## COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10381

Shall meet the tests, standards, and requirements of the N.F., including any supplements or revisions thereto.

The formulation of the Kaolin Mixture with Pectin shall be as indicated in the N.P., except that the quantity of pectin shall be such that the final mixture shall contain not more than 130 mg of pectin per fluid cunce. The quantity of all other ingredients used shall be 100 percent of thut called for in the formula.

Shall be suitable for use as an antidiarrheal.

The pH of the formulation shall be 3.00 to 5.00 at 25° C., when determined potentiometrically, using the U.S.P. method.

The Kaolin used in the manufacture of the product shall be in accordance with the tests, standards, and requirements of the N.F., including any supplements or revisions thereto, and, in addition, shall be of a sieve size so that not less than 99.8 percent of the powder shall pass through a No. 200 standard sieve.

The Pectin and Sodium Saccharin used in the manufacture of the product shall be in accordance with the tests, standards, and requirements of the N.F.. including any supplements or revisions thereto.

The Transcenth (powdered), Benzoic Acid, Glycerin, Peppermint Oil, and Purified Water used in the manufacture of the product shall be in accordance with the test standards, and requirements of the U.S.P., Including any supplements or revisions thereto.

Suitable, harmless, flavoring agents, buffering and/or preservative agents acceptable to the Food and Drug Administration may be contained in the product, provided the identities and quantities of such agents present in the preparation are declared on the label of the immediate container.

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

## PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

Immediate containers. Shall comply with the following classification: GROUP A. CLASS 1 TYPE e STYLE 1 GRADE 1 or 2

CLOSURE A

SEAL A

The immediate container shall be oversized in order to facilitate shaking of the mixture, prior to use.

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