

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD TESTING PROCEDURE FOR LABELS

1.0 DESCRIPTION:

Procedure:

Take a sample, observe it visually for the physical parameters mentioned in the specifications and record the observations.

2.0 ACCEPTANCE QUALITY LEVEL (AQL):

Procedure:

Select the labels for inspection as per the SOP "SAMPLING OF PACKAGING MATERIALS". The classification of defects & Acceptable Quality Levels for each defect is also mentioned below:

ACCEPTANCE QUALITY LEVEL(AQL)						
CRITICAL	MAJOR	MINOR				
0.000 %	0.4 %	1.0 %				

3.0 CLASSIFICATION OF DEFECTS:

Procedure:

S.No.	CRITICAL DEFECTS	S.No.	MAJOR DEFECTS	S.No.	MINOR DEFECTS
1.	Wrong text matter	1.	Improper cutting	1.	Minor ink spots
2.	Mix – up	2.	Illegible printing	2.	Minor smudge printing
			(readable)		
3.	Unprinted	3.	Major print registration	3.	Minor print registration shifting
			shifting		
4.	Illegible printing (not	4.	Major smudge printing	4.	Minor paper shade variation
	readable)				
5.	Misprinting	5.	Major ink spots	5.	Minor improper cutting
6.	Incomplete printed				
	matter				
7.	Major colour shade				
	variation				

4.0 PRINTING:

Procedure:

- I. Printing should be legible and there should not be any smudging.
- II. Check the sticker label for print registration and there should not be any shifting of print registration.
- III. There should not be any ink spots on the printed matter.
- IV. Printing should be clear and sharp.
- V. There should not be any blank or partially printed sticker labels.

5.0 SIZE:

Procedure:

Check the size of three sticker labels with Vernier calipers / scale and record their average result.



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6.0 TOTAL GRAMMAGE :

Procedure:

Take three sticker labels from the sampled labels. Mark their respective roll no. / Sheet no. (If any). Weigh them individually. Calculate the Grammage (g/m^2) as follows;

 $GSM (g/m^{2)} = \frac{Wt \times 100 \times 100}{L \times W}$

Where,

GSM = Gram per Square meter (g/m²)Wt = Weight of chromo art paper + adhesive + release liner L = Length of sample piece in cm W = Width of the sample piece in cm Take their average result.

7.0 GRAMMAGE OF THE CHROMO ART PAPER + ADHESIVE

Procedure:

Take above two specimens; mark the respective roll no (if any). Weigh them individually after removing the silicon release paper, record it and calculate their Grammage (g/m^2) by the formula given below:

 $GSM (g/m^2) = Wt \times 100 \times 100$

Where,

GSM = Gram per Square meter (g/m²)Wt = Weight of chromo art paper + adhesive L = Length of sample piece in cm W = Width of the sample piece in cm Take their average result.

8.0 GRAMMAGE OF CHROMO ART PAPER:

Procedure:

Take off the adhesive of above two specimens by rubbing it gently with a piece of cloth soaked in toluene. Dry and weigh the chromo art paper. Calculate the Grammage (g/m^2) by the formula given below:

GSM $(g/m^2) = Wt \times 100 \times 100$

 $L \times W$

Where,

GSM = Gram per Square meter (g/m²)Wt = Weight of chromo art paper L = Length of sample piece in cm W = Width of the sample piece in cm Take their average result.

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9.0 GRAMMAGE OF ADHESIVE:

Procedure:

Subtract the Grammage of the chromo art paper from the respective total Grammage of chromo art paper with adhesive and calculate the Grammage (g/m^2) as follows:

 $GSM (g/m^2) = (GSM \text{ of chromo art paper} + adhesive) - (GSM \text{ of chromo art paper})$ Also take their average result.

10.0 GRAMMAGE OF RELEASE LINER:

Procedure:

Take the release liner from the above two specimens and weigh them individually and calculate their grammage(g/m^2) as follows;

 $GSM (g/m^2) = \underline{Wt \times 100 \times 100}$

 $L \times W$

Where, CSM = C

GSM = Gram per Square meter (g/m²)Wt = Weight of liner

L = Length of sample piece in cm

W = Width of the sample piece in cm

Take their average result.

11.0 PERFORMANCE TEST:

Procedure:

A. Affix three sticker labels from the sampled labels on the plastic bottles and peel the sticker from the labels from the bottles after 10 minutes. The sticker label should not come out intact from the bottles and fibre tearing should take place.

B. Affix three sticker labels from the sampled labels on the plastic bottle and keep the bottles at $45^{\circ}C \pm 5^{\circ}C$ for 48 hour / room temperature. Observe after 24 hours and 48 hours respectively. There should not be any change in the surface paper colour, cutting from the sides, peeling of the label, blistering / tunneling, oozing of adhesive/adhesive stains e.t.c on the surface paper.

12.0 UNWINDING DIRECTION:

Procedure:

Check the unwinding direction of the roll label with the approved proof / artwork or as per the specified in specification.

13.0 GRAIN DIRECTION:

Procedure:

Take of the adhesive of one specimen by rubbing it gently with a piece of cloth soaked in toluene and dry the chromo art paper. Put this paper in water. Paper will become curly after few seconds. Observe and record the direction of curl. **Result**:

Direction perpendicular to the curl will be grain direction of paper. Record these observed result with respect to either length or width or as per specification.

Revision History: STP No.: