

10192 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-926-8985 (P. D. No. 3)

3.1.3.3 Alcohol. The finished preparation shall assay to contain not less than 1.1 percent and not more than 1.7 percent ethyl alcohol, by volume, when determined as specified in 4.3.3.

3.1.4 Identity. The retention time for the glyceryl guaiacolate extracted from the syrup shall be the same as the retention time of Glyceryl Guaiacolate N.F. Standard when determined as specified in 4.3.1.

A copy of the standard graph shall be kept on file at the Defense Personnel Support Center for use if samples are submitted.

3.1.5 Color. The finished preparation shall have a range of 55 to 65 percent transmittance when determined as specified in 4.3.5, using a 10 percent solution of the syrup.

3.1.6 pH. The pH of the finished preparation shall be between 2.00 and 3.00 at 25° C., when determined potentiometrically, using the U.S.P. method.

3.1.7 Specific gravity. The specific gravity of the finished preparation shall be not less than 1.235 and not more than 1.255 at 25° C., when determined using a pycnometer, hydrometer, or specific gravity balance.

3.1.8 Refractive index. The finished preparation shall have a refractive index of not less than 1.4300 and not more than 1.4400, when determined at 25° C., using an Abbe Refractometer or equivalent instrument giving comparable results.

3.1.9 Optical rotation. A 20 percent solution of the preparation shall have an optical rotation not less than +85° and not more than +100° when determined using a 100 mm tube and a sodium light source. Multiply the observed rotation by 10.

3.1.10 Flavor and palatability. The finished syrup shall be mentholated, cherry vanilla 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 offices six (6) individually packaged samples (each containing 1 fl oz) of Dextromethorphan Hydrobromide and Glyceryl Guaiacolate 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 4.3.6 - Palatability test). 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.