

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10283

6505-550-8464 (P. D. No. 7)

"S5.9 Aging test. 100 tablets of each lot shall be placed in an amber glass bottle, tightly sealed with Closure B. Place the bottle in an oven at 55° C. (between 53° and 56° C.) and maintain at that temperature for 10 consecutive days. At the end of that period, remove the bottle and allow to stand at room temperature overnight. Select a total of 18 tablets from the top, middle, and bottom of the bottle. Test the tablets for disintegration by the U.S.P. Tablet Disintegration Test for Meprobamate Tablets. Not less than 16 of the 18 tablets tested shall completely disintegrate within 30 minutes. In addition, the aged tablets shall comply with the dissolution test of the U.S.P."

S6.4.2 Color. Uncoated tablets shall be uniformly white.

S6.4.7 Scoring. Tablets shall be scored.

S6.4.8 Odor. Delete the first sentence and substitute the following: "Tablets shall be odorless or shall have not more than a slight odor, characteristic of meprobamate."

S6.4.9.1 Disintegration. The uncoated tablets shall disintegrate in not more than 30 minutes when tested by the U.S.P. method for "Uncoated Tablets."

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A	CLASS 1	TYPE c	STYLE 2	GRADE 1
CLOSURE B				SEAL A or B