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

Dissolution rate.

The capsules shall release not less than 40 percent sodium diphenylhydantoin in 10 minutes, not less than 80 percent sodium diphenylhydantoin in 20 minutes, not less than 90 percent sodium diphenylhydantoin in 30 minutes, and not less than 95 percent sodium diphenylhydantoin in 40 minutes, based upon the total sodium diphenylhydantoin released after one hour. In addition, the capsules shall release not less than 93 percent and not more than 107 percent of the labeled amount of sodium diphenylhydantoin after 60 minutes.

Apparatus: U.S.P. Disintegration Apparatus.
Medium: Purified Water.

Preparation of Standard.

Prepare a standard solution of diphenylhydantoin by adding 75.0 mg of sodium diphenylhydantoin standard* to 100 ml of purified water, slightly alkalized with sodium hydroxide (2 drops of 1 N Sodium Hydroxide per 100 ml). Transfer 2.0 ml of the solution to a glass-stoppered test tube. Proceed with the acidification, extraction into chloroform, etc., as described below under Procedure.

Procedure.

Note: Spectrophotometric Grade solvents shall be used in the determination.

Place 1 capsule in each of six tubes, inserting a plastic disk in each tube. Immerse the basket rack assembly in 800 ml of purified water maintained at 37° C. + 2° C. Operate the apparatus. Withdraw 5 ml aliquots of the solution after 10, 20, 30, 40, and 60 minutes.

*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.