



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Ferrous Gluconate Tablets

### [General Notices](#)

### Action and use

Used in prevention and treatment of iron deficiency.

### DEFINITION

Ferrous Gluconate Tablets contain Ferrous Gluconate Hydrate. They are coated.

*The tablets comply with the requirements stated under Tablets and with the following requirements.*

### Content of ferrous iron, Fe(II)

90.0 to 105.0% of the stated amount.

### IDENTIFICATION

A. Shake a quantity of the powdered tablets containing 0.5 g of Ferrous Gluconate Hydrate with 10 mL of [2M hydrochloric acid](#), filter and add to the filtrate 1 mL of [barium chloride solution](#). An opalescence may be produced but no precipitate is produced.

B. The powdered tablets yield reaction A characteristic of [iron salts](#), [Appendix VI](#).

### TESTS

#### Ferric iron

Dissolve a quantity of the powder prepared for the Assay containing 5 g of Ferrous Gluconate Hydrate as completely as possible, without heating, in a mixture of 100 mL of freshly boiled and cooled [water](#) and 10 mL of [hydrochloric acid](#); add 3 g of [potassium iodide](#). Close the vessel, allow to stand in the dark for 5 minutes and titrate the liberated iodine with 0.1M [sodium thiosulfate VS](#) using [starch mucilage](#) as indicator. Repeat the operation without the powder. The difference between the titrations represents the amount of iodine liberated by the ferric iron. Not more than 11.2 mL of 0.1M [sodium thiosulfate VS](#) is required.

### ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 1 g of Ferrous Gluconate Hydrate as completely as possible in a mixture of 30 mL of [water](#) and 20 mL of 1M [sulfuric acid](#) and titrate with [0.1M ammonium cerium\(IV\) sulfate VS](#) using [ferroin solution](#) as indicator. Each mL of [0.1M ammonium cerium\(IV\) sulfate VS](#) is equivalent to 5.585 mg of Fe(II).

## **LABELLING**

The quantity of active ingredient is stated both as the amount of ferrous gluconate and in terms of the equivalent amount of ferrous iron.