Cefaclor Capsules

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» Cefaclor Capsules contain the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of $C_{15}H_{14}ClN_3O_4S$.

Packaging and storage— Preserve in tight containers.

USP Reference standards ⟨11⟩ **—**
USP Cefaclor RS.
USP Cefaclor, Delta-3 Isomer RS  .

Identification— Mix the contents of 1 Capsule with water to obtain a concentration of about 2 mg of cefaclor per mL, and filter: the filtrate so obtained responds to *Identification* test *B* under *Cefaclor*.

Dissolution ⟨711⟩ **—**

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure— Determine the amount of cefaclor ($C_{15}H_{14}ClN_3O_4S$) dissolved from UV absorbances at the wavelength of maximum absorbances at about 264 nm of filtered portions of the solution under test, suitably diluted with water, in comparison with a Standard solution having a known concentration of *USP Cefaclor RS* in the same medium.

Tolerances— Not less than 80% *(Q)* of the labeled amount of cefaclor ($C_{15}H_{14}ClN_3O_4S$) is dissolved in 30 minutes.

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

Water, *Method I* ⟨921⟩ : not more than 8.0%.

Related compounds—

Solvent, *Blank solution*, *Solution A*, *Solution B*, *Mobile phase*, *Standard solution*, *System suitability solution*, and *Chromatographic system—* Proceed as directed for *Related compounds* under *Cefaclor*.

Test solution— Remove as completely as possible the contents of not fewer than 20 Capsules, and mix. Transfer an accurately weighed portion of the combined contents, equivalent to about 50 mg of cefaclor, to a 10-mL volumetric flask. Dissolve in *Solvent*, using brief sonication, if necessary, to achieve dissolution. Avoid heating. Dilute with *Solvent* to volume, mix, and filter. Use this *Test solution* within 3 hours if stored at room temperature, or within 20 hours when stored under refrigeration.

Procedure— Separately inject equal volumes (about 20 µL) of the *Standard solution* and the

Test solution into the chromatograph, record the chromatograms, and measure the peak area responses for all the peaks. Calculate the mg of each related compound in the portion of Capsules taken by the formula:

$$0.01CP(r_i / r_s)$$

in which the terms are as defined for *Related compounds* under *Cefaclor*. Not more than 0.5% of any individual cefaclor-related compound is found; and the sum of all cefaclor-related compounds found is not more than 2.0%, not including the contribution of any peak that gives a result of less than 0.1%.

Assay—

Mobile phase, *Standard preparation*, *Resolution solution*, and *Chromatographic system*— Proceed as directed in the *Assay* under *Cefaclor*.

Assay preparation— Remove, as completely as possible, the contents of not fewer than 20 Capsules, and weigh accurately. Mix the combined contents, and transfer an accurately weighed portion of the powder, equivalent to about 75 mg of cefaclor, to a 250-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Sonicate if necessary to ensure complete dissolution of the cefaclor. Filter to obtain the clear *Assay preparation*.

Procedure— Proceed as directed in the *Assay* under *Cefaclor*. Calculate the portion of $C_{15}H_{14}ClN_3O_4S$ in the portion of Capsules taken by the formula:

$$5W_s(P / 1000)(r_U / r_s)$$

in which the terms are as defined therein.

Auxiliary Information— *Staff Liaison* : Brian D. Gilbert, Ph.D., Scientist

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