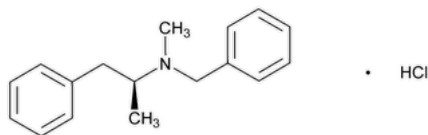


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Add the following:

▲Benzphetamine Hydrochloride



$C_{17}H_{21}N \cdot HCl$ 275.82
(+)-N-Benzyl-N, α-dimethylphenethylamine hydrochloride;
(S)-N-Benzyl-N-methyl-1-phenylpropan-2-amine hydrochloride CAS RN®: 5411-22-3; UNII: 43DWT87QT7.

DEFINITION

Benzphetamine Hydrochloride contains NLT 98.0% and NMT 102.0% of benzphetamine hydrochloride ($C_{17}H_{21}N \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. ▲[SPECTROSCOPIC IDENTIFICATION TESTS <197>](#), [Infrared Spectroscopy](#): 197A or 197K▲ (CN 1-May-2020)
- B. The retention time of the benzphetamine peak of the *Sample solution* corresponds to that of the *System suitability solution*, as obtained in the *Enantiomeric Purity* test.
- C. [IDENTIFICATION TESTS—GENERAL <191>](#), [Chemical Identification Tests, Chloride](#): Meets the requirements

ASSAY

• PROCEDURE

Buffer: 0.01 M [monobasic sodium phosphate](#) in [water](#)
Solution A: [Acetonitrile](#) and *Buffer* (10:90)
Solution B: [Acetonitrile](#) and [water](#) (70:30)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
30	70	30
35	60	40
40	10	90
45	0	100
47	100	0
55	100	0

Diluent: [Methanol](#) and [water](#) (50:50)
Standard solution: 0.1 mg/mL of [USP Benzphetamine Hydrochloride RS](#) in *Diluent*
Sample solution: 0.1 mg/mL of Benzphetamine Hydrochloride in *Diluent*

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 207 nm**Column:** 4.6-mm × 25-cm; 5-µm packing L1**Column temperature:** 30°**Flow rate:** 1.0 mL/min**Injection volume:** 10 µL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.5**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of benzphetamine hydrochloride ($C_{17}H_{21}N \cdot HCl$) in the portion of Benzphetamine Hydrochloride 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 = concentration of Benzphetamine Hydrochloride in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%• **ORGANIC IMPURITIES****Buffer, Solution A, Solution B, and Diluent:** Prepare as directed in the Assay.**Mobile phase:** See [Table 2](#).**Table 2**

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
30	70	30
35	60	40
45	55	45
60	15	85
62	100	0
70	100	0

System suitability solution: 1 mg/mL of [USP Benzphetamine Hydrochloride RS](#) and 0.001 mg/mL each of [USP Benzphetamine Related Compound E RS](#) and [USP Benzphetamine Related Compound F RS](#) in *Diluent***Sensitivity solution:** 0.0001 mg/mL of [USP Benzphetamine Hydrochloride RS](#) in *Diluent***Standard solution:** 0.001 mg/mL of [USP Benzphetamine Hydrochloride RS](#) in *Diluent***Sample solution:** 1 mg/mL of Benzphetamine Hydrochloride in *Diluent***Chromatographic system:** Proceed as directed in the Assay, except for *Injection volume*.**Injection volume:** 20 µL**System suitability**