

**BRIEFING**

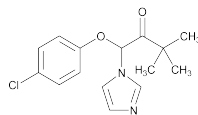
**Climbazole.** This monograph was posted on the USP Web page as a draft USP Pending Monograph, and has been available for public comment for more than 90 days. No comments were received. The SM3 Expert Committee has approved the monograph as an Authorized USP Pending Monograph. The liquid chromatographic procedures used in the *Assay* and in the test for *Organic Impurities* are based on analyses performed with the LiChrospher 60 RP-8 Select B brand of L7 column. The typical retention time for climbazole is about 17 min.

**Description and Solubility:** White to pale brownish, crystalline powder. Very soluble in benzyl alcohol and in phenoxyethanol; insoluble in water.

(SM3: F. Mao.)  
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**Climbazole**

v.1 Authorized November 1, 2011



C<sub>15</sub>H<sub>17</sub>ClN<sub>2</sub>O<sub>2</sub> 292.76  
1-(*p*-Chlorophenoxy)-1-imidazol-1-yl-3,3-dimethyl-2-butanone.  
[38083-17-9].

**DEFINITION**

Climbazole contains NLT 98.0% and NMT 102.0% of C<sub>15</sub>H<sub>17</sub>ClN<sub>2</sub>O<sub>2</sub>, calculated on the dried basis.

**IDENTIFICATION**

- **A. INFRARED ABSORPTION** (197K)
- **B. ULTRAVIOLET ABSORPTION** (197U)  
Sample solution: 1 mg/mL in alcohol  
Acceptance criteria: Meets the requirements

**ASSAY**

- **PROCEDURE**  
Solution A: 1.56 g/L of monobasic sodium phosphate anhydrous in a mixture of acetonitrile and water (20:80)  
Solution B: Acetonitrile and water (90:10)  
Mobile phase: See Table 1.

**Table 1**

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	60	40
26	0	100
30	0	100
35	100	0

**Standard solution:** 8 mg/mL of USP Climbazole RS in methanol  
**Sample solution:** 8 mg/mL of Climbazole in methanol  
**Chromatographic system**  
(See *Chromatography* (621), *System Suitability*.)

**Mode:** LC  
**Detector:** UV 280 nm  
**Column:** 4.0-mm × 25-cm; 5-μm packing L7  
**Column temperature:** 40°  
**Flow rate:** 1.8 mL/min  
**Injection size:** 2 μL

**System suitability**

**Sample:** Standard solution

**Suitability requirements**

**Relative standard deviation:** NMT 1.0%

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of climbazole (C<sub>15</sub>H<sub>17</sub>ClN<sub>2</sub>O<sub>2</sub>) in the portion of Climbazole taken:

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

- r<sub>U</sub> = peak response from the Sample solution
- r<sub>S</sub> = peak response from the Standard solution
- C<sub>S</sub> = concentration of USP Climbazole RS in the Standard solution (mg/mL)
- C<sub>U</sub> = concentration of Climbazole in the Sample solution (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the dried basis

**IMPURITIES**

- **RESIDUE ON IGNITION** (281): NMT 0.20%
- **HEAVY METALS, Method II** (231): NMT 10 ppm
- **ORGANIC IMPURITIES**

**Mobile phase and Sample solution:** Prepare as directed in the Assay.

**Standard solution:** 1.6 mg/mL of USP Climbazole RS in methanol

**Chromatographic system**

(See *Chromatography* (621), *System Suitability*.)

**Mode:** LC

**Detector:** UV 220 nm

**Column:** 4.0-mm × 25-cm; 5-μm packing L7

**Column temperature:** 40°

**Flow rate:** 1.8 mL/min

**Injection size:** 10 μL

**System suitability**

**Sample:** Standard solution

**Suitability requirements**

**Relative standard deviation:** NMT 2.0%

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of each impurity in the portion of Climbazole taken:

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

- r<sub>U</sub> = peak response of each impurity from the Sample solution
- r<sub>S</sub> = peak response of climbazole from the Standard solution
- C<sub>S</sub> = concentration of climbazole in the Standard solution (mg/mL)
- C<sub>U</sub> = concentration of Climbazole in the Sample solution (mg/mL)

**Acceptance criteria:** See Table 2.

**Table 2**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
4-Chlorophenol	0.44	0.015
Climbazole	1.0	—
Any unspecified impurity	—	0.10
Total impurities	—	0.2

**SPECIFIC TESTS**

- **LOSS ON DRYING** (731): Dry a sample at 50° at a pressure not exceeding 10 mm of mercury to constant weight: it loses NMT 0.25% of its weight.

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### **ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in well-closed containers at room temperature.
- **USP REFERENCE STANDARDS** <11>  
USP Climbazole RS