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

3.7 Accelerated aging test:

Randomly select four (4) units of each lot offered for delivery to the Government. *Two (2) units shall be stored at 25° C. ± 2° C. (these are called the unaged samples), and the other two (2) units shall be subjected to constant storage at 55° C. ± 2° C. for two weeks (these are called aged samples). At the end of the two-week period, the aged samples shall be allowed to return to room temperature. All samples shall be tested at room temperature, and the findings shall be as follows:

(a) Upon visual examination, there shall be no difference in clarity between the aged elixir and the unaged elixir.

(b) There shall be no difference in taste between the aged and the unaged elixirs.

(c) When tested in accordance with the N.F. assay, the acetaminophen content of the aged elixir shall be not less than 97.0 percent of that obtained from an equal volume of unaged elixir.

(d) The aged elixir shall comply with the identity test described in paragraph 4.4.1.1

(e) The limit of free-p-aminophenol in the aged solution shall be not more than 0.10 percent, when tested by the method given in paragraph 4.4.1.2

*If difficulty in storing gallon size containers is encountered, pint size samples taken from the gallon bottles shall be used for storage and testing.

3.8 Ingredients.

3.8.1 Acetaminophen. The acetaminophen used in the manufacture of the finished elixir shall be in accordance with the tests, standards and requirements of the N.F., including any supplements or revisions thereto, and in addition, shall comply with the following requirements:

3.8.1.1 Description. Shall be a white, odorless, crystalline powder.

3.8.2 Alcohol. The alcohol entering into the manufacture of the product shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

3.8.3 Other ingredients. All other ingredients entering into the manufacture of the product shall be of U.S.P. or N.F. quality or, if not included in either of these compendia, they shall be of the highest pharmaceutical grade.