Polymyxin B for Injection

Polymyxin B for Injection is a sterile material consisting of polymyxin B sulphate. It is filled in a sealed container.

The injection is constituted by dissolving the contents of the sealed container in the requisite amount of sterile Water for Injections, or 0.9 per cent w/v sodium chloride injection or 1 per cent w/v procaine hydrochloride injection, immediately before use.

The constituted solution complies with the requirements for Clarity of solution and Particulate matter stated under Parenteral Preparations (Injections).

Storage. The constituted solution should be used immediately after preparation but, in any case, with in the period recommended by the manufacturer.

Polymyxin B for Injection contains not less than 90.0 per cent and not more than 120.0 per cent of the stated amount of polymyxin B.

Usual strength. 500000 units per vial.

The contents of the sealed container comply with the requirements stated under Parenteral Preparations (Powders for Injection) and with the following requirements.

Identification

Determine by thin-layer chromatography (2.4.17), coating the plate with silica gel G.

Mobile phase. A mixture of 4 volumes of *methanol,* 2 volumes of *isopropyl alcohol*, 2 volumes of *methylene chloride*, 2 volumes of *ammonia solution* and 1.5 volumes of *water*.

Test solution. Dilute a suitable quantity of Polymyxin B for injection with *0.1M hydrochloric acid* to obtain a solution containing about 10000 polymyxin B units per ml.

Reference solution. Dissolve a suitable quantity of *polymyxin B sulphate IPRS* in *0.1M hydrochloric acid* to obtain a solution containing about 10000 polymyxin B units per ml.

Apply to the plate 10 µl of each solution. Place the plate in a presaturated chromatographic chamber and allow the mobile phase to rise about three-fourths of the length of the plate. Dry the plate at 105° for 10 minutes. Spray with 0.2 per cent w/v solution of *ninhydrin* in *butyl alcohol* and heat at 105° for 5 minutes. The principal spot in the chromatogram obtained with the test solution corresponds to spot in the chromatogram obtained with the reference solution.

NOTE- If the chromatogram of the test solution yield excessive streaking, proceed as directed for modified procedure.

Modified procedure: Transfer the test solution to a centrifuge tube, add 10 ml of 1.2 per cent w/v solution of *picric acid,* vortex for 1 minute, centrifuge for 10 minutes, and discard the supernatant. Wash the residue with 1 ml portion of *water* until no yellow colour is observed in the washing. Discard the washings and dry the residue under a stream of nitrogen at 50°. Dissolve the residue in 1 ml of *acetone,* add 1 ml of freshly prepared 1 per cent v/v solution of *sulphuric acid* in *acetone*, shake, centrifuge for 5 minutes, and discard the supernatant. Rinse the residue with 1 ml of *acetone*, centrifuge and discard the washing. Repeat the washing until no yellow colour is observed. Dry the residue under a stream of nitrogen at 50°. Dissolve the residue in 0.5 ml of *0.1 M hydrochloric acid*. Repeat the procedure using this modified test solution instead of the test solution.

Tests

pH (2.4.24). 5.0 to 7.5, determined in a 0.5 per cent w/v solution.

Sulphated ash (2.3.18). Not more than 5.0 per cent, charred the residue being moistened with 2 ml of *nitric acid* and 5 drops of *sulphuric acid*.

Loss on drying (2.4.19). Not more than 7.0 per cent, determined on 0.1 g in a capillary-stoppered bottle under vaccum at 60° for 3 hours.

Sterility (2.2.11). Complies with the test for sterility.

Pyrogens. Complies with the test for pyrogens (2.2.8), using the test dose being 1.0 ml per kg of a solution in pyrogen free 0.9 per cent w/v of sodium chloride injection containing 20000 polymyxin B units per ml.

Assay. Determine by the microbiological assay of antibiotics, Method A (2.2.10), and express the results in Units per ml.

Storage. Store protected from light, at a temperature between 20° to 25°.

Labelling. Label it to include that where it is administered intramuscularly and /or intrathecally. it is to be given to patients hospitalized so as to provide constant supervision by a physician.