

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10307

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

3.4.2 Alcohol (ethanol). The syrup shall assay to contain not less than 4.50 percent and not more than 5.50 percent alcohol v/v (90.0 to 110.0 percent of the required amount), when determined as specified in 4.4.3.

3.4.3 Chloroform and levorotatory menthol. Chloroform and levorotatory menthol content in the syrup shall be determined from the batch formulation sheet kept on file by the manufacturer. The contents of the two ingredients shall be in conformance with the formulation specified in 3.1.

3.4.4 pH. The pH of the syrup shall be not less than 4.00 and not more than 6.50, at 25° C., when determined potentiometrically using the U.S.P. method.

3.4.5 Specific gravity. Specific gravity of the syrup shall be not less than 1.225 and not more than 1.279 when determined, at 25° C., using a suitable pycnometer.

3.4.6 Refractive index. Refractive index of the syrup shall be not less than 1.431 and not more than 1.449 when determined, at 25° C., using a Bausch and Lomb Refractometer, Abbe-56, or equivalent instrument giving comparable results.

3.4.7 Absorption spectrum. Absorption spectrum of 10 ml of syrup diluted to 100 ml with purified water, when measured on a Beckman DK-2A spectrophotometer, or equivalent instrument, shall show maxima at 630 millimicrons (mu), 525 mu, and 430 mu (broad), and minima at 670 mu, 605 mu, 505 mu, and 350 mu (broad).

3.4.8 Optical rotation. Optical rotation of the syrup shall be not less than +26.5° and not more than +32.5°, when determined as specified in 4.6.

3.4.9 Stability. The finished syrup shall comply with the following:

- (a) Any sedimentation formed on standing or during storage shall be readily resuspendible after moderate shaking.
- (b) During storage, shall not thicken to point where contents cannot be poured readily from the immediate container (bottle).
- (c) Any crystals which develop in storage shall redissolve upon warming the syrup to room temperature.
- (d) Shall remain palatable and shall meet all specification requirements during storage.