



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

## Gentamicin Ointment

### [General Notices](#)

#### Action and use

Aminoglycoside antibacterial.

### DEFINITION

Gentamicin Ointment is a dispersion of [Gentamicin Sulfate](#) in [microfine powder](#) in White Soft Paraffin or other suitable anhydrous greasy basis.

*The ointment complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.*

### IDENTIFICATION

A. Carry out the method for [thin-layer chromatography, Appendix III A](#), using the following solutions.

- (1) Disperse a quantity of the ointment containing the equivalent of 7.5 mg of gentamicin in 20 mL of [chloroform](#), extract with 10 mL of [water](#) and use the aqueous layer.
- (2) A solution of [gentamicin sulfate](#) BPCRS in [water](#) containing the equivalent of 0.075% w/v of gentamicin.

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use a silica gel precoated plate (Merck silica gel 60 plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 20 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 [ninhydrin solution R1](#) and heat at 105° for 2 minutes.

#### MOBILE PHASE

The lower layer obtained by shaking together equal volumes of 13.5M [ammonia](#), [chloroform](#) and [methanol](#) and allowing to separate.

#### CONFIRMATION

The three principal spots in the chromatogram obtained with solution (1) correspond to the three principal spots in the chromatogram obtained with solution (2).

B. In the test for Composition of [gentamicin sulfate](#), the retention times of the four principal peaks in the chromatogram obtained with solution (1) correspond to those of the four principal peaks in the chromatogram obtained with solution (2).

### TESTS

#### Composition of [gentamicin sulfate](#)

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Disperse a quantity of the ointment containing the equivalent of 20 mg of gentamicin in 10 mL of [chloroform](#), add 20 mL of a 0.25% w/v solution of [sodium tetraborate](#), shake vigorously, centrifuge and separate the aqueous layer. Filter and dilute to 50 mL with [water](#). To 10 mL add 5 mL of [methanol](#), swirl, add 4 mL of [phthalaldehyde reagent](#), mix, add sufficient [methanol](#) to produce 25 mL, heat in a water bath at 60° for 15 minutes and cool. If the solution is not to be used immediately, cool to 0° and use within 4 hours
- (2) Prepare in the same manner as solution (1) but using 10 mL of a 0.065% w/v solution of [gentamicin sulfate BPCRS](#) place of the preparation being examined and beginning at the words 'To 10 mL add ...'.

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (12.5 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography](#) (5 µm) (Hypersil ODS and Kromasil C18 are suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.5 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 330 nm.
- (f) Inject 20 µL of each solution.

#### MOBILE PHASE

0.025M [sodium heptanesulfonate monohydrate](#) in a mixture of 5 volumes of [glacial acetic acid](#), 25 volumes of [water](#) and 70 volumes of [methanol](#).

When the chromatograms are recorded under the prescribed conditions the retention time of component C<sub>2</sub> is 10 to 20 minutes. The retention times relative to component C<sub>2</sub> are: about 0.13 (reagent); about 0.27 (component C<sub>1</sub>); about 0.65 (component C<sub>1a</sub>); about 0.85 (component C<sub>2a</sub>).

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the [resolution factor](#) between the peaks due to components C<sub>2a</sub> and C<sub>2</sub> is at least 1.3.

#### LIMITS

Using the chromatogram obtained with solution (1) calculate the percentage content of components C<sub>1</sub>, C<sub>1a</sub>, C<sub>2</sub> and C<sub>2a</sub> in the ointment by [normalisation](#). The proportions are within the following limits:

C<sub>1</sub>, 25.0 to 50.0%;

C<sub>1a</sub>, 10.0 to 35.0%;

C<sub>2</sub> plus C<sub>2a</sub>, 25.0 to 55.0%.

## ASSAY

Dissolve as completely as possible a quantity of the ointment containing the equivalent of 4 mg of gentamicin in 50 mL of [chloroform](#), extract with three 20-mL quantities of [phosphate buffer pH 8.0](#) and dilute the combined extracts to 100 mL with [phosphate buffer pH 8.0](#). Dilute 10 mL of the resulting solution to 50 mL with [phosphate buffer pH 8.0](#). 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.

Calculate the content of gentamicin in the ointment, taking each 1000 IU found to be equivalent to 1 mg of gentamicin. The upper fiducial limit of error is not less than 90.0% and the lower fiducial limit of error is not more than 120.0% of the stated content.

## LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of gentamicin.

