL is less than the quantity specified in Inspection Level Table.

4.5.3 If a material is approved, generate "QC APPROVED" labels for each pack as per Annexure - V with retest date wherever applicable. The retest period shall be considered as per SOP: ……. (Retesting of packing materials). Affix on each packs on the particular batch / lot over the "QC UNDER TEST" label in such a manner that "QC UNDER TEST" label is completed covered. Print one additional label, to affix on the back side of the GRN of QC copy. The generation of approved label from ERP has to follow similarly as described above at point no. 4.1.3.2.

Note: PVC & PVC-PVDC, Aluminum foil (printed & plain) two labels shall be generated and affix one on core (Inner side of roll) and other on polythene bag of foil for every pack.

4.5.4 In case extra labels of "QC Approved" is require follow the below procedure in ERP.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

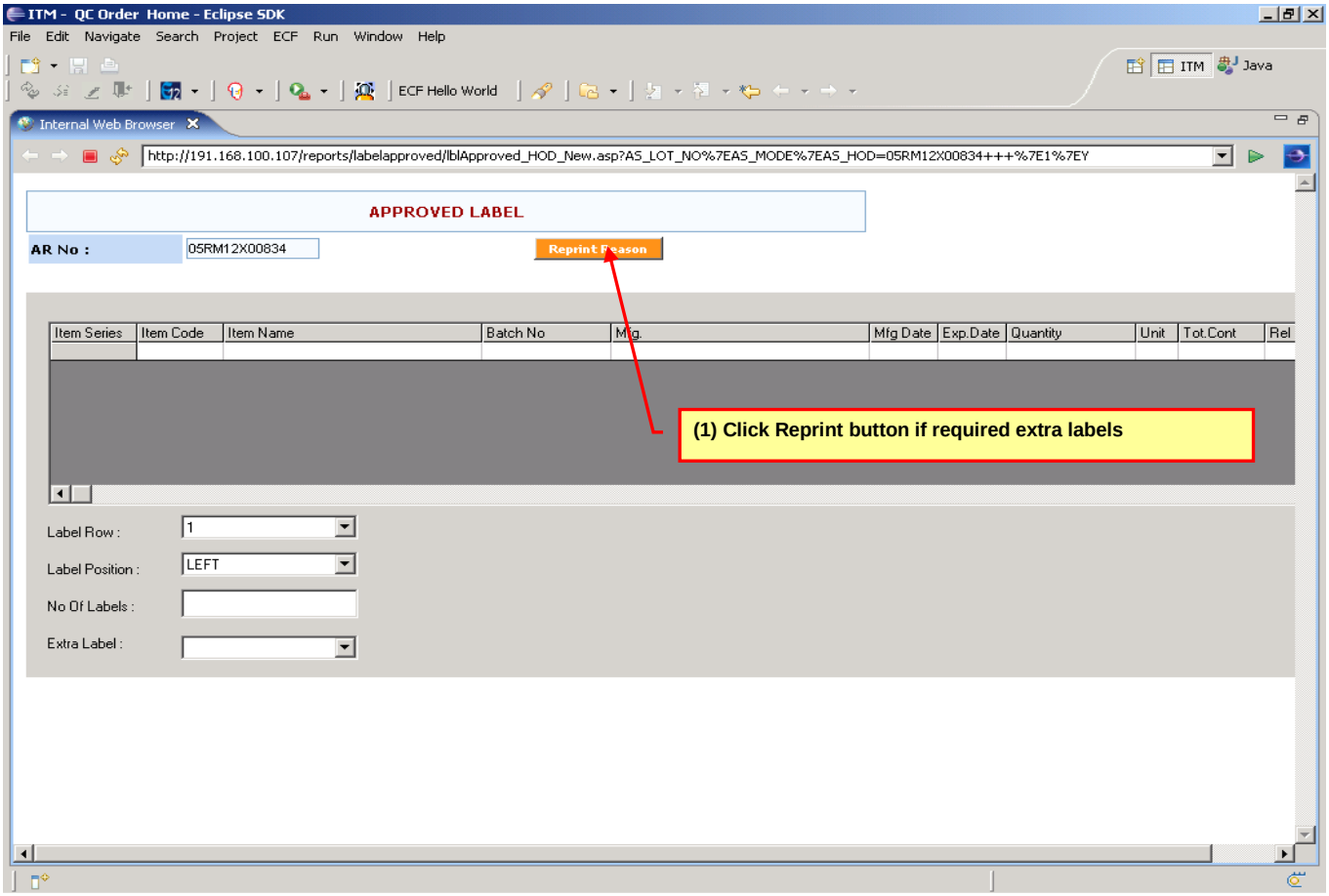

Fig. 5

1 In case extra labels of "QC Approved" is required. Select desired label having word "HOD" as shown in fig. 3 and proceed.

