

10328 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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

The Sodium Diphenylhydantoin used in the manufacture of the finished capsules shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

In addition to complying with the tests, standards, and requirements of the U.S.P., the sodium diphenylhydantoin used in the manufacture of the finished capsules shall comply with the following requirements:

Assay.

Shall assay to contain not less than 99.5 percent and not more than 100.5 percent sodium diphenylhydantoin, when assayed in accordance with the U.S.P. method.

Melting range.

The residue of diphenylhydantoin obtained in the U.S.P. assay shall melt between 294° C. to 297° C.

Thin layer chromatography.

The chromatograph of the sodium diphenylhydantoin powder used in the manufacture of the capsules shall match that of the sodium diphenylhydantoin standard* when determined by using the Thin Layer Chromatograph Procedure for the finished capsules, except that 100 mg of Sodium Diphenylhydantoin powder shall be used in lieu of the contents of a capsule, and a portion of the Standard Capsule Mixture.

The empty, hard, gelatin capsules used in the manufacture of the finished product shall be Size No. 3, and shall conform to the applicable paragraphs of Federal Specification U-C-115b, dated 10 February 1958, except as specified below:

3.1 Delete in its entirety and substitute:

"3.1 Material. The gelatin, used in the manufacture of the pharmaceutical capsules, shall be type A or type B or a suitable mixture of both and shall be in accordance with the requirements of the U.S.P. The gelatin may contain not more than 0.15 percent sulfur dioxide and may have a lower gel strength."

3.2.3.3 Appearance and color. The finished product (filled capsules) shall be white in color. The sealing band may be colored.

Capsules shall be uniform and free from manufacturing and other defects, such as, cracks, dents, splits, specks, etc.

*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.