Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-3B91E17F-C227-4CCA-A4BE-B71B7721C74D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14113_01_01
DOI Ref: b5lj5

Cefpodoxime Proxetil Tablets

» Cefpodoxime Proxetil Tablets contain an amount of Cefpodoxime Proxetil equivalent to 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 controlled room temperature.

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.*

Dissolution ⟨711⟩—

Medium—Dissolve 54.5 g of glycine and 42.6 g of sodium chloride in about 500 mL of water in a 1000-mL volumetric flask. Cautiously add, with swirling, 14.2 mL of hydrochloric acid, and allow to cool. Dilute with water to volume, and mix. Transfer 50 mL of this stock solution to a flask, and dilute with water to 900 mL to obtain a solution having a pH of 3.0 ± 0.1. [Note—If necessary, adjust the pH of the stock solution with 10 N sodium hydroxide so that when 50 mL is diluted with water to 900 mL the pH of the *Dissolution Medium* is 3.0 ± 0.1.]

Apparatus 2: 75 rpm.

Time: 30 minutes.

Procedure—Determine the amount of cefpodoxime ($C_{15}H_{17}N_5O_6S_2$) dissolved by employing UV absorption at about 259 nm on filtered portions of the solution under test in comparison with a Standard solution having a known concentration of USP Cefpodoxime Proxetil RS prepared by dissolving an accurately weighed portion in a small volume of methanol and diluting quantitatively with *Dissolution Medium*.

Tolerances—Not less than 70% *(Q)* of the labeled amount of cefpodoxime ($C_{15}H_{17}N_5O_6S_2$) is dissolved in 30 minutes.

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

Water Determination ⟨921⟩: not more than 5.0%.

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—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of cefpodoxime to a 100-mL volumetric flask. Dissolve in 40 mL of *Diluent*, sonicating for 5 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 Tablets 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 TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 47(1)
Current DocID: GUID-3B91E17F-C227-4CCA-A4BE-B71B7721C74D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14113_01_01
DOI ref: b5lj5