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Add the following:

▲Benzphetamine Hydrochloride Tablets

DEFINITION

Benzphetamine Hydrochloride Tablets contain NLT 93.0% and NMT 105.0% of the labeled amount of benzphetamine hydrochloride ($C_{17}H_{21}N \cdot HCl$).

IDENTIFICATION

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

ASSAY

• PROCEDURE

Buffer: Dissolve 2.76 g of [monobasic sodium phosphate dihydrate](#) in 1000 mL of [water](#). Add 1.0 mL of [triethylamine](#) and adjust with [phosphoric acid](#) to a pH of 4.5.

Solution A: [Acetonitrile](#) and *Buffer* (10:90)

Solution B: [Acetonitrile](#) and water (80:20)

Mobile phase: *Solution A* and *Solution B* (65:35)

Diluent: [Methanol](#) and [water](#) (50:50)

Standard solution: 0.2 mg/mL of [USP Benzphetamine Hydrochloride RS](#) in *Diluent*. Sonicate to dissolve if necessary.

Sample solution: Nominally 0.2 mg/mL of benzphetamine hydrochloride in *Diluent*, prepared as follows. Transfer an adequate amount of benzphetamine hydrochloride from NLT 20 finely powdered Tablets to a suitable volumetric flask. Add about 60% of the final volume of *Diluent* and shake vigorously to disperse the Tablet powder. Sonicate for an additional NLT 60 min with intermediate shaking. Cool to room temperature and dilute with *Diluent* to volume. Pass a portion through a suitable filter with a 0.45-μm pore size. Discard the first few milliliters of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 207 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-μm packing L7

Temperatures

Autosampler: 15°

Column: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 μL

Run time: NLT 2.1 times the retention time of benzphetamine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benzphetamine hydrochloride ($C_{17}H_{21}N \cdot HCl$) in the portion of Tablets taken:

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

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

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

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



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

Acceptance criteria: 93.0%–105.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Use plastic vials for analysis.

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: Dissolve 2.76 g of [monobasic sodium phosphate dihydrate](#) in 1000 mL of [water](#). Add 0.5 mL of [triethylamine](#) and adjust with [phosphoric acid](#) to a pH of 6.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (70:30)

Standard stock solution: 0.55 mg/mL of [USP Benzphetamine Hydrochloride RS](#), prepared as follows. Transfer an adequate amount of [USP Benzphetamine Hydrochloride RS](#) to a suitable volumetric flask. Add 5% of the final volume of [acetonitrile](#) and sonicate to dissolve. Dilute with *Medium* to volume.

Standard solution: 0.055 mg/mL of [USP Benzphetamine Hydrochloride RS](#) in *Medium* from *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 207 nm

Column: 4.6-mm × 25-cm; 5-μm packing L7

Column temperature: 25°

Flow rate: 1.0 mL/min

Injection volume: 10 μL

Run time: NLT 1.8 times the retention time of benzphetamine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benzphetamine hydrochloride ($C_{17}H_{21}N \cdot HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

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

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

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

V = volume of *Medium* (mL), 900

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of benzphetamine hydrochloride ($C_{17}H_{21}N \cdot HCl$) is dissolved.

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

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 1.38 g of [monobasic sodium phosphate dihydrate](#) in 1000 mL of [water](#)

Solution B: [Acetonitrile](#) and [water](#) (80:20)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20