

10296 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-890-2218 (P. D. No. 2)

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibilities for inspection. Such examinations and tests as are set forth in this specification, or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements, shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records of examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request at any time, or from time to time, for a period of 3 years after delivery of the supplies to which such records relate.

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

4.2 Sampling. Sampling shall be conducted in accordance with the procedures set forth in Military Standard 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.

4.3 Tests.

4.3.1 Aluminum content. The aluminum content in the finished suspension shall be determined as follows:

Reagents.

1. 0.1N EDTA solution.
2. 4M Ammonium acetate solution.
3. Hematoxylin indicator. Dissolve 1 gram of Hematoxylin in 40 ml of 0.05N hydrochloric acid. Neutralize with 1N sodium hydroxide. Dilute to 200 ml with SEA-3A alcohol.
4. Hydrochloric acid. Concentrated, and 1N strengths.

Sample preparation. Pipet 10.0 ml of finished suspension into a clean, 250-ml beaker. Cautiously add 5 ml of concentrated hydrochloric acid and 50 ml of purified water. Boil until sample dissolves. Filter the solution, while hot, through Whatman No. 541 filter paper and collect into a 100-ml volumetric flask. Cool to room temperature and dilute to mark with purified water. Transfer the solution to a 50-ml buret and drain excess to zero.