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# Gemfibrozil Capsules

» Gemfibrozil Capsules contain not less than 90.0 percent and not more than 110.0 percent 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**—Shake a portion of Capsule contents, equivalent to about 100 mg of gemfibrozil, with 10 mL of 0.1 N sodium hydroxide. Filter the mixture into a 50-mL centrifuge tube, and acidify the filtrate with 3 N sulfuric acid to obtain a copious precipitate. Centrifuge, and discard the clear solution. Wash the precipitate with small portions of water, and allow it to air-dry: the IR absorption spectrum of a potassium bromide dispersion of the precipitate, previously dried over silica gel for 4 hours, exhibits maxima only at the same wavelengths as those of a similar preparation of USP Gemfibrozil RS.

**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:* 45 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 45 minutes.

**Uniformity of dosage units** ⟨905⟩**:** meet the requirements.

**Assay**—

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

*Assay preparation*—Remove, as completely as possible, the contents of not fewer than 20 Capsules, weigh, and mix. 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 $C_{15}H_{22}O_3$ in the portion of Capsules taken by the formula:

$$500C(r_U/r_S)$$

in which the terms are as defined therein.

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| GEMFIBROZIL CAPSULES | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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