

about 100 mg of gemfibrozil, to a 100-mL volumetric flask, add about 80 mL of methanol, and shake to dissolve. Dilute with methanol to volume, mix, and filter. Transfer 5.0 mL of this clear solution to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

**Procedure**—Proceed as directed for *Procedure* in the *Assay* under *Gemfibrozil*. Calculate the quantity, in mg, of  $C_{15}H_{22}O_3$  in the portion of Capsules taken by the formula:

$$500C(r_u / r_s)$$

in which the terms are as defined therein.

## Gemfibrozil Tablets

» Gemfibrozil Tablets contain not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of gemfibrozil ( $C_{15}H_{22}O_3$ ).

**Packaging and storage**—Preserve in tight containers.

**USP Reference standards** (11)—

USP Gemfibrozil RS

**Identification**—A portion of finely ground Tablets, equivalent to about 100 mg of gemfibrozil, responds to the *Identification* test under *Gemfibrozil Capsules*.

**Dissolution** (711)—

**Medium:** 0.2 M pH 7.5 phosphate buffer prepared by dissolving 545 g of monobasic potassium phosphate in 5 L of water, adding 131 g of sodium hydroxide, diluting with water to about 19.5 L, and mixing well. Adjust with either 1 N phosphoric acid or 1 N sodium hydroxide to a pH of 7.5, and dilute with water to 20 L; 900 mL.

**Apparatus 2:** 50 rpm.

**Time:** 30 minutes.

**Procedure**—Determine the amount of  $C_{15}H_{22}O_3$  dissolved from UV absorbances at the wavelength of maximum absorbance at about 276 nm on filtered portions of the solution under test, suitably diluted with 1 N sodium hydroxide, in comparison with a Standard solution obtained as follows. Prepare a Standard stock solution of USP Gemfibrozil RS having a known concentration of about 0.33 mg per mL in *Medium*. [NOTE—Initially dissolve the USP Reference Standard in an amount of methanol not to exceed 1% of the volume of the Standard stock solution.] Quantitatively dilute the Standard stock solution with 1 N sodium hydroxide to obtain a Standard solution having a concentration estimated to correspond to that of the filtered and diluted solution under test.

**Tolerances**—Not less than 80% (Q) of the labeled amount of  $C_{15}H_{22}O_3$  is dissolved in 30 minutes.

**Uniformity of dosage units** (905): meet the requirements.

**Assay**—

*Mobile phase, Standard preparation, System suitability preparation, and Chromatographic system*—Proceed as directed in the *Assay* under *Gemfibrozil*.

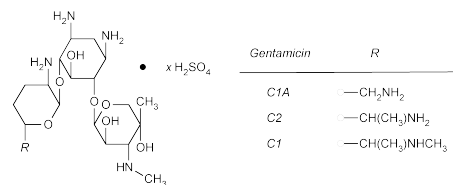
**Assay preparation**—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of gemfibrozil, to a 100-mL volumetric flask, add about 80 mL of methanol, and shake to dissolve. Dilute with methanol to volume, mix, and filter. Transfer 5.0 mL of this clear solution to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

**Procedure**—Proceed as directed for *Procedure* in the *Assay* under *Gemfibrozil*. Calculate the quantity, in mg, of gemfibrozil ( $C_{15}H_{22}O_3$ ) in the portion of Tablets taken by the formula:

$$500C(r_u / r_s)$$

in which the terms are as defined therein.

## Gentamicin Sulfate



Gentamicin sulfate (salt).  
Gentamycin sulfate [1405-41-0].

» Gentamicin Sulfate is the sulfate salt, or a mixture of such salts, of the antibiotic substances produced by the growth of *Micromonospora purpurea*. It has a potency equivalent to not less than 590 µg of gentamicin per mg, calculated on the dried basis.

**Packaging and storage**—Preserve in tight containers.

**Labeling**—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

**USP Reference standards** (11)—

USP Endotoxin RS

USP Gentamicin Sulfate RS

**Identification**—

**A:** *Infrared Absorption* (197K).

**B:** It responds to the tests for *Sulfate* (191).

**Specific rotation** (781S): between +107° and +121°.

**Test solution:** 10 mg per mL, in water.

**pH** (791): between 3.5 and 5.5, in a solution (1 in 25).

**Loss on drying** (731)—Dry it in vacuum at a pressure not exceeding 5 mm of mercury at 110° for 3 hours: it loses not more than 18.0% of its weight.

