melts between 174°C and 179°C. With the residue, proceed as directed in the Identification (1) and (2) under Phenobarbital.

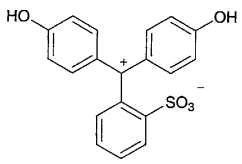
Assay Weigh accurately about 10 g of 10% Phenobarbital Powder, transfer to a glass-stoppered flask, and add exactly 100 mL of a mixture of chloroform and ethanol (95) (10:1). Stopper tightly, shake, and allow to stand for 30 minutes. Transfer the mixture to a glass-stoppered centrifuge tube, and centrifuge. Measure exactly 50 mL of the supernatant liquid, evaporate on a water bath to dryness, dissolve the residue in 50 mL of *N,N*-dimethylformamide, and proceed as directed in the Assay under Phenobarbital.

Each mL of 0.1 mol/L potassium hydroxide-ethanol VS
= 23.224 mg of $C_{12}H_{12}N_2O_3$

Containers and storage Containers—Well-closed containers.

Phenolsulfonphthalein

フェノールスルホンフタレイン



$C_{19}H_{14}O_5S$: 354.38
2-[Bis(4-hydroxyphenyl)methyliumyl]benzenesulfonate
[*143-74-8*]

Phenolsulfonphthalein, when dried, contains not less than 98.0% of $C_{19}H_{14}O_5S$.

Description Phenolsulfonphthalein occurs as a vivid red to dark red, crystalline powder.

It is very slightly soluble in water and in ethanol (95).

It dissolves in sodium hydroxide TS.

Identification **(1)** Dissolve 5 mg of Phenolsulfonphthalein in 2 to 3 drops of sodium hydroxide TS, add 2 mL of 0.05 mol/L bromine VS and 1 mL of dilute sulfuric acid, shake well, and allow to stand for 5 minutes. Render the solution alkaline with sodium hydroxide TS: a deep blue-purple color develops.

(2) Dissolve 0.01 g of Phenolsulfonphthalein in diluted sodium carbonate TS (1 in 10) to make 200 mL. To 5 mL of this solution add diluted sodium carbonate TS (1 in 10) to make 100 mL. Perform the test with this solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

Purity **(1)** Insoluble substances—To about 1 g of Phenolsulfonphthalein, accurately weighed, add 20 mL of a solution of sodium hydrogen carbonate (1 in 40). Allow the mixture to stand for 1 hour with frequent shaking, dilute with water to 100 mL, and allow to stand for 24 hours. Collect the insoluble substances using a tared glass filter (G4), wash with 25 mL of a solution of sodium hydrogen carbonate (1 in 100) and with five 5-mL portions of water, and dry at 105°C for 1 hour: the mass of the residue is not more than 0.2%.

(2) Related substances—Dissolve 0.10 g of Phenolsulfonphthalein in 5 mL of dilute sodium hydroxide TS, and use this solution as the sample solution. Pipet 0.5 mL of this solution, add dilute sodium hydroxide TS to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of *t*-amyl alcohol, acetic acid (100) and water (4:1:1) to a distance of about 15 cm, and air-dry the plate. After allowing the plate to stand in an ammonia vapor, examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 1.0% (1 g, silica gel, 4 hours).

Residue on ignition Not more than 0.20% (1 g).

Assay Weigh accurately about 0.15 g of Phenolsulfonphthalein, previously dried, transfer to an iodine flask, dissolve in 30 mL of a solution of sodium hydroxide (1 in 250), and add water to make 200 mL. Add exactly measured 50 mL of 0.05 mol/L bromine VS, add 10 mL of hydrochloric acid to the solution quickly, and stopper immediately. Allow the mixture to stand for 5 minutes with occasional shaking, add 7 mL of potassium iodide TS, stopper again immediately, and shake gently for 1 minute. Titrate the liberated iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 1 mL of starch TS). Perform a blank determination.

Each mL of 0.05 mol/L bromine VS
= 4.430 mg of $C_{19}H_{14}O_5S$

Containers and storage Containers—Well-closed containers.

Phenolsulfonphthalein Injection

フェノールスルホンフタレイン注射液

Phenolsulfonphthalein Injection is an aqueous solution for injection. It contains not less than 0.54 w/v% and not more than 0.63 w/v% of phenolsulfonphthalein ($C_{19}H_{14}O_5S$: 354.38).

Method of preparation

Phenolsulfonphthalein	6 g
Sodium Chloride	9 g
Sodium Bicarbonate	1.43 g
(or Sodium Hydroxide)	(0.68 g)
Water for Injection	a sufficient quantity
	To make 1000 mL

Prepare as directed under Injections, with the above in-