

## Phenytoin Powder

### Diphenylhydantoin Powder

フェニトイン散

Phenytoin Powder contains not less than 95% and not more than 105% of the labeled amount of phenytoin ( $C_{15}H_{12}N_2O_2$ ; 252.27).

**Method of preparation** Prepare as directed under Powders, with Phenytoin.

**Identification** Weigh a portion of Phenytoin Powder, equivalent to 0.3 g of Phenytoin according to the labeled amount, stir well with two 100-mL portions of diethyl ether, and extract. Combine the diethyl ether extracts, and filter. Evaporate the filtrate on a water bath to dryness, and proceed with the residue as directed in the Identification under Phenytoin.

**Assay** Weigh accurately Phenytoin Powder, equivalent to about 0.5 g of phenytoin ( $C_{15}H_{12}N_2O_2$ ), add exactly 100 mL of ethanol (95), stir for 30 minutes, and centrifuge. Pipet 50 mL of the supernatant liquid, add 0.5 mL of thymolphthalein TS, titrate with 0.1 mol/L sodium hydroxide VS until a light blue color develops, then add 1 mL of pyridine, 5 drops of phenolphthalein TS and 12.5 mL of silver nitrate TS, and titrate with 0.1 mol/L sodium hydroxide VS until a light red color persists for 1 minute.

$$\begin{aligned} \text{Each mL of 0.1 mol/L sodium hydroxide VS} \\ = 25.227 \text{ mg of } C_{15}H_{12}N_2O_2 \end{aligned}$$

**Containers and storage** Containers—Well-closed containers.

## Phenytoin Tablets

### Diphenylhydantoin Tablets

フェニトイン錠

Phenytoin Tablets contain not less than 95% and not more than 105% of the labeled amount of phenytoin ( $C_{15}H_{12}N_2O_2$ ; 252.27).

**Method of preparation** Prepare as directed under Tablets, with Phenytoin.

**Identification** Proceed with the residue obtained in the Assay as directed in the Identification under Phenytoin.

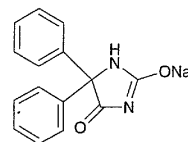
**Assay** Weigh accurately and powder not less than 20 Phenytoin Tablets. Weigh accurately a portion of the powder, equivalent to about 0.3 g of phenytoin ( $C_{15}H_{12}N_2O_2$ ), transfer to a separator, and add 1 mL of dilute hydrochloric acid and 10 mL of water. Extract with 100 mL of diethyl ether, then with four 25-mL portions of diethyl ether. Combine the extracts, and evaporate the diethyl ether. Dry the residue at 105°C for 2 hours, and weigh it as the mass of phenytoin ( $C_{15}H_{12}N_2O_2$ ).

**Containers and storage** Containers—Well-closed containers.

## Phenytoin Sodium for Injection

### Diphenylhydantoin Sodium for Injection

注射用フェニトインナトリウム



$C_{15}H_{11}N_2NaO_2$ : 274.25  
Monosodium 5,5-diphenyl-4-oxoimidazolidin-2-olate  
[630-93-3]

Phenytoin Sodium for Injection is a preparation for injection which is dissolved before use. When dried, it contains not less than 98.5% of phenytoin sodium ( $C_{15}H_{11}N_2NaO_2$ ), and contains not less than 92.5% and not more than 107.5% of the labeled amount of phenytoin sodium ( $C_{15}H_{11}N_2NaO_2$ ).

**Method of preparation** Prepare as directed under Injections.

**Description** Phenytoin Sodium for Injection occurs as white crystals or crystalline powder. It is odorless.

It is soluble in water and in ethanol (95), and practically insoluble in chloroform and in diethyl ether.

The pH of a solution of Phenytoin Sodium for Injection (1 in 20) is about 12.

It is hygroscopic.

A solution of Phenytoin Sodium for Injection absorbs carbon dioxide gradually when exposed to air, and a crystalline precipitate of phenytoin is produced.

**Identification (1)** With the residue obtained in the Assay, proceed as directed in the Identification under Phenytoin.

**(2)** Ignite 0.5 g of Phenytoin Sodium for Injection, cool, and dissolve the residue in 10 mL of water: the solution changes red litmus paper to blue, and responds to the Qualitative Tests (1) for sodium salt.

**Purity (1)** Clarity and color of solution—Dissolve 1.0 g of Phenytoin Sodium for Injection in 20 mL of freshly boiled and cooled water in a glass-stoppered test tube: the solution is clear and colorless. If any turbidity is produced, add 4.0 mL of 0.1 mol/L sodium hydroxide VS: the solution becomes clear and colorless.

**(2)** Heavy metals—Proceed with 1.0 g of Phenytoin Sodium for Injection according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

**Loss on drying** Not more than 2.5% (1 g, 105°C, 4 hours).

**Assay** Weigh accurately the content of not less than 10 preparations of Phenytoin Sodium for Injection, transfer about 0.3 g of the content, previously dried and accurately weighed, to a separator, dissolve in 50 mL of water, add 10 mL of dilute hydrochloric acid, and extract with 100 mL of diethyl ether, then with four 25-mL portions of diethyl ether. Combine the diethyl ether extracts, and evaporate on a water bath. Dry the residue at 105°C for 2 hours, and