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Strontium Chloride Sr 89 Injection

Change to read:

▲$^{89}SrCl_2$▲ (ERR 1-Mar-2021) 159.9

Strontium chloride ($^{89}SrCl_2$) CAS RN®: 38270-90-5; UNII: 5R78837D4A.

» Strontium Chloride Sr 89 Injection is a sterile solution of radioactive strontium (^{89}Sr) processed in the form of strontium chloride in Water for Injection.

Strontium Chloride Sr 89 Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{89}Sr as strontium chloride expressed in megabecquerels per mL (or in millicuries per mL) at the time indicated in the labeling. The strontium chloride content is not less than 90.0 percent and not more than 110.0 percent of the labeled amount.

Specific activity: not less than 2.96 MBq (80 µCi) per mg of strontium at the time indicated in the labeling.

Packaging and storage—Preserve in single-dose containers that are adequately shielded.

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 strontium chloride expressed as mg of strontium per mL; the amount of ^{89}Sr as labeled strontium chloride expressed as total megabecquerels (or millicuries) and concentration as megabecquerels per mL (or millicuries per mL) on the date and time of calibration; 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 also indicates that the radioactive half-life of ^{89}Sr is 50.5 days.

Radionuclide identification ⟨see *Radioactivity* ⟨821⟩⟩—Strontium 89 decays by beta emission to stable Yttrium 89 with 0.01% of disintegrations going via the metastable daughter ^{89m}Y with a half-life of 16 seconds, with which it rapidly establishes radioactive equilibrium. Its gamma-ray spectrum is identical to that of a specimen of strontium 89 in equilibrium with ^{89m}Y exhibiting bremsstrahlung and a gamma photopeak of 0.909 MeV. [Note—Use a plastic container to perform measurements.]

Bacterial Endotoxins Test ⟨85⟩—It meets the requirements, the limit of endotoxin content being 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 4.0 and 7.5.

Radionuclidic purity (see *Radioactivity* ⟨821⟩)—[Note—Use a plastic container to perform the following test.] Using a suitable counting assembly, determine the radioactivity of each gamma-emitting radionuclidic impurity, in kBq per MBq (or µCi per mCi) of ^{89}Sr, in the Injection by use of a calibrated system as directed under *Radioactivity* ⟨821⟩. The total activity of all gamma-emitting impurities is not greater than 370 kBq per 37 MBq (or 10 µCi per mCi) of ^{89}Sr at the expiration date stated in the labeling.

Chemical purity (Limit of aluminum)—[Note—The *Standard preparations* and the *Test preparation* may be modified, if necessary, to obtain solutions of suitable concentrations adaptable to the linear or working range of the instrument.]

Nitric acid diluent—Dilute 40 mL of nitric acid with water to 1000 mL.

Standard preparations—Transfer 2000 mg of aluminum metal to a 1000-mL volumetric flask, add 50 mL of 6 N hydrochloric acid, swirl to ensure contact of the aluminum and the acid, and allow the reaction to proceed until all of the aluminum has dissolved. Dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with *Nitric acid diluent* to volume, and mix. Transfer 1.0-, 2.0-, and 4.0-mL portions of this solution to separate 100-mL volumetric flasks, dilute with *Nitric acid diluent* to volume, and mix. These solutions contain 0.01, 0.02, and 0.04 µg of Al per mL, respectively.

Test preparation—Transfer 1.0 mL of Injection to a 100-mL volumetric flask, and carefully add 4 mL of nitric acid. Dilute with water to volume, and mix.

Procedure—Determine the absorbances of the *Standard preparations* and the *Test preparation* at the aluminum emission line at 309.3 nm with an atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with an aluminum hollow-cathode lamp and a flameless electrically heated furnace, using *Nitric acid diluent* as the blank. Plot the absorbances of the *Standard preparations* versus the

contents of Al, in µg per mL, drawing the straight line best fitting the three points. From the graph so obtained, determine the quantity, in µg, of Al in each mL of the *Test preparation*. Calculate the quantity, in µg per g, of Al in the specimen taken by multiplying this value by 100: the limit is 2 µg per g.

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

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that it is not subject to the recommendation on *Container Content*.

Assay—

Potassium chloride solution—Dissolve 1.9 g of potassium chloride in water, dilute with water to 1000 mL, and mix. This solution contains 1000 µg of potassium per mL.

Strontium stock solution—Transfer 1.685 g of strontium carbonate, accurately weighed, to a 100-mL volumetric flask, and add water to dissolve. Add 10 mL of hydrochloric acid, dilute with water to volume, and mix to obtain a solution containing 10,000 µg of strontium per mL.

Standard preparations—Pipet 10 mL of *Strontium stock solution* into a 100-mL volumetric flask. Add 10 mL of hydrochloric acid, dilute with *Potassium chloride solution* to volume, and mix. Transfer 10 mL and 20 mL, respectively, of this solution into separate 100-mL volumetric flasks, dilute with *Potassium chloride solution* to volume, and mix. These *Standard preparations* contain 100 and 200 µg of strontium per mL.

Assay preparation—Pipet 0.1 mL of Injection into a small beaker. Add 5 mL of *Potassium chloride solution*, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the strontium emission line of 407.8 nm with an atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy ⟨852⟩*) equipped with a strontium hollow-cathode lamp and a nitrous oxide–acetylene flame, using *Potassium chloride solution* as the blank. Plot the absorbances of the *Standard preparations* versus concentration, in µg per mL, of strontium, and draw the straight line best fitting the four plotted points. From the graph so obtained, determine the concentration, in µg per mL, of strontium in the *Assay preparation*. Calculate the quantity, in µg, of strontium in each mL of the Injection taken by the formula:

$$51C$$

in which C is the concentration, in µg per mL, of strontium in the *Assay preparation*.

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

Topic/Question	Contact	Expert Committee
STRONTIUM CHLORIDE SR 89 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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