



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Acceptance quality level of packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Acceptance Quality Level (AQL) of Packaging Material on receipt of each consignment.

2.0 SCOPE:

This SOP shall be applicable for all Packaging materials received.

3.0 RESPONSIBILITY - Execution - Executive QC

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control .

5.0 PROCEDURE

5.1 Sample the Packaging Material as per sampling procedure mentioned in current version of SOP.

5.2 For AQL of packaging material the defects are to be inspected on receipt of each consignment visually, in quantity sampled for visual inspection as per SOP.

5.3 Determine the AQL for its defect in terms of Critical, Major and Minor as mentioned in Annexure- I to V.

5.4 For "CRITICAL" defects there are no acceptance criteria in such case, reject the supply.

5.5 For "MAJOR" & "MINOR" defects, follow acceptance limit for defects as mentioned in Annexure I to V.

5.6 Initiate further analysis if Packaging Material meets acceptance criteria as mentioned in Annexure - I to V.



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5.7 If total defects exceed the acceptance limit mentioned in Annexure- I to V, reject the entire consignment

6.0 SAFETY & PRECAUTIONS:
Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Supersedes from & date
00	New	

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign / Date	By	Sign/ Date

9.0 REFERENCES

SOP: Sampling of Packaging material

10.0 ABBREVIATIONS & ANNEXURES

SOP : Standard Operating Procedure

No. : Number

Dept. : Department

QC : Quality Control



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AQL : Acceptance Quality level

ANNEXURES

Annexure-I : AQL For Carton / Catch Cover

Annexure-II : AQL For Label / Pack Insert

Annexure-III : AQL For Plain Foil/ PVC Film / PVDC Film

Annexure-IV : AQL For Printed Foil / Pouch fil

Annexure-V : AQL For Corrugated Box / Thermocol Box



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ANNEXURE-I ACCEPTANCE QUALITY LEVEL FOR CARTON / CATCH COVER

Name of packaging Material :

A.R. No. :

Sampling plan as SOP No :

S. No.	ATTRIBUTE	DEFECTS CLASSIFICATION OF PACKAGING MATERIAL	OBSERVATION			
			No. of samples	No. of Defective samples	%of Defective samples	Acceptance Limit For Defected samples
1.	Packing & Labeling	Critical				0 %
2.	Brand Name ,Generic Name & Label Claim	Critical				0 %
3.	Mix up	Critical				0 %
4.	Code No. Missing	Critical				0 %
5.	Barlines /Bar Code Shifting	Major				1 %
6.	Printing Quality					
	Inadequate space for over printing.	Critical				0%
	Mis Printing	Critical				0%
	Smudgy Printing	Major				1%
	Shifting of Printing	Major				1%
7.	Cutting & Flap	Major				1 %
8.	Pasting	Major				1 %

S.	ATTRIBUTE	DEFECTS	OBSERVATION
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No.		CLASSIFICATION OF PACKAGING MATERIAL	No. of samples	No. of Defective samples	%of Defective samples	Acceptance Limit For Defected samples
9.	Locking	Major				1 %
10.	Sticking	Minor				2 %
11.	Improper Folding	Minor				2 %
12.	Colour Shade Variation	Minor				2 %
	Total					3 %

Acceptance Limit for total Defects:

Total Major defects observed _____ % (NMT 1.0 %)
Total Minor defects observed _____ % (NMT 2.0 %)
Total defects observed _____ % (NMT 3.0 %)

Conclusion: The sample can be/ can not be further checked for the analysis as per specification.

