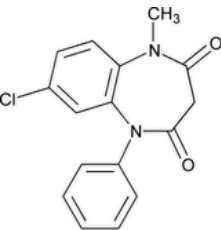


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Add the following:

▲Clobazam



$C_{16}H_{13}ClN_2O_2$ 300.74
1*H*-1,5-Benzodiazepine-2,4(3*H*,5*H*)-dione, 7-chloro-1-methyl-5-phenyl-;
7-Chloro-1-methyl-5-phenyl-1*H*-1,5-benzodiazepine-2,4-(3*H*,5*H*)-dione;
7-Chloro-1-methyl-5-phenyl-1,5-dihydro-2*H*-benzo[*b*][1,4]diazepine-2,4(3*H*)-dione CAS RN®: 22316-47-8; UNII: 2MRO291B4U.

DEFINITION
Clobazam contains NLT 97.0% and NMT 103.0% of clobazam ($C_{16}H_{13}ClN_2O_2$), calculated on the dried basis.

- IDENTIFICATION**
- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K or 197A
 - **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: Transfer 1.0 mL of [phosphoric acid](#) to a 1-L volumetric flask containing about 950 mL of [water](#). Dilute with [water](#) to volume.
Solution B: [Acetonitrile](#) and *Solution A* (30:70)
Solution C: [Acetonitrile](#) and *Solution A* (80:20)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	100	0
25	0	100
25.1	100	0
32	100	0

Diluent: [Acetonitrile](#) and [water](#) (60:40)
Standard stock solution: 0.5 mg/mL of [USP Clobazam RS](#) prepared as follows. Transfer a suitable amount of [USP Clobazam RS](#) to an appropriate volumetric flask and dissolve in 60% of the flask volume of [acetonitrile](#). Dilute with [water](#) to volume.
Standard solution: 0.125 mg/mL of [USP Clobazam RS](#) from the *Standard stock solution* in *Diluent*
Sample stock solution: 0.5 mg/mL of Clobazam prepared as follows. Transfer a suitable amount of Clobazam to an appropriate volumetric flask and dissolve in 60% of the flask volume of [acetonitrile](#). Dilute with [water](#) to volume.
Sample solution: 0.125 mg/mL of Clobazam from the *Sample stock solution* in *Diluent*

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 230 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)**Autosampler temperature:** 20°**Flow rate:** 1 mL/min**Injection volume:** 5 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** 0.8–1.5**Relative standard deviation:** NMT 1.10%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of clobazam ($C_{16}H_{13}ClN_2O_2$) in the portion of Clobazam taken:

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

 r_U = peak response of clobazam from the *Sample solution* r_S = peak response of clobazam from the *Standard solution* C_S = concentration of [USP Clobazam RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Clobazam in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–103.0% on the dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%• **ORGANIC IMPURITIES****Solution A, Solution B, Solution C, Diluent, and Chromatographic system:** Proceed as directed in the Assay.**Mobile phase:** See [Table 2](#).**Table 2**

Time (min)	Solution B (%)	Solution C (%)
0	100	0
25	0	100
35	0	100
35.1	100	0
42	100	0

Sensitivity solution: 0.25 μg/mL of [USP Clobazam RS](#) in *Diluent***Standard stock solution:** 50 μg/mL each of [USP Clobazam RS](#), [USP Clobazam Related Compound A RS](#), [USP Clobazam Related Compound E RS](#), and [USP Clobazam Related Compound G RS](#) in [acetonitrile](#)**Standard solution:** 0.5 μg/mL each of [USP Clobazam RS](#), [USP Clobazam Related Compound A RS](#), [USP Clobazam Related Compound E RS](#), and [USP Clobazam Related Compound G RS](#) from the *Standard stock solution* in *Diluent***Sample solution:** 500 μg/mL of Clobazam prepared as follows. Transfer a suitable amount of Clobazam to an appropriate volumetric flask and dissolve in 60% of the flask volume of [acetonitrile](#). Dilute with [water](#) to volume.**System suitability**