

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Aug-2017
 Document Type: USP Monographs
 DocId: GUID-3A1729C6-9E3C-4DFC-980E-511EEB0B3D89_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M11145_04_01
 DOI Ref: ya9wq

© 2025 USPC
 Do not distribute

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 μ L

Sample solution: 100 μ L

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*