Quality standards

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

Glucose Infusion

General Notices

Glucose Injection
Glucose Intravenous Infusion

DEFINITION

Glucose Infusion is a sterile solution containing Glucose or Glucose Monohydrate. It is supplied as a ready-to-use solution.

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

Content of glucose, C₆H₁₂O₆

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless solution. Solutions containing the equivalent of 200 g per litre or more of glucose, $C_6H_{12}O_6$, may be not more than faintly yellow in colour.

IDENTIFICATION

- A. Heat with *cupri-tartaric solution R1*. A red precipitate is produced.
- The solution prepared as directed in the Assay is dextrorotatory.

TESTS

Acidity

pH, 3.5 to 6.5, <u>Appendix V L</u>, when determined on a solution diluted, if necessary, with <u>water for injections</u>, to contain not more than the equivalent of 5% w/v of glucose, $C_6H_{12}O_6$, and to which 0.30 mL of a saturated solution of <u>potassium</u> <u>chloride</u> has been added for each 100 mL of solution.

5-Hydroxymethylfurfural and related substances

Dilute a volume containing the equivalent of 1.0 g of glucose, $C_6H_{12}O_6$, to 250 mL with <u>water</u>. The <u>absorbance</u> of the resulting solution at the maximum at 284 nm is not more than 0.25, <u>Appendix II B</u>.

Bacterial endotoxins

https://nhathuocngocanh.com/bp/
The endotoxin limit concentration is 0.25 IU per mL, <u>Appendix XIV C</u>. Dilute infusions containing more than 5% w/v of Glucose with water BET to contain 5% w/v.

ASSAY

To a volume containing the equivalent of 2 g to 5 g of glucose, $C_6H_{12}O_6$, add 0.2 mL of 5M <u>ammonia</u> and sufficient <u>water</u> to produce 100 mL. Mix well, allow to stand for 30 minutes and determine the optical rotation in a 2-dm tube, Appendix V F. The observed rotation in degrees multiplied by 0.9477 represents the weight in g of glucose, C₆H₁₂O₆, in the volume taken for assay.

LABELLING

The strength is stated as the equivalent number of grams of glucose, C₆H₁₂O₆, per litre.

When Glucose Infusion is required as a diluent for Injections or Infusions of the Pharmacopoeia, Glucose Infusion (50 g per litre) shall be used.