

10272 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-104-8672 (P. D. No. 1)

S6.4.7 Scoring. Tablets shall be scored.

S6.4.8 Odor. Delete the first sentence and substitute: "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, and as specified herein:

Immediate containers (strip pockets). Shall comply with the following: Twenty-five (25) tablets shall be packaged in a commercially available, continuous roll strip package. Each tablet shall be sealed in its own pocket and so designed that the end pocket can be removed and the seal on the adjoining pocket shall not be disturbed. The individual pockets shall be consecutively numbered from one (1) to twenty-five (25). One roll of twenty-five tablets shall be contained in a carton (box) as specified. The numbers on the strip package roll shall be in reverse order so that the first pocket removed shall be number twenty-five (25) and the second number shall be twenty-four (24), etc.

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container (pocket) shall be permanently and legibly marked with the following information. The labeling shall appear in the center of the pocket and shall not extend into the heat-sealed area:

Labeling information in accordance with commercial practice. In addition, the numbering shall be in reverse order as specified under "Immediate containers (strip pockets)" see above. The date of manufacture shall not be required.