

# COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10323

|                                       |                                                |             |                           |
|---------------------------------------|------------------------------------------------|-------------|---------------------------|
| DEFENSE MEDICAL PURCHASE DESCRIPTION  |                                                | NUMBER<br>3 | DATE<br>28 September 1967 |
| FEDERAL STOCK NO.                     | ITEM IDENTIFICATION                            |             | UNIT                      |
| 6505-116-9325<br>and<br>6505-584-2338 | SODIUM DIPHENYLHYDANTOIN CAPSULES, USP, 100 mg |             | Bottle                    |

Shall be Parke, Davis and Company's "Dilantin Capsules 100 mg", and shall comply with the following requirements:

Shall be Sodium Diphenylhydantoin Capsules, 100 mg, in the quantity of capsules per bottle, as indicated for the appropriate stock number and item identification:

| Federal Stock No. (FSN) | Item Identification                                      |
|-------------------------|----------------------------------------------------------|
| 6505-116-9325           | SODIUM DIPHENYLHYDANTOIN CAPSULES, USP,<br>100 mg, 100s  |
| 6505-584-2338           | SODIUM DIPHENYLHYDANTOIN CAPSULES, USP,<br>100 mg, 1000s |

FSN 6505-116-9325 and FSN 6505-584-2338 shall comply with the following:

Shall be Sodium Diphenylhydantoin Capsules and shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto. In addition, the capsules shall comply with the following:

Shall be suitable for use as an anticonvulsant.

Shall contain 100 mg of Sodium Diphenylhydantoin in each capsule, within the designated assay limit for the capsules.

The finished capsules shall contain not less than 95.0 percent and not more than 105.0 percent of the required amount of sodium diphenylhydantoin, when determined in accordance with the U.S.P. method of assay.

Capsule-to-Capsule Weight and Assay Variability Limit.

Accurately weigh the contents of 10 capsules individually. Assay the contents of an additional 10 capsules individually. The capsules shall comply with the following requirements:

1. The average weight of the contents of the 10 capsules shall be between 95 percent and 105 percent of the theoretical, in addition,
2. the weight of each of the 10 contents shall be between 90 percent and 110 percent of the theoretical.
3. The average of the 10 assays shall be between 95 percent and 105 percent of the required amount of sodium diphenylhydantoin, in addition,
4. each of the individual assays of the 10 contents shall be between 90 percent and 110 percent of the required amount of sodium diphenylhydantoin.

Page 1 of 9