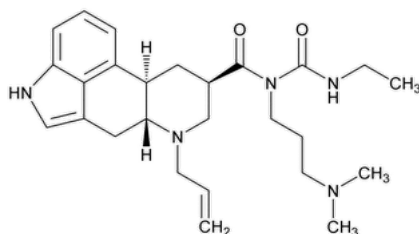


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2022
 Document Type: USP Monographs
 DocId: GUID-303485E4-6626-41EE-9517-311BFB886E09_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M11140_05_01
 DOI Ref: o7muq

© 2025 USPC
 Do not distribute

Cabergoline



$C_{26}H_{37}N_5O_2$ 451.60

Ergoline-8 β -carboxamide, *N*-[3-(dimethylamino)propyl]-*N*-[(ethylamino)carbonyl]-6-(2-propenyl)-;

1-[(6-Allylergolin-8 β -yl)carbonyl]-1-[3-(dimethylamino)propyl]-3-ethylurea CAS RN[®]: 81409-90-7; UNII: LL60K9J05T.

DEFINITION

Cabergoline contains NLT 98.0% and NMT 102.0% of cabergoline ($C_{26}H_{37}N_5O_2$), calculated on the anhydrous basis for the crystalline form and on the anhydrous and solvent-free basis for the amorphous form.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**

Change to read:

- **B.**

Proceed as directed for *Procedure 1* or *Procedure 2*. The criteria for *Procedure 1* or *Procedure 2* must be met.

Procedure 1: [Crystallinity \(695\)](#).

Acceptance criteria

For the crystalline form: Meets the requirements

For the amorphous form: Does not meet the requirements

Procedure 2: ▲ [X-Ray Powder Diffraction \(941\)](#) ▲ (CN 1-May-2022)

Acceptance criteria

For the crystalline form: A diffraction pattern is present.

For the amorphous form: No diffraction pattern is present.

- **C.** 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

Prepare solutions immediately before use, and protect from light.

Buffer: Dissolve 6.8 g of monobasic potassium phosphate in 900 mL of water, adjust with phosphoric acid to a pH of 2.0, and dilute to 1 L.

Add 0.2 mL of triethylamine to the resulting solution and mix.

Mobile phase: Acetonitrile and *Buffer* (4:21)

Standard solution: 0.25 mg/mL of [USP Cabergoline RS](#) in *Mobile phase*. Sonicate if needed.

Sample solution: 0.25 mg/mL of Cabergoline in *Mobile phase*. Sonicate if needed.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.0-mm × 25-cm; 10- μ m packing L1

Flow rate: 1.3 mL/min

Injection volume: 100 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0% for five replicate injections

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of cabergoline ($C_{26}H_{37}N_5O_2$) in the portion of Cabergoline taken:

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

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of [USP Cabergoline RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Cabergoline in the *Sample solution* (mg/mL)**Acceptance criteria****For the crystalline form:** 98.0%–102.0% on the anhydrous basis**For the amorphous form:** 98.0%–102.0% on the anhydrous and solvent-free basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%• **ORGANIC IMPURITIES**

Prepare solutions immediately before use, and protect from light.

Buffer and **Mobile phase:** Proceed as directed in the Assay.**System suitability solution:** To 10 mL of 0.1 M sodium hydroxide add 50 mg of Cabergoline and stir for about 15 min. To 1 mL of the suspension add 1 mL of 0.1 M hydrochloric acid, and dilute with *Mobile phase* to 10.0 mL. Sonicate until dissolution is complete. [NOTE—The main degradation product obtained is cabergoline related compound A.]**Sample solution:** 0.25 mg/mL of Cabergoline in *Mobile phase*. Sonicate if needed.**Chromatographic system**(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 280 nm**Column:** 4.0-mm × 25-cm; 10-μm packing L1**Flow rate:** 1.3 mL/min**Injection volume:** 100 μL**System suitability****Sample:** *System suitability solution*[NOTE—See [Table 1](#) for relative retention times.]**Suitability requirements****Resolution:** NLT 3.0 between cabergoline and cabergoline related compound A**Analysis****Sample:** *Sample solution*

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

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

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

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Cabergoline related compound D ^a	0.3	0.1
Cabergoline related compound B ^b	0.6	0.1
Cabergoline related compound A ^c	0.8	0.3
Cabergoline	1.0	