6505-890-2012 (P. D. No. 3)

U. S. PHARMACOPEIAL CONVENTION, INC.

Pharmacopeia of the United States.

(Application for copies should be addressed to the Mack Publishing Company, Easton, Pa. 18042.)

3. REQUIREMENTS

Federal Stock No. 6505-890-2012 and FSN 6505-926-8926 shall meet the following requirements:

3.1 Material. Each 5 ml of syrup shall contain the following:

Phenylephrine Hydrochloride	10.0 mg
Chlorpheniramine Maleate	2.0 mg
Codeine Phosphate	10.0 mg
Glyceryl Guaiacolate	100.0 mg
Chloroform (approximately)*	13.5 mg
Levorotatory Menthol	1.0 mg

in a suitable base containing 5% alcohol.

*NOTE: Sufficient quantity of chloroform shall be added to assure the above chloroform content (approximately 13.5 mg) at the time of delivery.

Shall be suitable for use in the treatment of bronchitis and coughs of allergic origin.

3.2 Description. The finished syrup shall be a clear, red-brown, fruit flavored preparation having a pleasant and palatable taste, and shall comply with the stability requirements specified herein.

3.3 Additives. The coloring, flavoring, and sweetening agents used in the syrup shall be in the amounts approved by the Federal Food and Drug Administration.

3.4 Finished syrup.

3.4.1 Assay. The syrup shall assay to contain not less than 93.0 percent and not more than 107.0 percent of the required amounts of phenylephrine hydrochloride, chlorpheniramine maleate, and codeine phosphate, when determined as specified in 4.4.1. The syrup shall assay to contain not less than 93.0 percent and not more than 107.0 percent of the required amount of glyceryl guaiacolate, when determined as specified in 4.4.2.