ESTRADIOL VALERATE 40-MG/ML IN OIL INJECTION

Rx

For 100 mL

Estradiol valerate		4 g
Benzyl benzoate		44.7 g
Benzyl alcohol		2 g
Castor oil	qs	100 mL

Note: This formulation should be prepared according to strict aseptic compounding technique in a laminar airflow hood in a cleanroom or via isolation barrier technology by a compounding pharmacist who is validated in aseptic compounding. This is a high-risk preparation.

METHOD OF PREPARATION

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Weigh and/or measure each ingredient accurately.
3. Mix the benzyl benzoate and benzyl alcohol.
4. Add the estradiol valerate and mix well.
5. Add sufficient castor oil to final volume and mix well.
6. Sterilize appropriately.
7. Package and label.

PACKAGING

Package in tight, light-resistant containers.[1]

LABELING

Keep out of reach of children. Use only as directed. For professional use.

STABILITY

Check the current edition of the *United States Pharmacopeia* for the appropriate beyond-use date for this compounded preparation.[1]

USE

Estradiol valerate injection is used as an estrogenic hormone.

QUALITY CONTROL

Quality-control assessment can include weight/volume, physical observation, pH, specific gravity, osmolality, assay, color, clarity, particulate matter, sterility, and pyrogenicity.[2,3]

DISCUSSION

Estradiol valerate ($C_{23}H_{32}O_3$, MW 356.50, Delestrogen) injection is currently in short supply. Estradiol Valerate Injection USP is a sterile solution of estradiol valerate in a suitable vegetable oil. It contains NLT 90.0% and NMT 115.0% of the labeled amount of estradiol valerate. Estradiol valerate occurs as a white, crystalline powder that is usually odorless but may have a faint, fatty odor. It is soluble in castor oil and benzyl benzoate; it is sparingly soluble in sesame oil and in peanut oil ,and practically insoluble in water.[1]

Benzyl benzoate ($C_{14}H_{12}O_2$, Mw 212.24) occurs as a clear, colorless, oily liquid with a slightly aromatic odor. It produces a sharp, burning sensation on the tongue. Below 17°C, it exists as clear, colorless crystals. It is soluble in acetone, practically insoluble in glycerin and water, and miscible with ethanol, fatty acids, and essential oils. It is incompatible with alkalis and oxidizing agents. It is used as a solubilizing agent and nonaqueous solvent in intramuscular injections at concentrations up to 46.0% v/v, and as a solvent and fixative for flavors and perfumes in cosmetics and food products. It is also used as a plasticizing agent. It has a specific gravity of 1.12.[4]

Benzyl alcohol (C_7H_8O, MW 108.14) is an antimicrobial preservative, disinfectant, and solvent. It is commonly used in concentrations up to 2% in pharmaceutical formulations as an antimicrobial preservative. As a solubilizer, it is used at a 5% concentration, and a 10% concentration is used as a disinfectant. Benzyl alcohol is a clear, colorless, oily liquid that has a faint, aromatic odor and a sharp, burning taste. It has a specific gravity of about 1.045, a boiling point of 204.7°C, and a freezing point of -15°C. It is soluble 1 g in 25 mL of water at 25°C and is miscible with ethanol. It will slowly oxidize in air to benzaldehyde and benzoic acid.[5]

Castor oil is a fixed oil obtained from the seed of Ricinus communis Linne′ (Fam Euphorbiaceae). It is composed primarily of the glycerides of ricinoleic and isoricinoleic acids. It occurs as a pale, yellowish or almost colorless, transparent, viscid liquid with a faint, mild odor and a bland taste. It is soluble in alcohol and miscible with dehydrated alcohol and glacial acetic acid. It has a specific gravity between 0.945 and 0.965 and is used externally as an emollient and internally as a laxative. It is a good emollient as the oil is bland and soothing to the skin.[6]

REFERENCES

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