IN THE NAME OF GOD

QUALITY CONTROL OF PACKAGING MATERIAL

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Packaging

Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use.
Quality of packaging material

- It must Protect against all adverse external influences that can alter the properties of the product, e.g. moisture, light, oxygen and temperature variations.
- Protect against biological contamination.
- Protect against physical damage.
- Carry the correct information and identification of the product.
Development of a package

It must be linked closely with the product to be packaged.
Selection of a suitable container

- It is necessary to know the full manufacturing formula of that.
Plastic containers

- A plastic container is a plastic article which contains a pharmaceutical product.
The most commonly used polymers

- Polyethylene
- Polypropylene
- Poly ( vinyl chloride )
- Poly( ethylene terephthalate )
- Poly ( ethylene-vinyl acetate )
Additives

- Antioxidants
- Stabilizers
- Plasticizers
- Lubricants
- Coloring matter
- Impact modifiers
Quality control tests for plastic containers

- Opalescence of solution S
- Colour of solution S
- Acidity or alkalinity of solution S
- Absorbance
- Reducing substances
- Ammonium
- Extractable zinc
- Extractable heavy metals
- Volatile sulphides
- Residue on evaporation
Glass containers are glass articles intended to come into direct contact with pharmaceutical preparations.
Types of glass containers

- Ampoules
- Bottles, vials, syringes and carpules
- Containers for blood and blood components
Essential requirements in the parenteral field

- High hydrolytic resistance
- High neutrality
- Chemical resistance
Hydrolytic stability

It is expressed by the resistance to the release of soluble mineral substance into water.
Types of glass

- Type I (Borosilicate glass)
- Type II (Soda-lime-silica glass)
- Type III (usually of soda-lime-silica)
Type I glass

- Preparations for parental use
- Injectable products with acid
- Neutral or slightly alkaline PH
Type II glass

- Holding acid
- Neutral preparations both for parental and other use.
Colourless and Coloured glass

Colourless glass: is highly transparent in the visible spectrum.

Coloured glass: is obtained by the addition of small amounts of metal oxides.
Interior and exterior treatments

- Highly water repellent
- Facilitates efficient emptying of the contents
- Eliminates dosage errors or wastage
- Lubricity of the closure system
Different types of siliconisation process

- Immersion
- Silicone swabbing
- Silicone spraying
Quality control tests

- Determination of the filling volume
- Test A: hydrolytic resistance of the inner surface of glass containers (surface test)
- Test B: hydrolytic resistance of glass grains (glass grains test)
- Test c: to determine whether the containers have been surface treated (etching test)
- Arsenic
Immunization programmes save millions of lives every year worldwide.
Vaccination is heralded one of the most cost-effective medical interventions.

WHO, the Red Cross and the safe Injection Global Network (SIGN) are supporting programs to improve injection safety worldwide.
Prefilled AD syringe

Refer to a specific type of single-dose format where a single dose of vaccine is prefilled into an AD injection device.
Auto-Disable (AD) Syringes
Comparison of single-dose and multi-dose vaccine formats

- Vaccine manufacturing costs
- Vaccine distribution
- Vaccine safety
- Vaccine wastage
- Coverage rates
- Medical waste
Vaccine manufacturing costs

- Production (labour and equipment)
  Filling costs for single-dose vials are higher than those for multi-dose vials.
- Vaccine overfill adjustment
- Material packaging and syringe
  Packaging costs including glass, metal, rubber, labels, and vaccine vial monitors.
Vaccine distribution

The primary vaccine distribution issues affected by vial size are inventory logistics and cold-chain capacity.
Vaccine safety

- Vial size affects injection safety in terms of contamination and reuse.
- Single-dose vials reduce many of the contamination risks of multi-dose vials.
- Prefilled AD devices protect against syringe reuse.
Vaccine wastage

Vaccine wastage (the amount of discarded efficacious vaccine) is a major economic consideration for most developing countries.
Coverage rates

Although opening a multi-dose vial to administer a single vaccine dose contributes to vaccine wastage, a health workers reluctance to open multi-dose vials for only a few children leads to missed opportunities and lower coverage rates.
Medical wastage

- Single-dose vials generate a large total volume of contaminated medical waste per dose than multi-dose vials.