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Formulation and Evalution of Parenterals

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ABSTRACT
A parenteral dosage is a sterile drug product, which is presented in the form of solution, suspension, emulsion, or reconstituted lyophilized powder, suitable for administration by injection. Typical routes of administration of a parenteral dosage form include subcutaneous, intramuscular, and intravenous delivery. Parenteral dosage forms can also be administered via intrathecal, intracisternal, intraarterial, intraspinal, intraepidural, and intradermal routes to achieve local or systemic effects. This chapter outlines the aspects of pharmaceutical analysis that are required to monitor the quality of parenteral products from development stage through to the marketing phase. Emphasis is placed on analytical methods or techniques that are either unique to or require some modification to be applicable to this class of pharmaceutical product. The chapter also examines the sterility test, microbial limit tests, bacterial endotoxin test, and particulate matter test. A detailed presentation of cleaning validation an increasingly critical aspect of pharmaceutical analysis is presented with practical examples including all necessary calculations.[1]

I. INTRODUCTION

The term parenteral is derived from two word(Para) means outside and (enteron) means intestine.it means that any dosage form which are given outside the intestine is called parenterals.these preparations are administered by other than oral routes.they are sterile preparations that are given directly into the systemic circulation. Common injection types are Intravenous (into a vein),Subcutaneous (under the skin),and Intramuscular(into muscle).[2]

Materials and Methods Components

Components of parenteral products include the active ingredient,formulation additives,vehicles and primary container and closure.establishing specifications to ensure the quality of each of these components of an injection essential.secondary packaging is relevant more to marketing considerations,although some drug is products might rely on secondary packaging for stability considerations,such as added protection from light exposure for light sensitive drugs and antimicrobial preservatives

Solvents And Vehicles

Water And Aqueous vehicles

Water for injection

- Sterile water for injection
- Bacteriosatic sodium chloride injection
- Sodium chloride injection
- Bacteriostatic sodium chloride injection

Non Aqueous solvent

- Fixed vegetable oils
- Alcohols

Added substances Preservatives

- Agent containing mercury in concentration not more than 0.01%
- Cationic surfactants
- Alcohols up to 2%
- Phenols up to 0.5%
- Others

Antioxidants Water soluble

- Sulfurous acid salts
- Ascorbic acid salts
- Thiol derivatives

Oil soluble

- Propyl gallate
- Butylated hydroxyanisole
- Ascorbyl palmitate
- a-Tocopherol

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Buffer Systems

PH	Buffer systems	Concentrations(%)
3.5-5.7	Acetic acid-acetate	1-2
2.5-6.0	Citric acid-citrate	1.5
8.2-10.2	Glutamic acid-glutamate	1-2

Preparations

- Primary washing and sterilization
- Compounding
- Terminal sterilization.[3]

Parenteral formulations

These are also called injectable formulations and are used with intravenous, subcutaneous, intramuscular, and intra-articular administration.The drug is stored in liquid or if unstable, lyophilized form.

Many parenteral formulations are unstable at higher temperatures and require storage at refrigerated or sometimes frozen conditions. The logistics process of delivering these drugs to the patient is called the cold chain. The cold chain can interfere with delivery of drugs, especially vaccines, to communities where electricity is unpredictable or nonexistent. NGOs like the Gates Foundation are actively working to find solutions. These may include lyophilized formulations which are easier to stabilize at room temperature.

Most protein formulations are parenteral due to the fragile nature of the molecule which would be destroyed by enteric administration. Proteins have tertiary and quaternary structures that can be degraded or cause aggregation at room temperature. This can impact the safety and efficacyof the medicine.

Liquid

Liquid drugs are stored in vials, IV bags, ampoules, cartridges, and prefilled syringes.

As with solid formulations, liquid formulations combine the drug product with a variety of compounds to ensure a stable active medication following storage. These include solubilizers, stabilizers, buffers, tonicity modifiers, bulking agents, viscosity enhancers/reducers, surfactants, chelating agents, and adjuvants.

If concentrated by evaporation, the drug may be diluted before administration. For IV administration, the drug may be transferred from a vial to an IV bag and mixed with othermaterials.

Lyophilized

Lyophilized drugs are stored in vials, cartridges, dual chamber syringes, and prefilled mixing systems.

Lyophilization, or freeze drying, is a process that removes water from a liquid drug creating a solid powder, or cake. The lyophilized product is stable for extended periods of time and could allow storage at higher temperatures. In protein formulations, stabilizers are added to replace the water and preserve the structure of the molecule.

Before administration, a lyophilized drug is reconstituted as a liquid before being administered. This is done by combining a liquid diluent with the freeze-dried powder, mixing, then injecting. Reconstitution usually requires a reconstitution and delivery system to ensure that the drug is correctly mixed and administered.[4]

Types of parenteral preparation

1. Small volume parenterals (SVP)

The volume of these parenteral preparations varies from fractions of few milliliters to not more than 500 ml.Small volume parenterals are available as solution,emulsion or suspensions contained in single dose ampoules or multi dose vials or mini bags in volumes of 100 ml,50 ml and 25 ml.these are administered through the route of intravenous,intramuscular ,intradermal and subcutaneous routes.

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preparations	Physical state	Route of administration	comments
Botulinum toxin type A	Powder ofinjection	I.M	For temporary improvement in appearance of glabellar lines around eyes and mouth (cosmetic applications)
Cimetidine HCL	Solution	I.M or I.V	For GI hypersecretory conditionsand ulcers
Digoxin	Solution	I.V	Cardiotonic

2. Large volume parenterals (LVP)

The volume of these preparations vary from 500 ml or above and these are available as solutions packed in single dose containers like pliable plastic bottles or bags. These are usually administered in volumes of 100 ml to 1 litre or more,per day by slow intravenous infusion with or without a controlled rate infusion systems.[5]

Preparations	Uses
Amino acid	Fluid and nutrient replenisher
Ringer injection,USP	Fluid and electrolyte replenisher
Sodium chloride injection,USP	Fluid and electrolyte replenisher,isotonic vehicle

Manufacturing of parenterals

Washing of containers

⇩

Preparation And compunding

⇩

Filteration And sterilization

⇩

filling

⇩

Sealing

⇩

sterilization

⇩

Packing And labeling

⇩

Inspection.[6]

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Evalution of parenterals

- Quality control tests
- Particulate contamination
- Sterility
- Bacterial endotoxins and pyrogens
- Uniformity of contents
- Uniformity of mass
- Uniformity of dosage unit
- Isotonicity
- Clearity test
- Leaker test[7]

II. CONCLUSION

- The test is positive when each rabbit show increase in the temperature it only 2 of thethree rabbits show increase in temperature.
- The test using group of five and test will be positive if the four of the rabbits showincrease the temperature.

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