QUALITY CONTROL TESTS FOR CONTAINERS, CLOSURES AND SECONDARY PACKING MATERIALS

(B. Pharm VI Sem Subject: Quality Assuarance)

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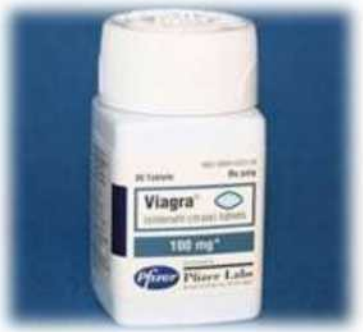
PACKING MATERIALS

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:

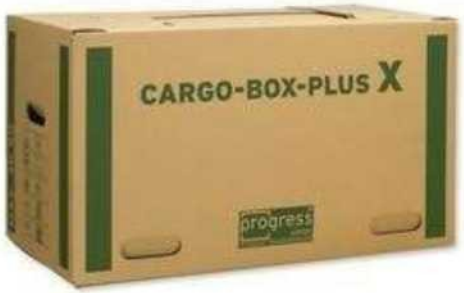
i. Primary packing material

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.

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

I

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

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

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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 $C0_2$ free water and filled with the same to their filling volume.

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

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

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

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

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It is titrated with 0.01M HC1 using methyl red as an indicator.

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.

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

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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.

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

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It is cooled and absorbance is measured at 840nm.

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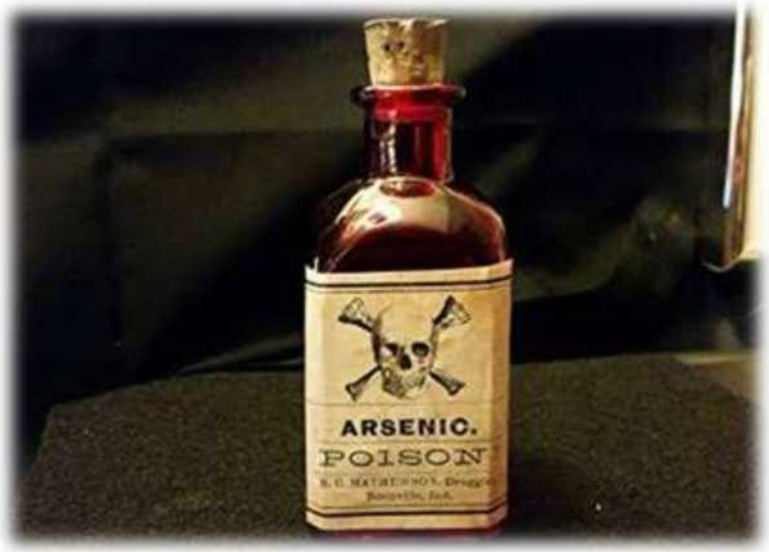
The absorbance of the test solution should be less than the absorbance obtained using 0.1ml of arsenic standard solution (10ppm).



QUALITY CONTROL TESTS FOR PLASTIC CONTAINERS FOR NON-PARENTERAL PREPARATIONS

1. Leakage test:

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

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They are kept inverted at room temperature for 24 hours.

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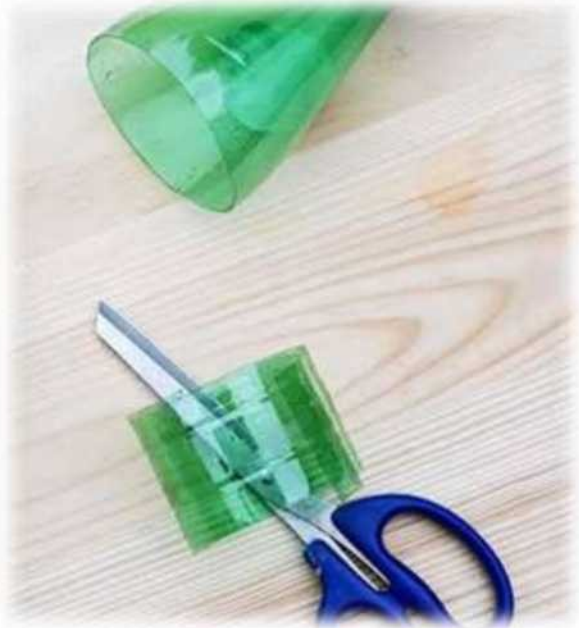
The test is said to be passed if there is no sign of leakage from any container. [2]

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 nonlaminated portions is selected.

