Quality standards

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

Phenol and Glycerol Injection

General Notices

DEFINITION

Phenol and Glycerol Injection is a sterile solution containing 5% w/v of Phenol in Glycerol that has been previously dried at 120° for 1 hour.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of phenol, C₆H₆O

4.75 to 5.25% w/v.

CHARACTERISTICS

A pale straw-coloured, viscous solution.

IDENTIFICATION

- A. Add <u>bromine water</u> to a 1% w/v solution. A white precipitate is produced, which, on the continued addition of <u>bromine</u> water, at first dissolves then reappears and becomes permanent.
- B. To 0.5 mL add 5 mL of <u>water</u> and 0.05 mL of <u>sodium nitrite solution</u> and carefully pour on to the surface of <u>sulfuric</u> <u>acid</u>. A coloured zone, red above and green below, appears at the junction of the two layers.
- C. When heated on a borax bead in a naked flame, it imparts a green colour to the flame.

ASSAY

Dissolve 2 g in sufficient <u>water</u> to produce 50 mL, transfer 25 mL to a 500 mL glass-stoppered flask and add 50 mL of $\underline{0.05}$ \underline{M} <u>bromine VS</u> and 5 mL of <u>hydrochloric acid</u>, stopper, swirl occasionally during 30 minutes and allow to stand for a further 15 minutes. Add 5 mL of a 20% w/v solution of <u>potassium iodide</u>, taking care to avoid loss of bromine, shake thoroughly and titrate with 0.1 m <u>sodium thiosulfate VS</u> until only a faint yellow colour remains. Add 0.1 mL of <u>starch mucilage</u> and 10 mL of <u>chloroform</u> and complete the titration with vigorous shaking. Repeat the operation without the injection. The difference between the titrations represents the amount of bromine required. Each mL of $\underline{0.05}$ <u>bromine VS</u> is equivalent to 1.569 mg of C_6H_6O . Determine the <u>weight per mL</u> of the injection, <u>Appendix V G</u>, and calculate the percentage w/v of C_6H_6O .

STORAGE

Phenol and Glycerol Injection should be protected from light.

https://nhathuocngocanh.com/bp/

LABELLING

The strength is stated as the percentage w/v of Phenol.