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Dihydroxyaluminum Aminoacetate Magma

» Dihydroxyaluminum Aminoacetate Magma is a suspension that contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of C₂H_EAINO_A.

Packaging and storage—Preserve in tight containers, and protect from freezing.

Identification—Dilute a volume of Magma, equivalent to about 1 g of dihydroxyaluminum aminoacetate, with water to 25 mL, add hydrochloric acid, dropwise, until a solution results, and then filter: the filtered solution responds to the <u>Identification</u> tests under <u>Dihydroxyaluminum</u>

<u>Aminoacetate</u>.

MICROBIAL ENUMERATION TESTS (61) and Tests for specified MICROORGANISMS (62).—The total bacterial count does not exceed 100 cfu per mL, and the test for Escherichia coli is negative.

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(0.0148D)

in which 0.0148 is the theoretical acid-neutralizing capacity, in mEq, of $C_2H_6AINO_4$, and D is the quantity, in mg, of $C_2H_6AINO_4$ in the specimen tested, based on the labeled quantity.

pH (791): between 6.5 and 7.5, in a dilution in water, equivalent to about 1 g of dihydroxyaluminum aminoacetate in 25 mL.

Assay-

Edetate disodium titrant—Prepare and standardize as directed in the Assay under Ammonium Alum.

Procedure—[Note—Shake the container by mechanical means for 1 hour before removing the specimen.] Weigh accurately in a tared beaker a quantity of Dihydroxyaluminum Aminoacetate Magma, equivalent to about 2.5 g of dihydroxyaluminum aminoacetate, add 15 mL of hydrochloric acid, and boil gently for about 5 minutes. Cool, transfer the solution with the aid of water to a 500-mL volumetric flask, dilute with water to volume, mix, and filter, if necessary, to obtain a clear solution. Proceed as directed in the <u>Assay</u> under <u>Dihydroxyaluminum</u> <u>Aminoacetate</u>, beginning with "Transfer 20.0 mL of this solution."

Auxiliary Information - Please <u>check for your question in the FAQs</u> before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|-------------------------------|---------------------------|
| DIHYDROXYALUMINUM AMINOACETATE MAGMA | Documentary Standards Support | SM32020 Small Molecules 3 |

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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