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Dihydroxyaluminum Sodium Carbonate Chewable Tablets

Former title: Dihydroxyaluminum Sodium Carbonate Tablets
» Dihydroxyaluminum Sodium Carbonate Chewable Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $\text{CH}_2\text{AlNaO}_5$.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label the Chewable Tablets to indicate that they are to be chewed before swallowing.

Identification—A 1 in 10 suspension of powdered Chewable Tablets in 3 N hydrochloric acid meets the requirements of the tests for [Aluminum \(191\)](#) and for [Sodium \(191\)](#).

UNIFORMITY OF DOSAGE UNITS (905): meet 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:

$$0.8(0.0278D)$$

in which 0.0278 is the theoretical acid-neutralizing capacity, in mEq, of $\text{CH}_2\text{AlNaO}_5$, and *D* is the quantity, in mg, of $\text{CH}_2\text{AlNaO}_5$ in the specimen tested, based on the labeled quantity.

Assay—

Edetate disodium titrant—Dissolve 18.6 g of edetate disodium in water to make 500 mL, and standardize as directed in the [Assay](#) under [Ammonium Alum](#).

Procedure—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 300 mg of dihydroxyaluminum sodium carbonate, to a 250-mL beaker, and proceed as directed in the [Assay](#) under [Dihydroxyaluminum Sodium Carbonate](#), beginning with “add 10 mL of 2 N sulfuric acid.” Each mL of 0.1 M *Edetate disodium titrant* is equivalent to 14.40 mg of $\text{CH}_2\text{AlNaO}_5$.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DIHYDROXYALUMINUM SODIUM CARBONATE CHEWABLE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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