6505-890-2010 (P. D. No. 3)

3.4 Finished preparation.

3.4.1 Assay. The finished preparation shall assay to contain not less than 95.0 percent and not more than 110.0 percent of the required amount of Promethazine Hydrochloride (10-(2-Dimethylaminopropyl) phenothiazine hydrochloride) when determined as specified in 4.4.1.

3.4.2 Specific gravity. The specific gravity of the preparation shall be not less than 1.28 and not more than 1.30 at 25° C., when determined, using a pycnometer or a specific gravity balance.

3.4.3 pH. The pH of the undiluted preparation shall be not less than 4.70 and not more than 5.20 at 25° C., when determined potentiometrically, using the U.S.P. method.

3.4.4 Identification. The promethazine in the preparation shall be identified by an absorbance ratio with limits of 8.0 - 8.8 and by yellow crystal formation when determined as specified in 4.4.2.

3.4.5 Alcohol content. The finished preparation shall assay to contain not less than 6.5 percent and not more than 7.5 percent of the required amount of alcohol when determined as specified in 4.4.3.

3.4.6 Chloroform content. The finished preparation shall assay to contain not less than 90.0 percent and not more than 125.0 percent of the required amount of chloroform when determined as specified in 4.4.4.

3.4.7 The syrup shall be suitably flavored, and shall be palatable and pleasant to the taste with no unpleasant after-taste. Not later than the time specified for opening of bids or receipt of proposals, the offeror shall submit to the contracting officer six (6) individually packaged samples (each containing 4 fl oz) of the finished syrup representative of the product which the offeror proposes to furnish. Two (2) samples will be subjected to panel testing for a determination of palatability (see "Palatability Test paragraph 4.4.5). The remaining samples will be used by cognizant Government inspection and quality assurance activities for determining compliance of supplies furnished hereunder with the palatability requirement. Approval as to palatability of any sample submitted by the offeror will not constitute approval of the sample as to any other requirement of this specification. The requirement for submission of samples for use in determining compliance with the palatability requirement may be waived, provided the offeror states, in his bid or proposal, that the product he proposes to furnish is the same product he has offered to the purchasing activity on a previous procurement and the contracting officer determines that such product was previously procured and/or tested by the purchasing activity and found to comply with the palatability requirement.