

10390 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-926-9055 (P. D. No. 3)

3.9 Workmanship. Workmanship shall be first class throughout. The material and its containers shall be free from defects which detract from their appearance or may impair their serviceability.

3.10 Delivery. Not more than 4 months shall have elapsed from the date of manufacture of the product, to the date of delivery to the Government.

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 Lot. For purpose of this specification, a lot, batch, or control is that single, uniform, and homogeneous quantity of the elixir, produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final containers.

4.3 Sampling. Sampling shall be conducted in accordance with the procedures set forth in MIL-STD-105, with an acceptable quality level (AQL) of 1.0 percent defective for major defects and 2.5 percent defective for minor defects.