BP606T. Pharmaceutical Quality Assurance.

Unit-Third

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PART-I	HOURS: 05
Quality Control: Quality control test for containers, rubber closures and secondary packing materials.	

Quality Control:

Packaging:

Packaging is the process by which the pharmaceuticals are suitably placed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. ′ Definition: “Packing is the art and science which involves preparing the articles for transport, storage, display and use.” ′ Pharmaceutical packaging is the means of providing protection, presentation, identification, information and convenience to encourage compliance with a course of therapy.

Composition of package: (a) Container (b) Closure (c) Carton or Outer (d) Box

The ideal container or package should:

a) Protect the contents from the following environmental hazards:

1. Light - protect the contents from light.
2. Temperature - be capable of withstanding extremes of temperature.
3. Moisture - be capable of withstanding extremes of humidity.
4. Atmospheric gases - protect the contents from the effect of atmospheric gases (e.g. aerial oxidation).
5. Particles - protect from particulate contamination.
6. Microorganisms - protect from microbial contamination.

b) Protects the content from the following mechanical hazards

1. Vibration - Usually due to transportation.

2. Compression - this usually includes pressure applied during stacking.

3. Shock - such as impact, drops or rapid retardation.

4. Puncture - penetration from sharp objects or during handling operations.

5. Abrasion - this may create electrostatic effects.

6. They must not add or permit loss to its contents:

7 Protect the contents from both loss and gain of water.

8 Protect the contents from loss of volatile materials

9 Must not shed particles into the contents.

10 Must not leach anything to the contents.

11. Must have a pharmaceutically elegant appearance: ′In a competitive market the appearance of a package first draws the attraction of the consumers than its contents. ′Must be easy to label and thus to identify the product.

12 Must be convenient and easy to use by the patient.

13. Must be cheap and economical.

14. Must not react with the content.

15. Must be biodegradable.

SELECTION OF PACKAGING MATERIAL

′ The materials selected for packaging must have the following characteristics:

1. They must protect the preparation from environmental conditions.
2. They must not be reactive with the product.
3. They must not impart tastes or odors to the products.
4. They must be non-toxic.
5. They must be FDA (Food & Drug Administration) approved.
6. They must meet applicable tamper-resistance requirements.
7. They must be adaptable to commonly employed high-speed packaging equipment.

8. They must have reasonable cost in relation to the cost of the product.

Categorically differentiating pharmaceutical packaging:

Primary Packaging:

This is the first packaging envelope which is in touch with the dosage form or equipment (i.e. bottle, cap, cap liner, label etc). The packaging needs to be such that there is no interaction with the drug and will provide proper containment of pharmaceuticals. E.g. Blister packages, Strip packages, etc. The main functions of the primary package are to contain and to restrict any chemical, climatic or biological or occasionally mechanical hazards that may cause or lead to product deterioration. Packaging must also function as a means of drug administrations.

Secondary Packaging:

This is consecutive covering or package which stores pharmaceuticals packages in it for their grouping. E.g. Cartons, boxes, etc. OR The packaging external to the primary package is known as the secondary packaging. The secondary packaging mainly provides the additional physical protection necessary to endure the safe warehousing and for refill packaging.

Tertiary packaging: This is to provide bulk handling and shipping of pharmaceuticals from one place to another. E.g. Containers, barrels, 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.

QUALITY CONTROL TESTS FOR CLOSURES

Preparation of sample:

1. The closures are washed in 0.2% w/v of anionic surface active agents for 5 mins.
2. Rinsed five times with distilled water and 200ml water is added.
3. Subjected to autoclave at 119°C to 123°C for 20-30 mins covering with aluminum foil.
4. Cooled and solution is separated from closures (Solution A).
5. Residue on evaporation:
6. 50ml of Solution A is evaporated to dryness on a water bath and dried at 105°C.
7. The residue weighs not more than 4 mg.

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.

pH of aqueous extract:

1. To 20ml of solution A, 0.1ml of bromothymol blue solution is added.
2. NMT 0.3ml of 0.01M NaOH or 0.8ml of 0.01M HCl is rqd.
3. to change the color of the solution to blue or yellow respt.

8. Self stability test:

1. Pierced ten times with hypodermic needle.
2. Immersed in 0.1% methylene blue solution and subjected to a pressure of about 27 KPa.
3. Restored to ATM pressure and made to stand for 30mins.
4. Traces of colored solution should not be found.