

B. GENERAL TESTS

Iron Limit Test

The Iron Limit Test is designed to determine the allowable limit of iron compounds contained as impurities in a sample.

Hereinafter in the Monographs, such a specification as “not more than 10 µg/g as Fe (1.0 g, Method 1, Control solution Iron Standard Solution 1.0 ml)” indicates that when determined by weighing 1.0 g of the test substance as the sample and proceeding as directed in Method 1, using 1.0 ml of Iron Standard Solution in the preparation of the control solution, the iron content of the substance is not more than 10 µg/g as Fe.

Procedure (1) Preparation of test solutions and control solutions

Unless otherwise specified, proceed according to Method 1 or Method 2, as appropriate.

Method 1 Test Solution Weigh the specified quantity of the sample, add 30 ml of acetic acid-sodium acetate buffer solution for iron limit test (pH4.5), dissolve by warming if necessary.

Control Solution To the amount of Standard Iron Solution specified in the individual monograph, add 30 ml of acetic-sodium acetate buffer solution for iron limit test (pH4.5).

Method 2 Test Solution Weigh the specified quantity of a sample, add 10 ml of dilute hydrochloric acid (1 : 4), and dissolve by warming if necessary. Dissolve 0.5 g of tartaric acid, and add one drop of phenolphthalein TS. Add ammonia TS until the solution develops a pale red color. Add 20 ml of acetic acid-sodium acetate buffer solution for iron limit test (pH4.5).

Control Solution To the amount of Standard Iron Solution specified in the individual monograph, add 10 ml of dilute hydrochloric acid (1 : 4), and proceed as directed for the test solution.

(2) Test

Unless otherwise specified, transfer the test solution and the control solution into separate Nessler tubes, to each add 2 ml of a solution of ascorbic acid for iron limit test (1 : 100), mix well, and allow to stand for 30 minutes. Add 1 ml of a solution of 2,2'-dipyridyl in ethanol (1 : 200), add water to make 50 ml, and allow to stand for 30 minutes. Then, compare the colors of both solutions against a white background. The color of the test solution is not deeper than the control solution.