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# Sodium Chromate Cr 51 Injection

Chromic acid ($H_2{}^{51}CrO_4$), disodium salt.

Disodium chromate ($Na_2{}^{51}CrO_4$)

CAS RN®: 7775-11-3.

» Sodium Chromate Cr 51 Injection is a sterile solution of radioactive chromium ($^{51}Cr$) processed in the form of sodium chromate in Water for Injection. For those uses where an isotonic solution is required, Sodium Chloride may be added in appropriate amounts as provided under Injections and Implanted Drug Products ⟨1⟩. Chromium 51 is produced by the neutron bombardment of enriched chromium 50.

Sodium Chromate Cr 51 Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $^{51}Cr$ as sodium chromate expressed in megabecquerels (millicuries) per mL at the time indicated in the labeling. The sodium chromate content is not less than 90.0 percent and not more than 110.0 percent of the labeled amount. The specific activity is not less than 370 megabecquerels (10 millicuries) per mg of sodium chromate at the end of the expiry period. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

**Packaging and storage**—Preserve in single-dose or in multiple-dose containers.

**Labeling**—Label it to include the following, in addition to the information specified for *Labeling* ⟨7⟩, *Labels and Labeling for Injectable Products*: the time and date of calibration; the amount of sodium chromate expressed in µg per mL; the amount of $^{51}Cr$ as sodium chromate expressed as total megabecquerels (millicuries) and as megabecquerels (millicuries) per mL at the time of calibration; a statement to indicate whether the contents are intended for diagnostic or therapeutic use; the expiration date; and the statement "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay and the quantity of chromium, and also indicates that the radioactive half-life of $^{51}Cr$ is 27.8 days.

**Radionuclide identification** (see *Radioactivity* ⟨821⟩)—Its gamma-ray spectrum is identical to that of a specimen of $^{51}Cr$ of known purity that exhibits a photopeak having an energy of 0.320 MeV.

**Bacterial Endotoxins Test** ⟨85⟩—It contains not more than 175/*V* USP Endotoxin Unit per mL of the Injection, when compared with the USP Endotoxin RS, in which *V* is the maximum recommended total dose, in mL, at the expiration date or time.

**pH** ⟨791⟩**:** between 7.5 and 8.5.

**Radiochemical purity**—Place a volume of Injection, appropriately diluted so that it provides a count rate of about 20,000 counts per minute, about 25 mm from one end of a 25- × 300-mm strip of chromatographic paper (see *Chromatography* ⟨621⟩), and immediately develop with a mixture of 5 parts of water, 2 parts of dilute alcohol (9.5 in 10), and 1 part of ammonium hydroxide. Air-dry the chromatogram, and determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. The radioactivity of the chromate band is not less than 90.0% of the total radioactivity. The $R_F$ value for the chromate band falls within ±10% of the value found for a known sodium chromate specimen when determined under identical conditions.

**Other requirements**—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩; not subject to *Container content*.

**Assay for sodium chromate**—

*Standard stock preparation*—Dissolve 3.735 g of potassium chromate in 1000 mL of water to obtain a solution having a known concentration of 1.0 mg per mL of chromium.

*Standard preparation*—Pipet 0.25, 0.50, 0.75, 0.100, 0.125, and 0.150 mL of the *Standard stock preparation*, accurately measured, into separate 100-mL volumetric flasks. To each flask add 0.42 mL of 0.1 N sodium bicarbonate, and dilute with water to volume to obtain solutions having final concentrations of 0.25, 0.50, 0.75, 1.00, 1.25, and 1.50 µg of chromium per mL.

*Assay preparation*—Use the Injection.

*Blank preparation*—Transfer 0.42 mL of 0.1 N sodium bicarbonate to a 100-mL volumetric flask, and dilute with water to volume.

*Procedure*—Concomitantly determine the absorbances of the *Assay preparation*, the *Standard preparations*, and the *Blank preparation* at the chromium emission line at 357.7 nm with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a chromium hollow-cathode lamp and an air–acetylene (fuel-rich) flame using water to set the instrument to zero. Plot the

absorbances of the *Standard preparations* and the *Blank preparation* versus concentration, in µg per mL, of chromium, and perform a regression analysis. A suitable standard curve will have an intercept between −0.002 and +0.002, and a regression coefficient of not less than 0.99. Using the standard curve so obtained, determine the concentration, *C*, in µg per mL, of chromium in the Injection taken. Calculate the quantity of sodium chromate, in µg per mL, by the formula:

$$3.115C$$

in which 3.115 is the conversion factor.

**Assay for radioactivity**—Using a suitable counting assembly, determine the radioactivity, in MBq (µCi) per mL, of Injection by use of a calibrated system as directed under *Radioactivity* ⟨821⟩.

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| SODIUM CHROMATE CR 51 INJECTION | Documentary Standards Support | SM42020 Small Molecules 4 |

**Chromatographic Database Information:** Chromatographic Database

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