

10196 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-935-5836 (P. D. No. 2)

All other ingredients used in the manufacture of the tablets shall comply with S5.1.

S6.4.2 Color. Uncoated tablets shall be white.

S6.4.5 Shape. The tablets shall be pentagonal.

S6.4.9 Disintegration and solubility. Tablets shall meet the requirements of the U.S.P. tablet disintegration test for uncoated tablets in not more than 15 minutes.

S6.4.10.1 Uncoated tablets. Tablets shall meet the requirements of the Weight Variation Test for Tablets, as set forth in the U.S.P., including any supplements or revisions thereto.

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

4.1.1 Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

4.1.2 No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

4.2 Sampling and inspection. The classification of defects as shown in Fed. Std. No. 140a shall be applicable.