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Oral Rehydration Salts

DEFINITION

Oral Rehydration Salts is a dry mixture of Sodium Chloride, Potassium Chloride, Sodium Bicarbonate, and Dextrose (anhydrous). Alternatively, it may contain Sodium Citrate (anhydrous or dihydrate) instead of Sodium Bicarbonate. It may contain Dextrose (monohydrate) instead of Dextrose (anhydrous), provided that the Sodium Bicarbonate or Sodium Citrate is packaged in a separate, accompanying container. It contains the equivalent of NLT 90.0% and NMT 110.0% of the amounts of sodium (Na), potassium (K), chloride (Cl), and bicarbonate (HCO_3) or citrate ($\text{C}_6\text{H}_5\text{O}_7$) calculated from the labeled amounts of Sodium Chloride, Potassium Chloride, and Sodium Bicarbonate [or Sodium Citrate (anhydrous or dihydrate)]. It contains NLT 90.0% and NMT 110.0% of the labeled amounts of anhydrous dextrose ($\text{C}_6\text{H}_{12}\text{O}_6$) or dextrose monohydrate ($\text{C}_6\text{H}_{12}\text{O}_6 \cdot \text{H}_2\text{O}$). It may contain suitable flavors.

IDENTIFICATION

- **A. SODIUM:** The sample imparts an intense yellow color to a nonluminous flame.
- **B. POTASSIUM:** The sample imparts a violet color to a nonluminous flame. Since the presence of small quantities of sodium masks the color, screen out the yellow color produced by sodium by viewing through a blue filter that blocks the emission at 589 nm (sodium), but is transparent to emission at 404 nm (potassium). [NOTE—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]
- **C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chloride](#):** Meets the requirements
- **D. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Bicarbonate](#)**
Analysis: Collect the gas that evolves upon dissolution.
Acceptance criteria: Where it contains Sodium Bicarbonate, it dissolves with effervescence, and the collected gas so obtained meets the requirements in test A.
- **E. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Citrate](#)**
Sample solution: Constitute the Oral Rehydration Salts as directed in the labeling.
Analysis: Add 3–5 drops of the *Sample solution* to 20 mL of the mixture of pyridine and acetic anhydride.
Acceptance criteria: Where it contains Sodium Citrate, it meets the requirements.
- **F.**
Sample solution: Constitute the Oral Rehydration Salts as directed in the labeling.
Analysis: Add a few drops of the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.
Acceptance criteria: Where it contains Dextrose, a copious red precipitate of cuprous oxide is formed (presence of dextrose).

ASSAY

• DEXTROSE

Sample stock solution: Nominally 200 mg/mL of dextrose from Oral Rehydration Salts prepared as follows. Transfer the contents of 1 or more unit-dose containers of Oral Rehydration Salts, or a portion of the contents of 1 multiple-unit container equivalent to 20 g of dextrose, to a 100-mL volumetric flask. Dilute with water to volume.

Sample solution: Nominally 100 mg/mL of dextrose from the *Sample stock solution* prepared as follows. Transfer 50.0 mL of the *Sample stock solution* to a 100-mL volumetric flask. Add 0.2 mL of 6 N ammonium hydroxide, and dilute with water to volume.

[NOTE—Reserve the remaining *Sample stock solution* for the Assay procedures for *Sodium and Potassium, Chloride, Bicarbonate, and Citrate*.]

Analysis: Determine the angular rotation in a suitable polarimeter tube (see [Optical Rotation \(781A\)](#), [Angular Rotation](#)).

Sample: *Sample solution*

Where Oral Rehydration Salts is labeled to contain anhydrous dextrose, calculate the observed concentration (g/100 mL) of anhydrous dextrose ($\text{C}_6\text{H}_{12}\text{O}_6$) in the portion of Oral Rehydration Salts taken:

$$\text{Result} = (100 \times a)/(l \times \alpha)$$

a = observed angular rotation of the *Sample solution* (°)

l = length of the polarimeter tube (dm)

α = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

Where Oral Rehydration Salts is labeled to contain dextrose monohydrate, calculate the observed concentration (g/100 mL) of dextrose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Oral Rehydration Salts taken:

$$\text{Result} = [(100 \times a)/(l \times \alpha)] \times (M_{r1}/M_{r2})$$

a = observed angular rotation of the *Sample solution* (°)

l = length of the polarimeter tube (dm)

α = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

M_{r1} = molecular weight of dextrose monohydrate, 198.17

M_{r2} = molecular weight of anhydrous dextrose, 180.16

Calculate the percentage of the labeled amount of anhydrous dextrose ($C_6H_{12}O_6$) or dextrose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Oral Rehydration Salts taken:

$$\text{Result} = (C_{U1}/C_{U2}) \times 100$$

C_{U1} = observed concentration of the *Sample solution* (g/100 mL)

C_{U2} = nominal concentration of the *Sample solution* (g/100 mL)

Acceptance criteria: 90.0%–110.0%

• SODIUM AND POTASSIUM

Sodium stock solution: 58.44 mg/mL of sodium chloride prepared as follows. Transfer 14.61 g of sodium chloride, previously dried at 105° for 2 h, to a 250-mL volumetric flask, and dilute with water to volume.

Potassium stock solution: 74.56 mg/mL of potassium chloride prepared as follows. Transfer 18.64 g of potassium chloride, previously dried at 105° for 2 h, to a 250-mL volumetric flask, and dilute with water to volume.

Diluent: 1.04 mg/mL of lithium nitrate prepared as follows. Transfer 1.04 g of lithium nitrate to a 1000-mL volumetric flask. Add a suitable nonionic surfactant, then add water to volume.

Standard stock solution: 0.5844 mg/mL of sodium chloride and 0.7456 mg/mL of potassium chloride in water from the *Sodium stock solution* and the *Potassium stock solution*, respectively

Standard solution: 0.01150 mg/mL of sodium and 0.01955 mg/mL of potassium from the *Standard stock solution* in *Diluent*

Sample stock solution A: Nominally 0.23 mg/mL of sodium from the *Sample stock solution* remaining from the Assay for Dextrose in water

Sample solution A: Nominally 0.0115 mg/mL of sodium from *Sample stock solution A* in *Diluent*

Sample stock solution B: Nominally 0.39 mg/mL of potassium from the *Sample stock solution* remaining from the Assay for Dextrose in water

Sample solution B: Nominally 0.01955 mg/mL of potassium from *Sample stock solution B* in *Diluent*

Instrumental conditions

Mode: Flame photometer

Analytical wavelengths

Potassium: 766 nm

Sodium: 589 nm

Blank: *Diluent*

Analysis

Samples: *Standard solution*, *Sample solution A*, *Sample solution B*, and *Blank*

Use the *Blank* to zero the instrument. Measure the emission responses for the *Standard solution*, *Sample solution A*, and *Sample solution B*.

Calculate the percentage of the labeled amount of sodium (Na) in the unit-dose container or containers taken or in the portion of Oral Rehydration Salts taken from the multiple-unit container:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = photometer reading of sodium from *Sample solution A*

r_S = photometer reading of sodium from the *Standard solution*