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

Neomycin Tablets

General Notices

Action and use

Aminoglycoside antibacterial.

DEFINITION

Neomycin Tablets contain Neomycin Sulfate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Shake a quantity of the powdered tablets containing 70,000 IU with 25 mL of *water* and filter.
(2) 0.4% w/v of *neomycin sulfate EPCRS* in *water*.
(3) Mix equal volumes of solutions (1) and (2).

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* (Merck silica gel 60 plates are suitable).
(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, allow it to dry in air, spray with a 1% w/v solution of *ninhydrin* in *butan-1-ol* and heat at 105° for 2 minutes.

MOBILE PHASE

20 volumes of *chloroform*, 40 volumes of 13.5M *ammonia* and 60 volumes of *methanol*.

CONFIRMATION

The principal red spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2) and the principal red spot in the chromatogram obtained with solution (3) appears as a single compact spot.

B. The powdered tablets yield the reactions characteristic of *sulfates*, Appendix VI.

TESTS

Neamine

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Add 5 mL of *water* to a quantity of the powdered tablets containing 7000 IU, shake for 5 minutes and filter.

(2) 0.004% w/v of *neamine EPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel H*.
(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 in a current of warm air, heat at 110° for 10 minutes and spray the hot plate with a solution prepared immediately before use by diluting *sodium hypochlorite solution* with *water* to contain 0.5% w/v of available chlorine. Dry in a current of cold air until a sprayed area of the plate below the line of application gives not more than a very faint blue colour with one drop of a 0.5% w/v solution of *potassium iodide* in *starch mucilage*; avoid prolonged exposure to cold air. Spray the plate with a 0.5% w/v solution of *potassium iodide* in *starch mucilage*.

MOBILE PHASE

A freshly prepared 3.85% w/v solution of *ammonium acetate*.

CONFIRMATION

Any spot corresponding to neamine in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2).

Neomycin C

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 17,500 IU with 20 mL of 0.02M *sodium tetraborate*, dilute to 25 mL with the same solvent, mix and centrifuge. To 0.5 mL of this solution add 1.5 mL of a freshly prepared 2% w/v solution of *1-fluoro-2,4-dinitrobenzene* in *methanol*, heat in a water bath at 60° for 1 hour and cool; dilute the solution to 25 mL with the mobile phase, allow to stand and use the clear lower layer.
(2) Add 1.5 mL of a freshly prepared 2% w/v solution of *1-fluoro-2,4-dinitrobenzene* in *methanol* to 0.5 mL of a 0.10% w/v solution of *neomycin sulfate EPCRS* in 0.02M *sodium tetraborate*, heat in a water bath at 60° for 1 hour and cool; dilute the solution to 25 mL with the mobile phase, allow to stand and use the clear lower layer.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *silica gel for chromatography* (5 µm) (Nucleosil 100-5 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.6 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 350 nm.
(f) Inject 10 µL of each solution.
(g) Record the chromatograms for 1.4 times the retention time of the peak due to neomycin B.

MOBILE PHASE

Mix 97 mL of *tetrahydrofuran*, 1.0 mL of *water* and 0.5 mL of *glacial acetic acid* with sufficient of a 2.0% v/v solution of *absolute ethanol* in *ethanol-free chloroform* to produce 250 mL. Pass the mobile phase through the column for several hours before injecting the solutions.

SYSTEM SUITABILITY

The test is not valid unless:

the chromatogram obtained with solution (2) shows a principal peak due to neomycin B and a major *secondary peak* due to neomycin C with a retention time relative to neomycin B of about 0.6;

the *column efficiency*, determined using the peak due to neomycin B in the chromatogram obtained with solution (2), should be not less than 13,000 *theoretical plates* per metre.

LIMITS

In the chromatogram obtained with solution (1) the area of the peak corresponding to neomycin C is not less than 3% and not more than 15% of the sum of the areas of the peaks corresponding to neomycin B and neomycin C.

ASSAY

Weigh and powder 20 tablets. Transfer an accurately weighed quantity of the powder containing 15,000 IU to a flask containing 150 mL of sterile *phosphate buffer pH 8.0* and add sufficient of the buffer solution to produce 250 mL. Allow to stand, dilute 10 mL of the clear supernatant liquid to 100 mL with the buffer solution and carry out the *microbiological assay of antibiotics*, Appendix XIV A. The precision of the assay is such that the fiducial limits of error are not less than 95% and not more than 105% of the estimated potency. The upper fiducial limit of error is not less than 97.0% and the lower fiducial limit of error is not more than 110.0% of the stated number of IU.

STORAGE

Neomycin Tablets should be protected from light and stored at a temperature not exceeding 30°.

LABELLING

The quantity of active ingredient is stated in terms of the number of IU (Units).