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## **Chromic Chloride Injection**

» Chromic Chloride Injection is a sterile solution of Chromic Chloride in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of chromium (Cr).

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

**Labeling**—Label the Injection to indicate that it is to be diluted to the appropriate strength with Sterile Water for Injection or other suitable fluid prior to administration.

**Identification**—The Assay preparation, prepared as directed in the Assay, exhibits an absorption maximum at about 360 nm when tested as directed for *Procedure* in the Assay.

BACTERIAL ENDOTOXINS TEST (85) —It contains not more than 16.70 USP Endotoxin Units per µg of chromium.

**PH** (791): between 1.5 and 2.5.

Other requirements—It meets the requirements under Injections and Implanted Drug Products (1).

#### Assay-

Sodium chloride solution-Dissolve 54 g of sodium chloride in water, dilute with water to 2000 mL, and mix.

Chromium stock solution—Transfer 2.829 g of potassium dichromate, accurately weighed, to a 1000-mL volumetric flask, dissolve in water, dilute with water to volume, and mix. This solution contains 1000 µg of chromium per mL. Store in a polyethylene bottle.

Standard preparations—Pipet 10 mL of the Chromium stock solution into a 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL and 20.0 mL, respectively, of this stock solution to separate 100-mL volumetric flasks, and transfer 15.0 mL and 20.0 mL, respectively, of the stock solution to separate 50-mL volumetric flasks. Add 20 mL of Sodium chloride solution to each 100-mL volumetric flask, and 10 mL of Sodium chloride solution to each 50-mL volumetric flask, dilute the contents of each flask with water to volume, and mix. These Standard preparations contain, respectively, 1.0, 2.0, 3.0, and 4.0 µg of chromium per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 60 µg of chromium, to a 25-mL volumetric flask. From the labeled amount of sodium chloride, if any, in the Injection, calculate the amount, in mg, of sodium chloride in the volume of Injection taken, and add sufficient *Sodium chloride solution* to bring the total sodium chloride content of the flask to 135 mg. Dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the Standard preparations and the Assay preparation at the chromium emission line of 357.9 nm, with a suitable atomic absorption spectrophotometer (see <u>Atomic Absorption Spectroscopy (852)</u>) equipped with a chromium hollow-cathode lamp and an air—acetylene flame, using a 1:5 dilution of the Sodium chloride solution as the blank. Plot the absorbances of the Standard preparations versus concentration, in μg per mL, of chromium, and draw the straight line best fitting the four plotted points. From the graph so obtained, determine the concentration, in μg per mL, of chromium in the Assay preparation. Calculate the quantity, in μg, of chromium in each mL of the Injection taken by the formula:

#### 25C/V

in which C is the concentration, in µg per mL, of chromium in the Assay preparation, and V is the volume, in mL, of Injection taken.

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

Topic/Question	Contact	Expert Committee
CHROMIC CHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

 $\textbf{Chromatographic Database Information:} \ \ \underline{\textbf{Chromatographic Database}}$ 

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