Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-95FB7049-44F1-4CEE-902C-C3CF27E1F015_1_en-US
DOI: https://doi.org/10.31003/USPNF_M46693_01_01
DOI Ref: 7xdn0

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Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension

» Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of $MgCO_3$ and $NaHCO_3$. It may contain suitable flavors.

Packaging and storage—Preserve in tight containers.

Identification—

A: Place about 1 g in a flask equipped with a stopper and glass tubing, the tip of which is immersed in calcium hydroxide TS in a test tube. Add 5 mL of 3 N hydrochloric acid to the flask, and immediately insert the stopper: gas evolves in the flask and a precipitate is formed in the test tube.

B: The solution remaining in the flask responds to the tests for *Magnesium* ⟨191⟩ and for *Sodium* ⟨191⟩.

Minimum fill ⟨755⟩: meets the requirements.

Acid-neutralizing capacity ⟨301⟩—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and not less than the number of mEq calculated by the formula:

$$0.8(0.024M) + 0.8(0.0119S)$$

in which 0.024 and 0.0119 are the theoretical acid-neutralizing capacities, in mEq, of $MgCO_3$ and $NaHCO_3$, respectively; and M and S are the quantities, in mg, of $MgCO_3$ and $NaHCO_3$ in the specimen tested, based on the labeled quantities.

Assay for magnesium carbonate—Transfer an accurately weighed portion of Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension, equivalent to about 4.2 g of $MgCO_3$, to a 500-mL volumetric flask. Add 200 mL of 1 N hydrochloric acid, and mix. When dissolved, dilute with water to volume, and mix. Transfer 10.0 mL of this stock solution to a suitable container, dilute with water to 100 mL, add 10 mL of ammonia–ammonium chloride buffer TS, 5 mL of triethanolamine, and 0.3 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium consumed is equivalent to 4.216 mg of $MgCO_3$.

Assay for sodium bicarbonate—

Standard preparations—Dissolve a suitable quantity of sodium chloride, previously dried at 125° for 30 minutes and accurately weighed, in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 600 µg per mL. On the day of use, further dilute this solution quantitatively with water to obtain three solutions containing 6.0, 12.0, and 18.0 µg of sodium chloride per mL, respectively.

Assay preparation—Transfer an accurately measured volume of the stock solution remaining from the *Assay for magnesium carbonate*, equivalent to about 180 mg of $NaHCO_3$, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of the resulting solution to a 1000-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the sodium emission line at about 589.0 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a sodium hollow-cathode lamp and an air–acetylene flame, using water as the blank. Plot the absorbances of the *Standard preparations* versus concentration, in µg of sodium chloride per mL, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, in µg per mL, of sodium chloride equivalent in the *Assay preparation*. Calculate the quantity, in g, of $NaHCO_3$ in the portion of Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension taken by the formula:

$$(84.01/58.44)(5C/V)$$

in which 84.01 and 58.44 are the molecular weights of sodium bicarbonate and sodium chloride, respectively; C is the concentration, in µg per mL, of sodium chloride equivalent in the *Assay preparation;* and V is the volume, in mL, of the stock solution remaining from the *Assay for magnesium carbonate* taken.

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Topic/Question	Contact	Expert Committee
MAGNESIUM CARBONATE AND SODIUM BICARBONATE FOR ORAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-95FB7049-44F1-4CEE-902C-C3CF27E1F015_1_en-US
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