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Dimercaprol Injection

» Dimercaprol Injection is a sterile solution of Dimercaprol in a mixture of Benzyl Benzoate and vegetable oil. It contains, in each 100 g, not less than 9.0 g and not more than 11.0 g of dimercaprol ($C_3H_8OS_2$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I or Type III glass.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1 USP Endotoxin Unit per mg of dimercaprol.

Limit of 1,2,3-trimercaptopropane and related impurities—

Adsorbent, Standard buffer solution, Acid-washed solvent hexane, Diisopropyl ether, Solvent hexane-diisopropyl ether mixture, Chromatographic tube, and *Chromatographic column*—Prepare as directed in the test for *Limit of 1,2,3-trimercaptopropane and related impurities* under *Dimercaprol*.

Procedure—Place about 1 g of Injection, accurately weighed and demonstrated to be free from hydrogen sulfide as directed in the *Assay* under *Dimercaprol*, in a 5-mL beaker, add 2 mL of *Solvent hexane-diisopropyl ether mixture*, and mix. Transfer the resulting solution to the prepared *Chromatographic column.* When the liquid has passed into the column, wash the beaker with two 2-mL portions of *Solvent hexane-diisopropyl ether mixture,* and allow the washings to fall to the level of the *Adsorbent.* Proceed as directed for *Procedure* in the test for *Limit of 1,2,3-trimercaptopropane and related impurities* under *Dimercaprol.* The limit of 1,2,3-trimercaptopropane ($C_3H_8S_3$) is not more than 4.5%, by weight, of the content of dimercaprol.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that at times it may be turbid or contain small amounts of flocculent material.

Assay—Transfer about 2 mL of Injection to a tared conical flask, and weigh accurately. Add 100 mL of a mixture of 1 volume of chloroform and 3 volumes of methanol, agitate to dissolve the Injection, and titrate with 0.1 N iodine VS to the production of a permanent yellow color. Perform a blank determination, and make any necessary correction. Calculate the percentage of dimercaprol ($C_3H_8OS_2$) in the portion of Injection taken by the formula:

$$0.6211(V/W - v/w)$$

in which V is the volume, in mL, of 0.1 N iodine used; W is the weight, in g, of Injection taken; and v and w are the volume, in mL, of 0.1 N iodine and the weight, in g, of Injection, respectively, used in the test for *Limit of 1,2,3-trimercaptopropane and related impurities.*

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DIMERCAPROL INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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