

Status: Currently Official on 13-Feb-2025
 Official Date: Official as of 01-Jul-2021
 Document Type: USP Monographs
 DocId: GUID-E55A8C6E-0D6A-4D5B-8DF1-B2CE6BFFDA62_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M7495_04_01
 DOI Ref: 3p1j1

© 2025 USPC
 Do not distribute

Benazepril Hydrochloride Tablets

DEFINITION

Benazepril Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: Dissolve 0.81 g of [tetrabutylammonium bromide](#) in 360 mL of [water](#) containing 0.2 mL of [acetic acid, glacial](#).

Mobile phase: [Methanol](#) and *Solution A* (64:36)

System suitability solution: 0.4 mg/mL each of [USP Benazepril Hydrochloride RS](#) and [USP Benazepril Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.2 mg/mL of [USP Benazepril Hydrochloride RS](#) in *Mobile phase*

Sample solution: Nominally 0.2 mg/mL of benazepril hydrochloride in *Mobile phase* prepared as follows. Transfer a portion from NLT 20 finely powdered Tablets, equivalent to 50 mg of benazepril hydrochloride, to a 250-mL volumetric flask. Add 150 mL of *Mobile phase*, and shake by mechanical means for 30 min. Dilute with *Mobile phase* to volume, mix, and centrifuge. Pass an aliquot of the supernatant through a suitable filter, discarding the first 6 mL of the filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 240 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Columns

Guard: 4.6-mm × 3-cm; 7-μm packing L7

Analytical: 3.9-mm × 30-cm; 10-μm packing L1

Flow rate: 1 mL/min

Injection volume: 25 μL

Run time: NLT 3 times the retention time of benazepril

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for benazepril and benazepril related compound B peaks are about 1.0 and 1.5, respectively.]

Suitability requirements

Resolution: NLT 2.0 between benazepril and benazepril related compound B peaks

Relative standard deviation: NMT 2.0% for both benazepril and benazepril related compound B peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of benazepril from the *Sample solution*

r_S = peak response of benazepril from the *Standard solution*

C_S = concentration of [USP Benazepril Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of benazepril hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)

Test 1**Medium:** Water; 500 mL**Apparatus 2:** 50 rpm**Time:** 30 min**Solution A, Mobile phase, System suitability solution, and System suitability:** Proceed as directed in the Assay.**Standard solution:** 0.02 µg/µL of [USP Benazepril Hydrochloride RS](#) in *Medium***Sample solution:** Pass a portion of the solution under test through a suitable filter. [NOTE—The amount of benazepril injected should not exceed 125% of the quantity of the *Standard solution* (1.5 µg).]**Chromatographic system:** Proceed as directed in the Assay, except for the *Injection volume*.**Injection volume:** 25 µL for *System suitability solution*; 60 µL for *Standard solution* and *Sample solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times V \times 100$$

 r_U = peak response of benazepril from the *Sample solution* r_S = peak response of benazepril from the *Standard solution* C_S = concentration of [USP Benazepril Hydrochloride RS](#) in the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 500 mL**Tolerances:** NLT 80% (Q) of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$) is dissolved.**Test 2:** If the product complies to this test, the labeling indicates that the product meets USP *Dissolution Test 2*.**Medium, Apparatus 2, Standard solution, Sample solution, Chromatographic system, and Analysis:** Proceed as directed in *Dissolution Test 1*.**Solution A, Mobile phase, System suitability solution, and System suitability:** Proceed as directed in the Assay.**Time:** 45 min**Tolerances:** NLT 70% (Q) of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES• **ORGANIC IMPURITIES****Solution A, Mobile phase, System suitability solution, Sample solution, and System suitability:** Proceed as directed in the Assay.**Standard solution:** 0.006 mg/mL of [USP Benazepril Related Compound C RS](#) in *Mobile phase***Chromatographic system:** Proceed as directed in the Assay, except for the *Injection volume*.**Injection volume:** 25 µL for *System suitability solution*; 80 µL for *Standard solution* and *Sample solution***Analysis****Samples:** *Sample solution* and *Standard solution*

Calculate the percentage of benazepril related compound C in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of benazepril related compound C from the *Sample solution* r_S = peak response of benazepril related compound C from the *Standard solution* C_S = concentration of [USP Benazepril Related Compound C RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of benazepril hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_T) \times 100$$

 r_U = peak response of each impurity from the *Sample solution* r_T = sum of the responses of all the peaks including benazepril related compound C from the *Sample solution***Acceptance criteria:** See [Table 1](#).**Table 1**