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QUALITY CONTROL TESTS FOR PARENTRALS

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DESCRIPTION

Parenteral are those preparations which are injected through skin or other external boundary tissue rather than through alimentary canal Medications can be developed into the body through a variety of groups. Drug characteristics and pharmacodynamics properties vary depending on the route of administration chosen for the drug. Parenteral preparation circumvents the intestinal tract and therefore is not subject to pharmacodynamics properties associated with oral or other formulations. While many routes of parenteral administration are available all of which bypass the intestinal tract, intravenous intramuscular and subcutaneous routes of administration are delivery commonly used. Intrathecal and epidural administration of indications offer routes of administration with in spinal cord.

The USP defines 5 main types of preparations intended for parenteral administration:

- Injection: liquid preparations that are drug substances and solutions therefore
- For injections; dry solids that, upon addition of suitable vehicles, yield solutionsconfirming in all respects to the requirements for injections.
- Injectable emulsions: liquid preparations of drug substances dissolved or dispersed ina suitable emulsion medium.
- Injectable suspension. Liquid preparations of soils suspended in a suitable liquid medium.
- For injectable suspension: dry solids that, upon addition of suitable vehicles yield preparations confirming in all respects to the requirements of injectable suspensions

Quality control tests for parenterals include Sterility tests, Pyrogen test, Leaker tests, Particulate matter testing. Sterility tests are performed by direct transfer method and membrane filtration method.

Pyrogen is a product of metabolism in microorganisms Gram-ve bacteria produces most potent pyrogen. These are lipopolysaccharides chemically and heat stable and are capablee of Passing through bacteria retentive filter. When these pyrogen produce a mark responseof fever with body ache and vasoconstriction within an on hour. Basically there are test performed to detect the presence of pyrogen in sterile parenteral products .They are of two types:

a) Rabbit test

b) LAL. Test

Rabbit test basically involves the injection of sample solution which is to be tested into a rabbits which are used as test animals through ear vein. The temperature sensing probe is insisted in clinical thermometer, Thermistor or similar probe into a rectum cavity of rabbit at the depth of 7.5 mm, the test solution must be warmed at 37 °C prior to injection. Then rectal temperature is recorded at 1, 2, 3 hr subsequent to injection. This test is performed in separate area designed solely for this purpose under environmental conditions similar to animal house and should be free from disturbances that likely to excite them individually. This test is performed on three rabbits but if required results are not obtained this test is performed on 5 additional rabbits with sample solution administered to initial 3 rabbits. Prior

to one hour of injecting sample solutions, control temperatures of rabbits are determined. Rabbits whose control temperature does not vary by more than 1℃ are only used. This test is considered to be acceptable when the individual temperature rise is 0.6 ℃ in individual and 1.4℃ in group of three rabbits.

LAL test is a recently developed *in vitro* test method for pyrogen unitizing gelling property of lysates amoebocytes *of Limulus polyphemus* which is found only at specific locations along the east coast of North America and along southeast Asia. It is derived from horse shoe crab; the basic procedure is the combination of 0.1 mL of test sample with LAL reagent after incubation for one hour at 37 ℃ the mixture is analysed for the presence of gel clot. The LAL test is positive in the presence of endotoxin. Its applications are mainly to pharmaceutics, biological devices, disease states, food and validation of heat cycles. This method has several advantages over rabbit test. They are greater sensitivity and reliability, specificity, less variation, wider application, less expensive and simplicity.