

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10325

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

Preparation of Standard Capsule Mixture.

Standard Capsule Mixture is prepared with the same components and in the same proportions as is used in the manufacture of the finished product, except that the Sodium Diphenylhydantoin Standard* is used in lieu of the commercial Sodium Diphenylhydantoin bulk. A quantity of the Standard Capsule Mixture, equivalent to 100 mg of Sodium Diphenylhydantoin is used for this test. /k

Procedure.

Prepare three 15-ml, conical, centrifuge tubes as follows:

Tube No. 1 - contents of one finished capsule (sample); Tube No. 2 - 100 mg of Sodium Diphenylhydantoin Standard*; Tube No. 3 - a portion of the Standard Capsule Mixture equivalent to 100 mg of Sodium Diphenylhydantoin.

To each tube, add 5 ml of a 1:1 pyridine:water solution. Mix thoroughly and centrifuge. Spot the activated plate with 5 μ l of each supernatant liquid. Before placing the plate in the developing chamber, remove the solvent by placing the plate in an oven at 105° C. for 10 to 15 minutes. Develop the plate for 60 minutes (10 cm) in a suitable developing chamber using n-butanol:acetone:water (40:50:10) as the developing solvent. After removing the plate from the chamber, place the plate in an oven at 105° C. to remove all solvents.

Observe the plate after spraying with a universal type solvent (0.5 Gm Potassium Permanganate in 15 ml concentrated Sulfuric Acid. Caution: Cool the Sulfuric Acid before adding the Potassium Permanganate.) Examine the plate using a shortwave ultraviolet light.

Disintegration test. Using the U.S.P. method, apparatus, and procedures for determining disintegration of uncoated tablets, the finished capsules shall disintegrate in one (1) hour. No retest is allowed.

Note: Although some particles may rise to the surface instead of settling through the screen during the operation of the apparatus, no particles shall remain which can be judged too large to pass through the screen. U.S.P. reference to soft mass as evidence of disintegration does not apply to the test.

*Available upon request from Directorate of Medical Materiel, Technical Operations Division, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa., 19101, Attention: Material Standards Branch, DPSC-ATSB-1.