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Oral Rehydration Salts

General Notices

Oral Rehydration Oral Powder

Action and use

Prevention and treatment of dehydration.

DEFINITION

Oral Rehydration Salts are *oral powders* containing either Glucose or Glucose Monohydrate, Sodium Chloride, Potassium Chloride and Sodium Citrate or Sodium Bicarbonate. After being dissolved in the requisite volume of Water they are intended for the prevention and treatment of dehydration due to diarrhoea, including maintenance therapy. Oral Rehydration Salts may contain suitable flavouring agents. Where necessary they may also contain suitable flow agents in the minimum quantity required to achieve a satisfactory product.

The composition of one of the formulations in use is described below in terms of the amount in grams to be dissolved in sufficient Water to produce 1000 mL. It is that recommended by the Diarrhoeal Diseases Control Programme of the World Health Organization (WHO) and the United Nations Childrens Fund (UNICEF).

Sodium Chloride	2.6 g
Potassium Chloride	1.5 g
Sodium Citrate	2.9 g
Glucose	13.5 g

The oral powders comply with the requirements stated under Oral Powders and with the following requirements.

Content of potassium, K, sodium, Na, bicarbonate, HCO_3, chloride, Cl, and citrate, $C_6H_5O_7$, as appropriate,

90.0 to 110.0% of the requisite amount, the latter being calculated from the stated amounts of the relevant constituents.

Content of anhydrous glucose, $C_6H_{12}O_6$,

As appropriate 90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. When heated with *cupri-tartaric solution R1* a copious precipitate of copper(I) oxide is produced.
B. Yield reaction B characteristic of *potassium salts*, Appendix VI.
C. Yield reaction A characteristic of *sodium salts*, Appendix VI.
D. Yield reaction A characteristic of *chlorides*, Appendix VI.
E. For preparations containing Sodium Citrate a quantity of the oral powder containing the equivalent of 50 mg of citric acid yields reactions A and B characteristic of *citrates*, Appendix VI.
F. For preparations containing Sodium Bicarbonate add 2 mL of *hydrochloric acid*. A vigorous effervescence is produced.

ASSAY

Carry out the following assays on the well-mixed contents of an individual sachet or on a suitable sample from the well-mixed contents of a bulk container. Where the amount in an individual sachet is insufficient to carry out all the assays, thoroughly mix the contents of sufficient sachets to provide enough material for all of the assays.

For the Assays for potassium, for sodium, for chloride and for bicarbonate dissolve 8 g in sufficient *water* to produce 500 mL (solution A).

For potassium

Dilute a suitable volume of solution A with a solution of *strontium chloride* such that there is a 1500- to 2000-fold excess of strontium ions in the final solution and determine by Method I for *atomic emission spectrophotometry*, Appendix II D, measuring at 767 nm. Use *potassium standard solution* (*600 ppm K*), suitably diluted with the strontium chloride solution, for the standard solutions. Each mg of Potassium Chloride is equivalent to 0.5245 mg of K.

For sodium

Dilute a suitable volume of solution A with a solution of *strontium chloride* such that there is a 1500- to 2000-fold excess of strontium ions in the final solution and determine by Method I for *atomic emission spectrophotometry*, Appendix II D, measuring at 589 nm. Use *sodium standard solution* (*200 ppm Na*), suitably diluted with the strontium chloride solution, for the standard solutions. Each mg of Sodium Chloride, of Sodium Bicarbonate and of Sodium Citrate is equivalent to 0.3934, 0.2737 and 0.2345 mg of Na respectively.

For chloride

Titrate a suitable volume (50 mL for the formula stated above) of solution A with *0.1M silver nitrate VS* using a 5% w/v solution of *potassium chromate* as indicator. Each mL of *0.1M silver nitrate VS* is equivalent to 3.545 mg of Cl. Each mg of Potassium Chloride and of Sodium Chloride is equivalent to 0.4756 mg and 0.6066 mg of Cl respectively.

For citrate

Disperse 2.8 g in 80 mL of *anhydrous acetic acid*, heat to about 50°, cool, dilute to 100 mL with *anhydrous acetic acid*, allow to stand for 10 minutes and carry out Method I for *non-aqueous titration*, Appendix VIII A, using 20 mL of the supernatant liquid and *1-naphtholbenzein solution* as indicator. Each mL of *0.1M perchloric acid VS* is equivalent to 6.303 mg of $C_6H_5O_7$. Each mg of Sodium Citrate is equivalent to 0.6430 mg of $C_6H_5O_7$.

For bicarbonate

Titrate 200 mL of solution A with *0.1M hydrochloric acid VS* using *methyl orange solution* as indicator. Each mL of *0.1M hydrochloric acid VS* is equivalent to 6.101 mg of HCO_3. Each mg of Sodium Bicarbonate is equivalent to 0.7263 mg of HCO_3.

For glucose

Dissolve 7.5 g in 40 mL of *water*, add 0.5 mL of 1M *ammonia*, dilute to 50 mL with *water*, mix well and allow to stand for not less than 5 hours. If necessary use a suitable method of filtration to obtain a clear solution. Determine the *optical rotation* of the solution, Appendix V F. The observed rotation in degrees multiplied by 0.9477 represents the weight, in g, of $C_6H_{12}O_6$ in the weight taken for the Assay.

STORAGE

Oral Rehydration Salts should be protected from moisture. They should be kept in sachets, preferably made of aluminium foil, containing sufficient for a single dose or for a single day's treatment. Powders for use in hospitals may be presented in bulk containers containing sufficient to produce a volume of solution appropriate to the daily requirements of the establishment concerned.

LABELLING

The label states (1) for sachets the total weights, in grams, of each of the constituents; (2) for bulk containers the weights, in grams, of each of the constituents in a stated quantity, in grams, of the oral powder.