2 Enter desired information as per Fig. 4 and Fig. 5 will appear.

3 Click on re-print reason button, Fig 6 appear on screen.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

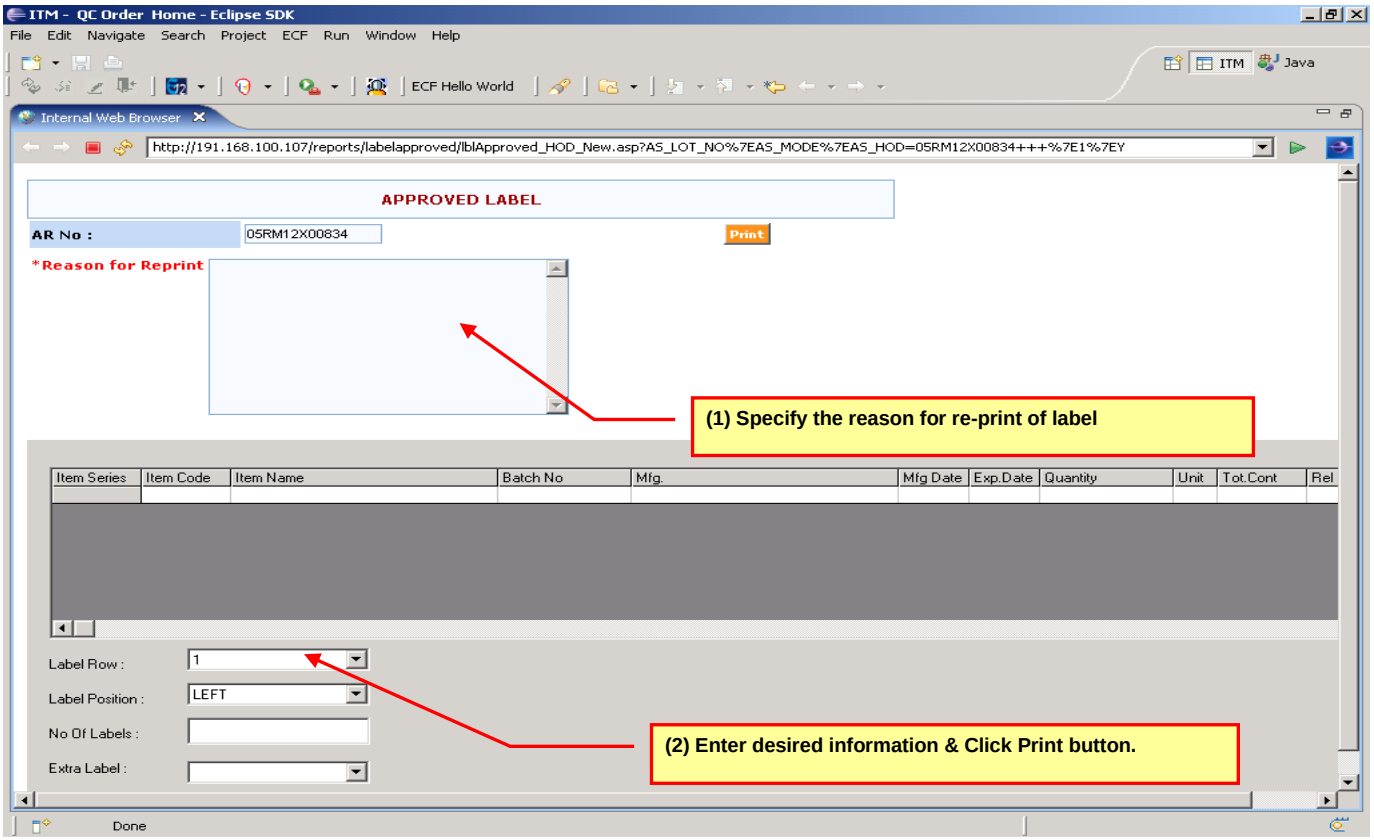

Fig. 6

1 Specify the reason of requiring re-print of already printed labels.

2 Enter all the desired information as per Fig. 4.

3 Click on print button to get printed labels.

4 Note: This right of re-printing is only accessible from HOD login only.

5 Save the above entered data.

4.5.5 If a material is rejected, generate "QC REJECTED" labels (Annexure-VI) from ERP and follow similarly proceed as described above at point no. 4.1.3.2 and affix on each container / drum / bag over the "QC UNDER TEST" label in such a manner that the entire "QC UNDER TEST" label is completely covered by the "QC REJECTED" label and generate "Rejection Note" (Annexure-VII) for respective consignment from ERP. Print one additional label, to affix on the back side of the GRN of QC copy.