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These portions are cut into strips, none of which has a total surface area of $20cm^2$.

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

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

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

30 mins.

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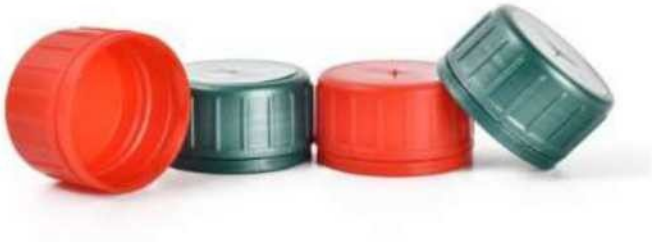
The extract is cooled and examined. It should be colorless and free from turbidity.

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]

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.

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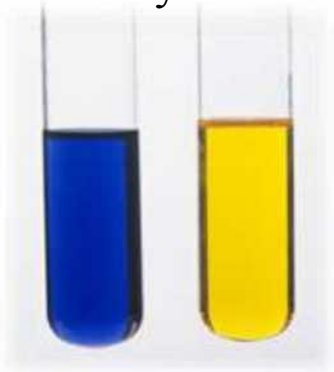
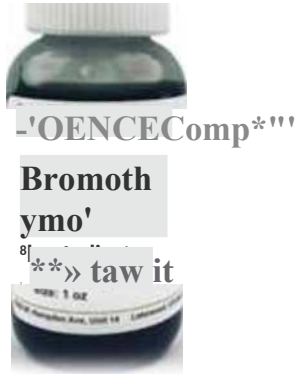
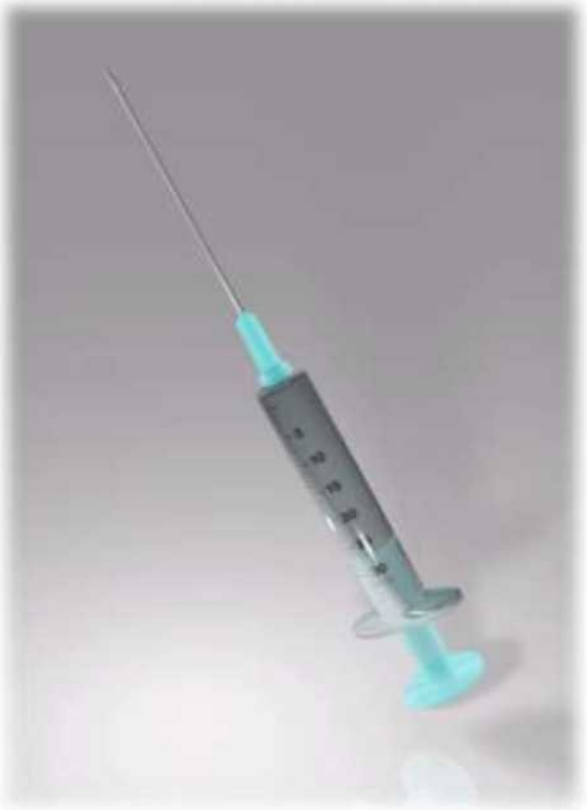
NMT 0.3ml of 0.01M NaOH or 0.8ml of 0.01M HCl is rqd. to change the color of the solution to blue or yellow respt.





4. Self stability test:



Pierced ten times with hypodermic needle

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

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Restored to ATM pressure and made to stand for 30mins

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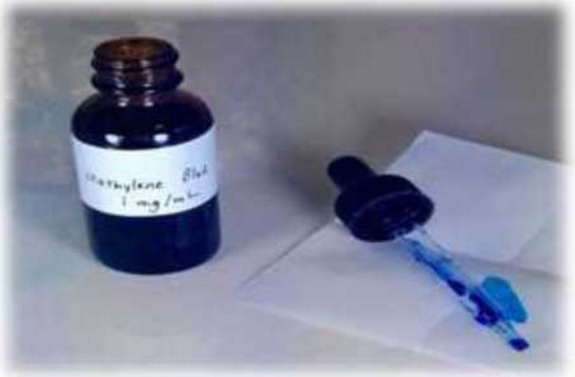
Traces of colored solution should not be found.



