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Cefpodoxime Proxetil for Oral Suspension

» Cefpodoxime Proxetil for Oral Suspension contains Cefpodoxime Proxetil and one or more buffers, suspending agents, sweeteners, flavorings, and preservatives. When constituted as directed in the labeling, it contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of cefpodoxime ($C_{15}H_{17}N_5O_6S_2$).

Packaging and storage—Preserve in tight containers, at a temperature not exceeding 30°. Store the constituted Oral Suspension in a refrigerator.

USP Reference standards ⟨11⟩—

USP Cefpodoxime Proxetil RS

Identification—The retention times of the cefpodoxime proxetil *R*-epimer peak and the cefpodoxime proxetil *S*-epimer peak in the chromatogram of the *Assay preparation* correspond to those 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 4.0 and 5.5, in the suspension constituted as directed in the labeling.

Water Determination ⟨921⟩: not more than 1.5%.

Assay—

Mobile phase, *Diluent*, and *Chromatographic system*—Prepare as directed in the *Assay* under *Cefpodoxime Proxetil.*

Standard preparation—Transfer about 30 mg of USP Cefpodoxime Proxetil RS, accurately weighed, to a 50-mL volumetric flask, dissolve in 5 mL of methanol, dilute with *Diluent* to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix. Pass through a filter having a 0.45-µm or finer porosity.

Assay preparation—Constitute a container of Cefpodoxime Proxetil for Oral Suspension as directed in the labeling. Shake the resulting suspension thoroughly, and determine its density. Transfer an accurately weighed quantity of the suspension, equivalent to about 50 mg of cefpodoxime, to a 100-mL volumetric flask. Add 10 mL of water, and shake to disperse. Add 20 mL of acetonitrile, and sonicate for 15 minutes. Cool to room temperature, dilute with *Diluent* to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with *Diluent* to volume, mix, and pass through a filter having a 0.45-µm or finer porosity.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg of cefpodoxime ($C_{15}H_{17}N_5O_6S_2$) in the portion of Oral Suspension taken by the formula:

$$2CP(r_U/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Cefpodoxime Proxetil RS in the *Standard preparation; P* is the designated potency, in µg per mg, of cefpodoxime ($C_{15}H_{17}N_5O_6S_2$) in USP Cefpodoxime Proxetil RS; and r_U and r_S are the sums of the peak responses for cefpodoxime proxetil *S*-epimer and cefpodoxime proxetil *R*-epimer obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
CEFPODOXIME PROXETIL FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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