Quality standards

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

Glycine Irrigation Solution

General Notices

DEFINITION

Glycine Irrigation Solution is a sterile solution of Glycine in Water for Irrigation.

The irrigation solution complies with the requirements stated under Preparations for Irrigation and with the following requirements.

Content of glycine, C2H5NO,

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless solution.

IDENTIFICATION

- A. Evaporate 5 mL to dryness on a water bath and dry at 105° for 1 hour. The <u>infrared absorption spectrum</u>, <u>Appendix II</u> <u>A</u>, is concordant with the <u>reference spectrum</u> of glycine <u>(RS 171)</u>.
- B. Carry out the method for thin-layer chromatography, Appendix III A, using the following solutions.
- (1) Dilute the irrigation solution with water to contain 0.25% w/v of Glycine.
- (2) 0.25% w/v of *glycine* in *water*.

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating <u>silica gel GF</u>₂₅₄.
- (b) Use the mobile phase as described below.
- (c) Apply 2 µL of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry it at 100° to 105° for 10 minutes, spray with <u>ninhydrin solution</u> and heat at 100° to 105° for 2 minutes.

MOBILE PHASE

30 volumes of 13.5м <u>ammonia</u> and 70 volumes of <u>propan-1-ol</u>.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).

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TESTS

Acidity

pH, 4.5 to 6.5, Appendix V L.

Ammonium compounds

Dilute a volume containing 0.2 g of Glycine to 70 mL with <u>water</u> in an ammonia-distillation apparatus, add 25 mL of a solution prepared by boiling 25 mL of 5M <u>sodium hydroxide</u> with 50 mL of <u>water</u> and 50 mg of <u>aluminium</u> until the volume is reduced to 25 mL and distil into 2 mL of a saturated solution of <u>boric acid</u> until 50 mL is obtained. Add 2 mL of a solution prepared by boiling 25 mL of 5M <u>sodium hydroxide</u> with 50 mL of <u>water</u> until the volume is reduced to 25 mL and 2 mL of <u>alkaline potassium tetraiodomercurate solution</u>. Any colour produced is not more intense than that obtained by treating 70 mL of <u>water</u> containing 4 mL of <u>ammonia</u> standard solution (10 ppm NH₄) in the same manner, beginning at the words 'add 25 mL of...' (200 ppm, calculated with reference to the content of glycine).

ASSAY

Dilute a volume containing 0.15 g of Glycine to 25 mL with <u>water</u> and add 10 mL of <u>formaldehyde solution</u> previously adjusted to pH 9.0 and 0.25 mL of a mixed indicator solution prepared by dissolving 75 mg of <u>phenolphthalein</u> and 25 mg of <u>thymol blue</u> in 100 mL of <u>ethanol</u> (50%). Titrate with <u>0.1m sodium hydroxide VS</u> until the yellow colour disappears and a faint violet colour is produced. Each mL of <u>0.1m sodium hydroxide VS</u> is equivalent to 7.507 mg of C₂H₅NO₂.