

PACKING MATERIALS

- Any material that is used for packaging of products for their distribution and sale is said to be the packing material.
- **Two types** of packing material:
 - i. Primary packing material**

Comes in direct contact with the product **e.g.** bottles, vials, ampoules, tin, etc.



ii. Secondary packing material

Used to cover primary packs **e.g.** cartons, boxes, etc.



QUALITY CONTROL TESTS FOR GLASS CONTAINERS

1. Powdered glass test:

Done to estimate the amount of alkali leached from the powdered glass, which usually happens at elevated temperatures.

Sample containers are rinsed with purified water and dried.



The containers are grinded in a mortar to a fine powder and passed through sieve no. 20 and 50.



10gm of the sample is washed with acetone and dried.



50 ml of purified water is added to the dried sample and autoclaved at 121°C for 30 mins and cooled and decanted.



The decanted liquid is titrated with 0.02 N H_2SO_4 using methyl red as indicator.



2. Hydrolytic resistance of glass containers:

Each container is rinsed at least three times with CO₂ free water and filled with the same to their filling volume.



Vials and bottles are covered and autoclaved at 100°C for 10 mins.



The temp. is risen from 100°C to 121°C over 20 mins.



The temp. is maintained at 121°C to 122°C for 60 mins.



The containers are cooled and the liquids are combined and volume measured.



It is titrated with 0.01M HCl using methyl red as an indicator.



Capacity of container [corresponding to 90 per cent average overflow volume (ml)]	Volume of 0.01M hydrochloric acid per 100 ml of test solution	
	Type I or II glass (ml)	Type III glass (ml)
Not more than 1	2.0	20.0
More than 1 but not more than 2	1.8	17.6
More than 2 but not more than 5	1.3	13.2
More than 5 but not more than 10	1.0	10.2
More than 10 but not more than 20	0.80	8.1
More than 20 but not more than 50	0.60	6.1
More than 50 but not more than 100	0.50	4.8
More than 100 but not more than 200	0.40	3.8
More than 200 but not more than 500	0.30	2.9
More than 500	0.20	2.2

3. Arsenic test:

This test is for glass containers intended for aqueous parenterals.

The inner and outer surface of container is washed with fresh distilled water for 5 min.



Then similar steps are followed as performed in the hydrolytic test, previously described, till obtaining the final combined solution.



10ml from the final combined volume is pipetted out and to it 10 ml of HNO_3 is added and dried in an oven at 130°C .



10ml of hydrogen molybdate is added and refluxed for 25 mins.



It is cooled and absorbance is measured at 840nm.



The absorbance of the test solution should be less than the absorbance obtained using 0.1ml of arsenic standard solution (10ppm).



QUALITY CONTROL TESTS FOR PLASTIC CONTAINERS FOR NON-PARENTERAL PREPARATIONS

1. Leakage test:

10 containers are filled with water and fitted with intended closures.



They are kept inverted at room temperature for 24 hours.



The test is said to be passed if there is no sign of leakage from any container.



2. Collapsibility test:

- This test is applicable to containers which are to be squeezed in order to remove the contents.
- A container by collapsing inward during use, yield at least 90% of its normal contents at the required rate of flow at ambient temperature.



3. Clarity of aqueous extract:

A suitable container is taken at random, and unlabeled, unmarked and non-laminated portions is selected.



These portions are cut into strips, none of which has a total surface area of 20cm².



The strips are washed free from extraneous matter by shaking them with at least two separate portions of distilled water for about 30 secs.



The processed sample is taken in to the flask, previously cleaned with chromic acid and rinsed with distilled water.



250ml of distilled water is added to the flask, covered and autoclaved at 121°C for 30 mins.



The extract is cooled and examined. It should be colorless and free from turbidity.



QUALITY CONTROL TESTS FOR CLOSURES



Preparation of sample:

- The closures are washed in 0.2% w/v of anionic surface active agents for 5 mins.
- Rinsed five times with distilled water and 200ml water is added.
- Subjected to autoclave at 119°C to 123°C for 20-30 mins covering with aluminum foil.
- Cooled and solution is separated from closures (Solution A).

1. Residue on evaporation:

- 50ml of Solution A is evaporated to dryness on a water bath and dried at 105°C.
- The residue weighs not more than 4 mg.

2. Sterilisation test:

The closures used for the preparation of the sample solution shall not soften or become tacky and there shall be no visual change in the closure.



3. pH of aqueous extract:

To 20ml of solution A, 0.1ml of bromothymol blue solution is added.



NMT 0.3ml of 0.01M NaOH or 0.8ml of 0.01M HCl is reqd. to change the color of the solution to blue or yellow respt.



4. Self stability test:

Pierced ten times with hypodermic needle



Immersed in 0.1% methylene blue solution and subjected to a pressure of about 27 KPa



Restored to ATM pressure and made to stand for 30mins



Traces of colored solution should not be found.



QUALITY CONTROL TESTS FOR CARTONS



1. Compression:

- Used to assess the strength of erected package there by estimating the degree of protection that it confers on the contents.
- This is useful for products with no inherent strength in one plane or another.

2. Carton opening force:

- The carton should spring open in to its original shape without a need for unreasonable force.
- If the carton does not spring open or buckles in on itself, it may cause problems on cartooning machine.

QUALITY CONTROL TESTS FOR PAPER AND BOARD

Test conditions:

Temperature- $23 \pm 1^{\circ}\text{C}$; Relative humidity- $50 \pm 2\%$



<i>Name of the test</i>	<i>Description</i>
Moisture content	All the substances will be measured at temperature specified for test
Folding endurance	Fold the test piece back and forth until rupture occurs
Air permeability	Important for using light weight uncoated paper on machine having vacuum pick up system.
Tensile strength	The max tensile force per unit width that a paper or board will withstand before breaking.
Tear strength	The mean force required to continue the tearing of an initial cut in a single sheet of paper.
Stiffness	Degree of resistance offered by paper/board when it is bent.
Burst resistance	The max uniformly distributed pressure, applied at right angles to the surface that a test piece of paper and board will stand under conditions of test. Hydraulic pressure is applied to diaphragm, bulging it until test piece bursts.

REFERENCES:

- C, Rambabu, V, Ananth, R. T, Srikanth, S. K, Dona, K. G, Arun, T, Tinu, Manavalan, B. M, Venkanna, S. H, Viswa, J. K, Ghaharin. *A Concise Textbook of QC & QA*. KMCH College of Pharmacy, Coimbatore. 2011. 179-189.
- Government of India, Ministry of Health. *Indian Pharmacopoeia Volume I*. The Indian Pharmacopoeia Commission, Ghaziabad. 2010. 683-692.