**Residue on ignition** (281): not more than 1.0%.

**Limit of methanol**—

**Internal standard solution**—Transfer 2.5 mL of *n*-propyl alcohol to a 500-mL volumetric flask, dilute with water to volume, and mix. This solution contains 0.50% (v/v) of *n*-propyl alcohol.

**Standard preparation**—Transfer 1.25 mL of methanol and 1.25 mL of *n*-propyl alcohol to a 500-mL volumetric flask, dilute with water to volume, and mix to obtain a *Standard preparation* containing 0.25% (v/v) of methanol and 0.25% (v/v) of *n*-propyl alcohol.

**Control solution**—Dissolve 0.50 g of Gentamicin Sulfate in 2.0 mL of water.

**Test preparation**—Dissolve 0.50 g of Gentamicin Sulfate in 1.0 mL of *Internal standard solution*, add 1.0 mL of water, and mix.

**Chromatographic system** (see *Chromatography* (621))—The gas chromatograph is equipped with a flame-ionization detector and a 4-mm × 1.5-m column packed with support S3. The column temperature is maintained at a constant temperature between 120° and 140°, and the injection port and detector block are maintained at a constant temperature at least 50° higher than the column temperature. Nitrogen is used as the carrier gas at a constant flow rate of between 30 and 40 mL per minute. Chromatograph the *Standard preparation*, and measure the peak responses as directed under *Procedure*: the resolution, *R*, between the *n*-propyl alcohol peak and the methanol peak is not less than 1.0. Chromatograph the *Control solution*, measure the peak responses as directed under *Procedure*, and examine the chromatogram: if any peak is observed at a retention time corresponding to that of *n*-propyl alcohol, use the response of that peak to correct the *n*-propyl alcohol peak

response in the chromatogram obtained from the *Test preparation*.

**Procedure**—Using a syringe with a polytef-tipped plunger, separately inject equal volumes (about 2  $\mu$ L) of the *Standard preparation* and the *Test preparation* into the chromatograph, record the chromatograms, and measure the *n*-propyl alcohol and the methanol peak area responses. Calculate the per centage of methanol in the Gentamicin Sulfate taken by the formula:

$$1.58(P/M)(R_U/R_S)$$

in which *P* is the per centage (v/v) of methanol in the *Standard preparation*; *M* is the quantity, in g, of Gentamicin Sulfate taken to prepare the *Test preparation*; *R<sub>U</sub>* is the ratio of the methanol peak area response to the *n*-propyl alcohol peak area response (corrected, if necessary, by subtracting the response of any peak at the locus of the *n*-propyl alcohol peak observed in the chromatogram of the *Control solution*) in the chromatogram obtained from the *Test preparation*; and *R<sub>S</sub>* is the ratio of the methanol peak area response to the *n*-propyl alcohol peak area response in the chromatogram obtained from the *Standard preparation*: not more than 1.0% of methanol is found.

#### Content of gentamicins—

***o*-Phthalaldehyde solution**—Dissolve 1.0 g of *o*-phthalaldehyde in 5 mL of methanol, and add 95 mL of 0.4 M boric acid, previously adjusted with 8 N potassium hydroxide to a pH of 10.4, and 2 mL of thioglycolic acid. Adjust the resulting solution with 8 N potassium hydroxide to a pH of 10.4.

**Mobile phase**—Mix 700 mL of methanol, 250 mL of water, and 50 mL of glacial acetic acid. Dissolve 5 g of sodium 1-heptanesulfonate in this solution. Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

**Standard preparation**—Prepare a solution of USP Gentamicin Sulfate RS in water containing about 0.65 mg per mL. Transfer 10 mL of this solution to a suitable test tube, add 5 mL of isopropyl alcohol and 4 mL of *o*-Phthalaldehyde solution, mix, and add isopropyl alcohol to obtain 25 mL of solution. Heat at 60° in a water bath for 15 minutes, and cool.

