

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10295

6505-890-2218 (P. D. No. 2)

tive ingredients.

Magnesium hydroxide. The magnesium hydroxide used in the : of the finished suspension shall be of the highest pharmaceutical use in this suspension.

1.2 Aluminum hydroxide gel. The aluminum hydroxide gel used in the cure of the finished suspension shall comply with the following:

Shall be a smooth white paste.

Shall comply with the U.S.P. Identification test for Aluminum Hydroxide Gel.

Shall contain not less than 9.3 percent and not more than 10.5 percent aluminum oxide when tested by the U.S.P. assay method for Aluminum Hydroxide Gel.

Shall consume not less than 50 ml and not more than 60 ml of 0.1 N hydrochloric acid per gram (g.) when tested by the U.S.P. acid-consuming capacity test for Aluminum Hydroxide Gel.

3.11.3 Simethicone emulsion. The simethicone emulsion used in the manufacture of the finished suspension shall comply with the following:

Shall be a white, creamy liquid having a slight characteristic odor and taste.

Shall be miscible with water.

The collapse time for the foam shall not exceed 15 seconds when determined as specified in 4.3.8.

3.12 Added substances. Added substances may be included to assure a suitable, stable product. Such substances shall be nontoxic and harmless in the amounts administered and shall not interfere with the therapeutic efficacy of the finished suspension or with the tests and assays specified herein. In addition, when such added ingredients are used in the manufacture of the finished suspension, they shall be of U.S.P. or N.F. quality or, if not included in either of these compendia, they shall be suitable for use in this suspension.

3.13 Delivery. Not more than 6 months shall have elapsed from the date of manufacture of the product, to the date of delivery to the Government.