Cefaclor for Oral Suspension

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» Cefaclor for Oral Suspension is a dry mixture of Cefaclor and one or more suitable buffers, colors, diluents, and flavors. It contains 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— The retention time of the major peak for cefaclor in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Uniformity of dosage units ⟨905⟩ **—**

FOR SOLID PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩ : meets the requirements.

pH ⟨791⟩ : between 2.5 and 5.0, in the suspension constituted as directed in the labeling.

Water, *Method I* ⟨921⟩ : not more than 2.0%.

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— Constitute Cefaclor for Oral Suspension as directed in the labeling. Transfer an accurately measured portion of Cefaclor for Oral Suspension, freshly mixed and free from air bubbles, 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 Cefaclor for Oral Suspension 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 1.0% of any individual cefaclor-related compound is found; and the sum of all cefaclor-related compounds found is not more than 3.0%, 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— Constitute Cefaclor for Oral Suspension as directed in the labeling. Transfer an accurately measured portion of the resulting suspension, freshly mixed and free from air bubbles, dilute quantitatively with *Mobile phase* to obtain a final solution containing about 0.3 mg of cefaclor per mL. 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 quantity, in mg, of $C_{15}H_{14}ClN_3O_4S$ in the portion of the constituted Cefaclor for Oral Suspension taken by the formula:

$$V_U (W_S / 50)(P/1000)(r_U / r_S)$$

in which V_U is the final volume, in mL, of the *Assay preparation*, and the other terms are as defined therein.

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

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