

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10337

6505-753-4766 (P. D. No. 7)

S6.4.11 Moisture content. Loss on drying shall be not more than 2.50 percent, when determined as follows:

Grind 20 tablets to a fine powder. Take about 1.5 gram of powder and weigh accurately. Record the weight. Dry to constant weight at 105°C. (usually requires about 4 hours). Cool in a desiccator and weigh accurately. Calculate the percent loss on drying.

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, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1

CLOSURE B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall include the following information. However, the information is not required to appear in the sequence indicated.

- (a) the item identification designated as "THEOPHYLLINE, EPHEDRINE HYDROCHLORIDE, AND PHENOBARBITAL TABLETS, N.F."
- (b) the phrase "1000 tablets" or a similar phrase
- (c) the formula of the tablets
- (d) the lot or control number
- (e) the Federal Stock No.

(See additional label information on page 5)