Note: PVC & PVC-PVDC, Aluminum foil (printed & plain) two label shall be generate and affix one on core (Inner side of roll) and other on polythene bag of foil for every

pack.

4.5.6 In case extra labels of "QC Rejected" is required follow the procedure 4.5.4.

4.5.7 If any material does comply with the acceptance criteria mentioned in the Normal Sampling plan for AQL mentioned in "Inspection level table 1b" but does not complies to the concern specification; in such case; material shall be rejected.

4.5.8 Send the rejection note to Stores and ensure that the material is transferred to Rejected area.

5.0 ANNEXURE (S):

Annexure – I : Packing Material Inward Record

Annexure – II : Specimen label for "QC Under Test"

Annexure – III : Specimen label for "QC Sampled"

Annexure – IV : Specimen label for "Packing Material Sample Slip"

Annexure – V : Specimen label for "QC Approved"

Annexure – VI : Specimen label for "QC Rejected"

Annexure – VII : Template for Rejection note

Annexure – VIII : Packing Material Sampler's Remark Sheet

Annexure – IX : Nature of Defects

6.0 REFERENCE (S):

SOP No. : Retesting of packing material

SOP No. : Sampling, Testing, Release & Reject of Raw materials

SOP No. : Procedure for protecting password in ERP.

SOP No. : QC Release of RM, PM & FG in ERP.

SOP No. : Operation and Cleaning of Sampling Area

SOP No. : Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

7.0 ABBREVIATION (S) / DEFINITION (S):

7.1 ABBREVIATION (S):

GRN : Goods Receipt Note

HDPE : High Density Polyethylene

PVC : Poly Vinyl Chloride

PVDC : Poly Vinyl Dichloride

QC : Quality Control

AQL : Acceptance Quality Level

RLAF : Reverse Laminar Airflow

7.2 DEFINITION (S):

7.2.1 **Primary packaging material:**

Packing material, which are direct contact with drugs (eg: Tablets, capsules etc.) are called primary packaging material.

7.2.2 **Secondary packaging material:**

Those packing materials, which are covered primary packaging material, are called secondary packaging material.

7.2.3 **Tertiary packaging material:**

Those packing material, which are used to cover secondary packing material, is called tertiary packing Material.

7.2.4 **Critical Defect:**

A critical defect is a defect that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product, or a defect that judgment and experience indicate is likely to prevent performance of the tactical function of a major end item like tablet, capsules, etc.

7.2.5 **Major Defect:**

A major defect is a defect, other than a critical defect, that is likely to cause non-conformance of product during manufacturing, testing shipment, storage, or use such failures do not constitute a potential risk to the patient.

7.2.6 **Minor Defect:**

A minor defect is a non-conformance that may detract product elegance, but is expected to have little or no effect on the suitability of the Finished Product for its intended use.

7.2.7 **Acceptance Quality Level:**

AQL is the basic measure of non-conformance & is stated as percent defective or defects per 100 units of sample. The AQL is the maximum percent defective that can be considered acceptable.

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	NA	NA	New SOP	NA

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I

PACKING MATERIAL INWARD RECORD

S.No.	Date	GRN No./Date	Item Code	Name of material	B. No. / AR No.	Mfg. Date	Exp. Date	Manufacturer / Supplier	Qty Received	Manual AR No.	Sampled By	Analysed by	Status	Remarks

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE IV

SPECIMEN LABEL FOR PACKING MATERIAL SAMPLE SLIP

PACKING MATERIAL SAMPLE SLIP			
Material Name	**:**		
Item Code	**:**	**B. No./AR No. :**	
GRN No.	**:**	**Qty. Received:**	
Mfg. Date	**:**	**Exp. Date :**	

Mfg. / Supplier Name	**:**
Qty. for Analysis	**:**
Sign / Date	**:**

ANNEXURE V

SPECIMEN LABEL FOR QC APPROVED

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Green Color

QC APPROVED

MACLEODS

Location :
Item :