Checked By: _____

Verified By: _____



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ACCEPTANCE QUALITY LEVEL FOR LABEL / PACK INSERT

Name of Packaging Material :

A.R. No. :

Sampling plan as per SOP No. :

S.No.	ATTRIBUTE	DEFECTS CLASSIFICATION OF PACKAGING MATERIAL	OBSERVATION			
			No. of Samples	No. of Defective Samples	% of Defective Samples	Acceptance limit for defects
1.	Brand Name , Generic Name & Label Claim	Critical				0 %
2.	Packing & Labeling	Critical				0 %
3.	Code No. Missing	Critical				0 %
4.	Printing Quality					
	Inadequate space for over printing	Critical				0%
	Mis Printing	Critical				0%
	Smudgy Printing	Major				1%
	Shifting of Printing	Major				1%
5.	Flap to remove the Backside paper (For Sticker)	Major				1 %
6.	Sticking	Major				1 %
7.	Colour Shade Variation	Minor				2 %
	Total					3%

Acceptance limit for total defects:

Total Major defects observed _____ % (NMT 1.0 %)

Total Minor defect observed _____ % (NMT 2.0 %)

Total defects observed _____ % (NMT 3.0 %)

Conclusion: The sample can be/ can not be further checked for the analysis as per specification.

Checked By: _____

Verified By: _____.



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ANNEXURE-III

ACCEPTANCE QUALITY LEVEL FOR PLAIN FOIL / PVC FILM /PVDC FILM

Name of Packaging Material :

A.R. No. :

Sampling plan as per SOP No. :

S.No.	ATTRIBUTE	DEFECTS CLASSIFICATION OF PACKAGING MATERIAL	OBSERVATION			
			No. of samples	No. of Defective samples	% of Defective samples	Acceptance limit for defects
1.	Mix Up	Critical				0 %
2.	Core Damaged	Critical				0 %
3.	Packing & Labeling	Critical				0 %
4.	Loose Winding	Major				1 %
5.	Telescopic Winding	Major				1%
6.	Colour (PVC/PVDC Film)	Major				1 %
	Total					3%

Acceptance limit for total defects:

Total Major defects observed _____ % (NMT 1.0 %)

Total defects observed _____ % (NMT 3.0 %)

Conclusion: The sample can be/ can not be further checked for the analysis as per specification.

Checked By: _____

Verified By: _____.



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ANNEXURE-IV

ACCEPTANCE QUALITY LEVEL FOR PRINTED FOIL / POUCH FILM

Name Of Packaging Material :

A.R. No. :

Sampling plan as per SOP No. :

S.No.	ATTRIBUTE	DEFECTS CLASSIFICATION OF PACKAGING MATERIAL	OBSERVATION			
			No. of Samples	No. of Defective Samples	% of Defective Samples	Acceptance limit for defects
1.	Brand Name , Generic Name & Label Claim	Critical				0 %
2.	Core Damaged	Critical				0 %
3.	Loose Winding	Critical				0 %
4.	Packing & Labeling (Poly bag Wrapping)	Critical				0 %
5.	Printing Quality					
	Mis Printing	Critical				0%
	Shifting of Printing	Major				1%
	Illegible Text Matter	Major				1%
	Smudgy Printing.	Major				1%
6.	Code No. Missing	Major				1 %
7.	Colour Shade Variation.	Minor				2 %
	Total					3%

Acceptance limit for total defects:

Total Major defects observed _____ % (NMT 1.0 %)

Total Minor defects observed _____ % (NMT 2.0 %)

Total defects observed _____ % (NMT 3.0 %)

Conclusion: The sample can be/ can not be further checked for the analysis as per specification.

Checked By: _____

Verified By: _____.



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ANNEXURE-V

ACCEPTANCE QUALITY LEVEL FOR CORRUGATED BOX /THERMOCOL BOX

Name of Packaging Material:

A.R. No. :

Sampling plan as per SOP No. :

S.No.	ATTRIBUTE	DEFECTS CLASSIFICATION OF PACKAGING MATERIAL	OBSERVATION			
			No. of samples	No. of Defective samples	% of Defective samples	Acceptance limit for defects
1.	Cutting & Flap	Critical				0 %
2.	Shape of Corrugated Box	Critical				0 %
4.	Wetness (Moisture)	Critical				0 %
5.	Pasting/ Stapling	Major				1 %
6.	Shade variation	Minor				2%
	Total					3%

Acceptance limits for total defects:

Total Minor defects observed _____ % (NMT 2.0 %)

Total Major defects observed _____ % (NMT 1.0 %)

Total defects observed _____ % (NMT 3.0 %)

Conclusion: The sample can be/ can not be further checked for the analysis as per specification.

Checked By: _____

Verified By: _____