

10324 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-116-9325 (P. D. #3)

If two capsules, but not more than two capsules fail paragraph 2, above, or if one capsule, but not more than one capsule fails paragraph 4, above, accurately weigh and assay the contents of an additional 20 capsules, individually. The capsules shall comply with the following requirements:

1. The average of the 30 weight shall be between 95 percent and 105 percent of the theoretical, in addition,
2. the weight of not more than 3 of the 30 contents shall be less than 90 percent or more than 110 percent of the theoretical; the weight of not more than 1 of the 30 capsules shall be less than 85 percent or more than 115 percent of the theoretical; and none of the 30 capsules shall weigh less than 75 percent or more than 125 percent of the theoretical.
3. The average of the 30 assays shall be between 95 percent and 105 percent of the required amount of sodium diphenylhydantoin, in addition,
4. the assay of not more than 3 of the 30 contents shall be less than 90 percent or more than 110 percent of the required amount of sodium diphenylhydantoin; the assay of not more than 1 of the 30 contents shall be less than 85 percent or more than 115 percent of the required amount of sodium diphenylhydantoin; and the assay of none of the contents shall be less than 75 percent or more than 125 percent of the required amount of sodium diphenylhydantoin.

The sodium diphenylhydantoin content (assay) of each capsule shall be determined in accordance with the U.S.P. method, suitably modified to accommodate assaying one capsule. The theoretical weight of each capsule shall be determined from the batch formulation record.

Melting range. The diphenylhydantoin obtained in the U.S.P. assay shall melt between 294° C. and 297° C.

Thin Layer Chromatography.

The pattern of the chromatograph for the capsules shall match that of the Standard Capsule Mixture, when determined using the following method:

Preparation of plate.

Coat a suitable plate using a slurry prepared by mixing 30 Gm Silica Gel D-5 and 60 ml of 0.1N Boric Acid. Activate the plate at 105° C. for 15 to 30 minutes.