**Test preparation**—Using Gentamicin Sulfate, proceed as directed for *Standard preparation*.

**Chromatographic system** (see *Chromatography* (621))—The liquid chromatograph is equipped with a 330-nm detector and a 5-mm  $\times$  10-cm column that contains 5- $\mu$ m packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure*: the resolution, *R*, between any two peaks is not less than 1.25, the capacity factor determined from the gentamicin C<sub>1</sub> peak is between 2 and 7, the column efficiency determined from the gentamicin C<sub>2</sub> peak is not less than 1200 theoretical plates, and the relative standard deviation for replicate injections is not more than 2.0%.

**Procedure**—Separately inject equal volumes (about 20  $\mu$ L) of the *Standard preparation* and the *Test preparation* into the chromatograph, record the chromatograms, and measure the area responses for the major peaks. The elution order is gentamicin C<sub>1</sub>, gentamicin C<sub>1a</sub>, gentamicin C<sub>2a</sub>, and gentamicin C<sub>2</sub>. Calculate the per centage contents of gentamicin C<sub>1</sub>, gentamicin C<sub>1a</sub>, gentamicin C<sub>2a</sub>, and gentamicin C<sub>2</sub> in the portion of Gentamicin Sulfate taken by the formula:

$$100r_i/r_s$$

in which *r<sub>i</sub>* is the peak area response corresponding to the particular gentamicin; and *r<sub>s</sub>* is the sum of the area responses of all four peaks: the content of gentamicin C<sub>1</sub> is between 25% and 50%, the content of gentamicin C<sub>1a</sub> is between 10% and 35%, and the sum of the contents of gentamicin C<sub>2a</sub> and gentamicin C<sub>2</sub> is between 25% and 55%.

**Other requirements**—Where the label states that Gentamicin Sulfate is sterile, it meets the requirements for *Sterility Tests* (71) and for *Bacterial endotoxins* in *Gentamicin Injection*. Where the label states that Gentamicin Sulfate must be subjected to fur-

ther processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* in *Gentamicin Injection*.

**Assay**—Proceed with Gentamicin Sulfate as directed under *Antibiotics—Microbial Assays* (81).

---

## Gentamicin Sulfate Cream

---

» Gentamicin Sulfate Cream contains the equivalent of not less than 90.0 per cent and not more than 135.0 percent of the labeled amount of gentamicin.

**Packaging and storage**—Preserve in collapsible tubes or in other tight containers, and avoid exposure to excessive heat.

#### USP Reference standards (11)—

USP Gentamicin Sulfate RS

**Identification**—Shake a quantity of Cream, equivalent to about 5 mg of gentamicin, with a mixture of 200 mL of chloroform and 5 mL of water. Allow to separate, and filter the aqueous phase: the filtrate so obtained meets the requirements of the *Identification* test under *Gentamicin Injection*.

**Minimum fill** (755): meets the requirements.

**Assay**—Proceed with Cream as directed in the *Assay* under *Gentamicin Sulfate Ointment*.

---

## Gentamicin Uterine Infusion

---

» Gentamicin Uterine Infusion is a sterile solution of Gentamicin Sulfate in Water for Injection. It contains not less than 90.0 per cent and not more than 125.0 per cent of the labeled amount of gentamicin. It may contain suitable buffers, preservatives, and sequestering agents.

**Packaging and storage**—Preserve in single-dose or multiple-dose containers, preferably of T type I glass.

**Labeling**—Label Uterine Infusion to indicate that it is for veterinary use only. The label states that it must be diluted with 0.9% Sodium Chloride Irrigation before aseptic uterine infusion.

#### USP Reference standards (11)—

USP Gentamicin Sulfate RS

**Identification**—It responds to the *Identification* test under *Gentamicin Injection*, Uterine Infusion being used instead of Injection.

**Sterility** (71)—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

**pH** (791): between 3.0 and 5.5.

**Assay**—Proceed as directed for gentamicin under *Antibiotics—Microbial Assays* (81), using an accurately measured volume of Uterine Infusion diluted quantitatively and stepwise with *Buffer No. 3* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard (0.1  $\mu$ g of gentamicin per mL).

---

## Gentamicin Injection

---

» Gentamicin Injection contains an amount of Gentamicin Sulfate equivalent to not less than