

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-C69CAD6C-0CD7-47AE-BC69-BAB8EC0A78F9_3_en-US
DOI: https://doi.org/10.31003/USPNF_M2413_03_01
DOI Ref: o38af

© 2025 USPC
Do not distribute

Articaine Hydrochloride and Epinephrine Injection

DEFINITION

Articaine Hydrochloride and Epinephrine Injection is a sterile solution of Articaine Hydrochloride and Epinephrine, in Water for Injection, and contains NLT 95.0% and NMT 105.0% of the labeled amount of articaine hydrochloride ($C_{13}H_{20}N_2O_3S \cdot HCl$) and NLT 90.0% and NMT 115.0% of the labeled amount of epinephrine ($C_9H_{13}NO_3$).

IDENTIFICATION

• **A.** The retention times of the articaine and epinephrine peaks from the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assays for *Articaine Hydrochloride* and *Epinephrine*, respectively.

ASSAY

• ARTICAINES HYDROCHLORIDE

Buffer: Glacial acetic acid and water (50:930). Adjust with 2 N sodium hydroxide to a pH of 3.4.

Mobile phase: Acetonitrile and *Buffer* (22:78)

Standard stock solution: 40 mg/mL of [USP Articaine Hydrochloride RS](#) in water

Standard solution: 0.8 mg/mL of [USP Articaine Hydrochloride RS](#) in *Mobile phase* from *Standard stock solution*

Sample solution: Equivalent to 0.8 mg/mL of articaine hydrochloride in *Mobile phase* from a portion of Injection

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Flow rate: 1 mL/min

Injection size: 10 μL

Run time: 2.5 times the retention time of articaine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.2

Relative standard deviation: NMT 1.0%, from six injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of articaine hydrochloride ($C_{13}H_{20}N_2O_3S \cdot HCl$) in the portion of Injection 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 Articaine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of articaine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

• EPINEPHRINE

Mobile phase: Mix 50 mL of glacial acetic acid and 930 mL of water. Adjust with 2 N sodium hydroxide to a pH of 3.4. In this solution, dissolve 1.2 g of sodium 1-heptanesulfonate, and add 1.0 mL of 0.1 M edetate disodium and 0.298 g of potassium chloride. Add 150 mL of methanol.

Diluent: 0.5 mg/mL potassium metabisulfite in water

System suitability solution: 22 μg/mL of epinephrine from [USP Epinephrine Bitartrate RS](#) and 20 μg/mL of norepinephrine from [USP Norepinephrine Bitartrate RS](#) in *Diluent*

Standard stock solution: 0.55 mg/mL of epinephrine from [USP Epinephrine Bitartrate RS](#) in *Diluent*

Standard solution: Dilute a suitable volume of the *Standard stock solution* with *Diluent* to obtain a final concentration of L mg/mL of epinephrine, where L is the label claim of epinephrine in the Injection.

Sample solution: Use the Injection directly.

Chromatographic system

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

Mode: LC

Detector: Amperometric electrochemical

Reference electrode: Silver/silver chloride

Working electrode: Glassy carbon

Potential: +650 mV

Detector temperature: $28 \pm 2^\circ$

Column: 4.0-mm $\times$ 25-cm; 5- μ m packing L7

Flow rate: 1 mL/min

Injection size: 2 μ L

Run time: 1.7 times the retention time of epinephrine

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for norepinephrine and epinephrine are 0.90 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the norepinephrine and epinephrine peaks

Tailing factor: NMT 2.0 for the epinephrine peak

Relative standard deviation: NMT 1.0% for the epinephrine peak, from six injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of epinephrine ($C_9H_{13}NO_3$) in the portion of Injection 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 epinephrine in the *Standard solution* (mg/mL)

C_U = nominal concentration of epinephrine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• [DELIVERABLE VOLUME \(698\)](#)

For Articaïne Hydrochloride and Epinephrine Injection packaged in single-dose containers: Meets the requirements

IMPURITIES

• ORGANIC IMPURITIES, LIMIT OF ARTICAÏNE RELATED COMPOUNDS

Mobile phase, Standard stock solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay for Articaïne Hydrochloride.

Standard solution: 0.8 mg/mL of [USP Articaïne Hydrochloride RS](#) from *Standard stock solution* and 40 μ g/mL of [USP Articaïne Related Compound B RS](#) in *Mobile phase*

System suitability

Sample: *Standard solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Tailing factor: NMT 2.2 for the articaïne peak

Resolution: NLT 1.25 between the articaïne related compound B and articaïne peaks

Relative standard deviation: NMT 1.0% for the articaïne peak

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—Articaïne related compounds elute at relative retention times of NMT 2.0 with respect to the articaïne peak.]

Calculate the percentage of articaïne related compounds and any other individual impurity in the portion of Injection taken:

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

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