**Sodium citrate dihydrate**

**Natrii citras dihydricus**

2-Hydroxypropane-1,2,3-trisodium tricarbonate dihydrate



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| C6H5Na3O7·2H2O | М.w. 294,10 |
| Contains not less than 99.0% and not more than 101.0% of sodium citrate C6H5Na3O7 2H2O in terms of the anhydrous substance.**Description.** White or off-white crystalline powder or white or off-white, granular crystals, slightly diffusing in humid air.**Solubility.** Easily soluble in water, practically insoluble in alcohol.**Authenticity.** 1. Qualitative test. The substance gives characteristic reactions A and B to citrates (General Reactions to Authenticity General Pharmacopoeia Monograph).2. Qualitative test. The substance gives a characteristic reaction B to sodium (General Reactions to Authenticity General Pharmacopoeia Monograph).\* The clarity of the solution. A solution of 5 g of the substance in 50 ml of water must be transparent (General Pharmacopoeia Monograph "Transparency and turbidity of liquids").\* The color of the solution. The solution obtained in the test "The clarity of the solution" must be colorless (CFS "Degree of color of liquids", method 2).**pH.** From 7.8 to 8.3 (10% solution, OFS "Ionometry", method 3).**Water.** Not less than 11.0% and not more than 13.0% (General Pharmacopoeia Monograph "Determination of water", method 1). For determination, about 0.3 g (accurately weighed) of the substance and, as a solvent, a mixture of 20 ml of methanol, 30 ml of formamide and 5 g of salicylic acid are used.**Heavy metals.** Not more than 0.001%. The determination is carried out in accordance with "Heavy metals" using the solution prepared in the test "Solution clarity".**Iron.** Not more than 0.005%. The determination is carried out in accordance with the General Pharmacopoeia Monograph "Iron", method 1, in the ash residue obtained after combustion of 0.6 g of the substance (OFS "Sulphated ash"), using a standard solution of iron (III) -ion 30 μg / ml.**Calcium.** Not more than 0.03% (OFS "Calcium", method 1). 1 g of the substance is placed in a platinum crucible, carefully charred and calcined at a temperature of 600 ± 50 ° C. The residue in the crucible is dissolved in 2 ml of diluted acetic acid 30%, filtered, the crucible and the filter are washed with 2 times 3 ml each time, attaching the washing solution to the basic one, and the volume is adjusted to 10.0 ml with water.**Easily charring substances**. To 0.2 g of the substance add 10 ml of sulfuric acid and heat in a water bath at 90 ± 1 ° C for 60 minutes. Cool quickly. The color of the solution must withstand comparison with the standard Y2 or GY2 (General Pharmacopoeia Monograph "Color Degree of Liquids", method 2).**Arsenic.** Not more than 0.0002% (OFS "Arsenic", method 1). For determination, use 0.25 g of the substance.**Oxalates.** 1 g of the drug is dissolved in a mixture of 1 ml of water and 3 ml of diluted hydrochloric acid 8.3%, add 4 ml of alcohol 95% and 0.2 ml of 20% calcium chloride solution. After 1 hour, the solution should remain clear.**Sulfates.** Not more than 0.01% (OFS "Sulfates", method 1). For determination, use 10 ml of the solution obtained in the test "Solution clarity".**Tartrates.** 1 g of the substance is dissolved in 2 ml of water. Add 1 ml of 10% aqueous solution of potassium acetate and 1 ml of diluted acetic acid 30%. When rubbing the walls of the test tube with a glass rod, no crystalline precipitate should form.**Chlorides.** Not more than 0.002% (OFC "Chlorides"). For determination, use 10 ml of the solution obtained in the test "Solution clarity".**\* Pyrogenicity.** The substance must be pyrogen-free (OFS "Pyrogenicity"). Test dose: 10 ml of the prepared solution per 1 kg of rabbit weight. Solution preparation: 100 mg of the substance and 75 mg of calcium chloride are dissolved in 10 ml of water for injection.**Microbiological purity.** In accordance with the General Pharmacopoeia Monograph "Microbiological purity".**Quantitation.** About 0.2 g (accurately weighed) of the substance is dissolved by heating to 50 ° C in 50 ml of anhydrous acetic acid and titrated with 0.1 M perchloric acid solution. The end point of titration is determined potentiometrically (OFS "Potentiometric titration") or with an indicator (0.25 ml of 2% naphtholbenzein solution) until a green color appears.A control experiment is carried out in parallel.1 ml of 0.1 M perchloric acid solution corresponds to 8.602 mg of anhydrous sodium citrate C6H5Na3O7.**Ion exchange chromatography:** About 1.0 substance (accurately weighed) is dissolved in freshly boiled and cooled water in a volumetric flask with a capacity of 100 ml and the volume of the solution is brought to the mark with water. 10 ml of the resulting solution is quantitatively transferred to a column with a cation exchanger (Universal cation exchanger -1 or Universal cation exchanger -2 in the H-form). The liquids are allowed to drain at a rate of 20-25 drops per minute. The column is washed with freshly boiled and cooled water (50-70 ml) until neutral to methyl orange. The filtrate and wash water are collected in a flask and titrated with 0.05 M sodium hydroxide solution (indicator is phenolphthalein. 1 ml of 0.05 M sodium hydroxide solution corresponds to 4.301 mg of the substance**Storage.** In a tightly closed package.\* Control according to the quality indicators "Solution clarity", "Solution color" and "Pyrogenicity" is carried out in a substance intended for the production of drugs for parenteral use. |  |