B. No. : Code :
Mfg. Dt. : Exp. Dt.: Retest Dt:
No of con.:
Qnty. :
Mfg. :

Rel. Dt. : QC Retest Dt.:
AR No. : Analyst:
Storage Condition :

Format No.: ERP/F/032-01

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE VI

SPECIMEN LABEL FOR QC REJECTED

Red colour

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

QC REJECTED

Location :
Item :
B. No. : Code :
Mfg. Dt. : Exp. Dt.: Retest Dt:
No of con.: Qnty:
Rejc. Qty. : Rejc. Date:
Mfg. :
Reason :
AR No. : Analyst:
Storage Condition :
Format No.: ERP/F/033-00

ANNEXURE VII

TEMPLATE FOR REJECTION NOTE

Date :	
Rejection Note	
Item code :	
Material Name :	**AR No. :**

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Batch No.	**:**	**Manual AR No.**	**:**
Mfg. By	**:**	**Supplied By**	**:**
Receipt Qty.	**:**	**Challan No. / Date**	**:**
GRN No. / Date	**:**	**Date of Sampling**	**:**
Reason for Rejection :			
Rejected Quantity :			
Analyzed By		**Manager Quality Control**	

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE VIII

PACKING MATERIAL SAMPLER'S REMARK SHEET

Reference SOP No.:

Material Name :					
Item Code :				GRN No. :	
Batch No. / AR No. :				Manual AR No. :	
Total no. of cont. / Pack :				Qty. Received :	
1.	Storage condition	Temp & RH confirms / does not confirm			
2.	Packaging condition	(Satisfactory / not satisfactory) (State observations if not satisfactory)			
3.	Container label details verification (State whether 'Yes' or 'No')	a	Manufacturer / Supplier name		
		b	Batch number		
		c	Quantity		
		d	Container number (if any)		
		e	Any other remarks		
4.	No. of joints (Roll form materials)	Not more than 3 joints per roll (Confirm / Does not confirmed)			
5.	Approved vendor	Yes / No			
6.	Sampled Conts. / Packs/Rolls no.				
7.	Visual inspection sample quantity				

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

8.	Sample quantity for QC Analysis	
Sampled By / Date :		

ANNEXURE IX

NATURE OF DEFECTS

Reference SOP No.:

Product	Critical	Major	Minor
Printed Aluminium Foil	Text Matter Pin Holes Dimension Wet in condition	Joints in Foils Printing quality Shade Variation	Dark Spots Appearance Core Damage
Unprinted Aluminium Foil	Dimension Pin Holes Wet in condition	Joints in Foils Printing quality Shade Variation	Dark Spots Appearance Core Damage
Cold Thermoformed laminated foil	Dimension Wet in condition	Joints in Foils Shade Variation	Dark Spots Appearance Core Damage
Triple laminated foil	Dimension Text matter	Joints in Foils Printing quality Shade Variation	Appearance Core damage
Laminated Tube with cap	Text Matter Pin Holes Dimension Wet in condition	Printing quality Shade Variation	Dark Spots Appearance
PVC / PVC coated PVDC	Dimension Colour Scheme	Joints in Foils Shade Variation	Core Damage Appearance

	Wet in condition	Wrinkles	
Carton / Catch cover	Text Matter Mix up Dimension	Shade Variation Printing quality Appearance Wet in condition	Spots Pasting Locking
Label	Cut Mark on Roll Text Matter Dimension	Colour Shade Printing quality	Dark Spot Core Damage
Leaflet	Text Matter Mix up Dimension	Colour scheme Appearance Printing quality Wet in condition	Dark spot Folding

NATURE OF DEFECTS

Product	Critical	Major	Minor
Shipper	No. of Ply Mix up Text matter	Improper creasing Printing quality Wet in condition	Appearance Rusted Staplers Gap between flaps
Partition	No. of ply Mix up	Dimension Wet in condition	Appearance
Poly Bag	Foreign Particles Mix up Improper sealing	Dimension	Appearance
Silica gel bag	Text matter Mix up	Printing quality Damage	Appearance
BOPP Tape (Printed/Plain)	Text matter Dimension Cut Mark	Colour scheme Appearance Printing quality	Dark Spot Core Damage
Cello Tape	Dimension Cut Mark	Appearance	Dark Spot Core Damage

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling, Testing, Release & Reject of Packing Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**