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Cabergoline Tablets

DEFINITION
Cabergoline Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cabergoline ($C_{26}H_{37}N_5O_2$).

IDENTIFICATION
• **A.** The retention time of the major peak of the *Identification sample solution* corresponds to that of the *Identification standard solution*, as obtained in the *Assay*.
• **B.** The UV-Vis spectrum of the major peak of the *Identification sample solution* corresponds to that of the *Identification standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**
Prepare solutions immediately before use, and protect from light.

Buffer: Transfer 6.8 g of monobasic potassium phosphate to a 1-L volumetric flask. Dissolve the contents in 900 mL of water. Adjust with phosphoric acid to a pH of 2.0. Dilute with water to volume, and add 0.2 mL of triethylamine.

Mobile phase: Acetonitrile and *Buffer* (16:84)

Standard solution: 0.25 mg/mL of USP Cabergoline RS in *Mobile phase*. Sonication may be used to aid in the dissolution of cabergoline.

Identification standard solution: 0.1 mg/mL of USP Cabergoline RS from the *Standard solution* in *Mobile phase*. [Note—This solution is used for *Identification A* and *Identification B*.]

Sample solution: Nominally 0.25 mg/mL of cabergoline from finely powdered Tablets in solution prepared as follows. Finely powder NLT 20 Tablets, and transfer a suitable portion of this fine powder to an appropriate volumetric flask. Dilute with *Mobile phase* to volume, and sonicate until completely dissolved. The resulting solution may be passed through a PVDF-type filter of 0.45-µm pore size before analysis.

Identification sample solution: Nominally 0.1 mg/mL of cabergoline from the *Sample solution* in *Mobile phase*. [Note—This solution is used for *Identification A* and *Identification B*.]

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

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

Flow rate: 1.3 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution*, *Identification standard solution*, *Sample solution*, and *Identification sample solution*

Calculate the percentage of the labeled amount of cabergoline ($C_{26}H_{37}N_5O_2$) in the portion of Tablets 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 = nominal concentration of cabergoline in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 500 mL, degassed with helium

Apparatus 2: 50 rpm

Time: 15 min

Buffer, Mobile phase, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.001 mg/mL of USP Cabergoline RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter, discarding the first few mL.

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3000 theoretical plates

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cabergoline ($C_{26}H_{37}N_5O_2$) dissolved:

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

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)

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of cabergoline ($C_{26}H_{37}N_5O_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Prepare solutions immediately before use, and protect from light.

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

System suitability solution: To 10 mL of 0.1 N sodium hydroxide, add 50 mg of cabergoline. Stir for 15 min. To 1 mL of the suspension, add 1 mL of 0.1 N hydrochloric acid, and dilute with *Mobile phase* to 10 mL. Sonicate until dissolution is complete. The main degradation product obtained is cabergoline acid.

Chromatographic system: Proceed as directed in the *Assay*, except for the *Injection volume*.

Injection volume

System suitability solution: 20 µL

Sample solution: 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 acid

Analysis

Sample: *Sample solution*

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

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

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of peak responses of all impurities and cabergoline from the *Sample solution*

Calculate the percentage of total impurities in the portion of Tablets taken:

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

r_U = sum of peak responses of all impurities from the *Sample solution*

r_T = sum of peak responses of all impurities and cabergoline from the *Sample solution*

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Cabergoline acid[a]	0.8	2.0
Cabergoline	1.0	—
Cabergoline *N*-oxide[b]	1.4	1.0
Any unspecified degradation product	—	0.5
Total impurities	—	2.5

[a] (6a*R*,9*R*,10a*R*)-7-Allyl-4,6,6a,7,8,9,10,10a-octahydroindolo[4,3-*fg*]quinoline-9-carboxylic acid.

[b] (6a*R*,9*R*,10a*R*)-7-Allyl-*N*-(3-(dimethylazinoyl)propyl)-*N*-(ethylcarbamoyl)-4,6,6a,7,8,9,10,10a-octahydroindolo[4,3-*fg*]quinoline-9-carboxamide.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in light-resistant, tight containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Cabergoline RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CABERGOLINE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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