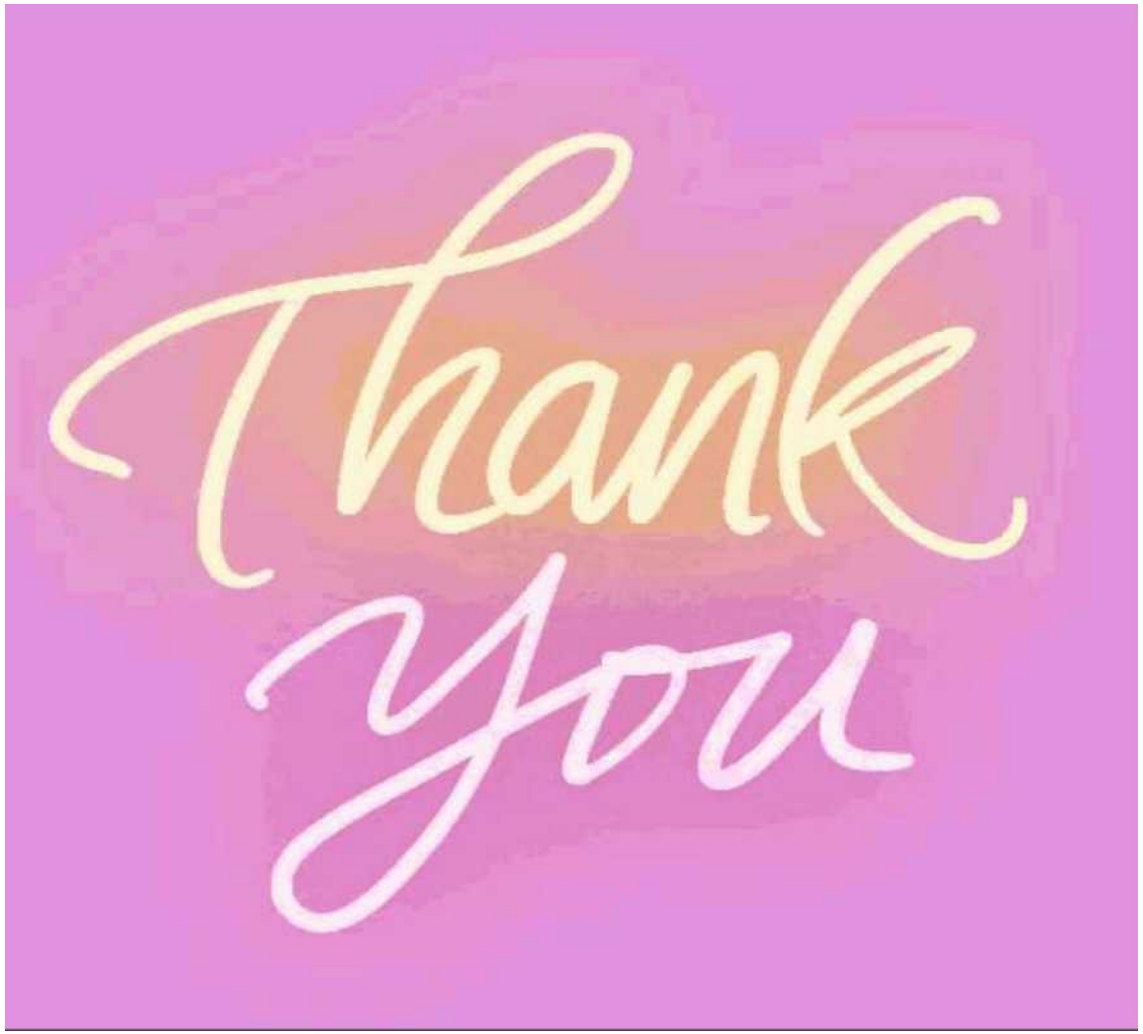
QUALITY CONTROL TESTS FOR CARTONS

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.


thank
you