Interim Revision Announcement
Official: March 1, 2021

Triamcinolone Acetonide Nasal Spray

DEFINITION

Triamcinolone Acetonide Nasal Spray is an aqueous suspension of Triamcinolone Acetonide. It is supplied in a form suitable for nasal administration. It contains NLT 90.0% and NMT 110.0% of the labeled amount of triamcinolone acetonide ($C_{24}H_{31}FO_6$).

IDENTIFICATION

● **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

● **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

● **Procedure**

Buffer A: 3.4 g/L of monobasic potassium phosphate prepared as follows. Dissolve 3.4 g of monobasic potassium phosphate in 900 mL of water, adjust with 5 M sodium hydroxide to a pH of 7.0, and dilute with water to 1000 mL.

Buffer B: 3.4 g/L of monobasic potassium phosphate prepared as follows. Dissolve 3.4 g of monobasic potassium phosphate in 900 mL of water, adjust with phosphoric acid to a pH of 3.0, and dilute with water to 1000 mL.

Solution A: Acetonitrile and *Buffer A* (27.5: 72.5)

Solution B: Acetonitrile and *Buffer A* (60:40)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
30	60	40
30.1	0	100
44	0	100
44.1	100	0
52	100	0

Diluent: Acetonitrile and *Buffer B* (27.5: 72.5)

Standard stock solution: 0.4 mg/mL of USP Triamcinolone Acetonide RS in acetonitrile. Sonication for 15 min may be used to aid in dissolution.

Standard solution: 40 µg/mL of USP Triamcinolone Acetonide RS from *Standard stock solution* in *Diluent*

System suitability stock solution: 0.04 mg/mL of USP Triamcinolone Acetonide Related Compound B RS and USP Triamcinolone Acetonide Related Compound C RS in *Diluent*

System suitability solution: 40 µg/mL of USP Triamcinolone Acetonide RS and 0.8 µg/mL each of USP Triamcinolone Acetonide Related Compound B RS and USP Triamcinolone Acetonide Related Compound C

Tier 1 criteria 1–3 must be met. If criterion 4 or 5 cannot be met, proceed to *Tier 2*.

Tier 2: If NMT 3 unit delivery means are outside 80.0%–120.0% of the labeled amount of triamcinolone acetonide ($C_{24}H_{31}FO_6$) and none of the unit delivery means is outside 75.0%–125.0% of the labeled amount of triamcinolone acetonide ($C_{24}H_{31}FO_6$), test an additional 20 units. All 30 unit delivery means (including the results from *Tier 1*) meet the following acceptance criteria.

1. NMT 3 of 30 unit delivery means are outside 80.0%–120.0% of the labeled amount of triamcinolone acetonide ($C_{24}H_{31}FO_6$).
2. None of the 30 unit delivery means is outside 75.0%–125.0% of the labeled amount of triamcinolone acetonide ($C_{24}H_{31}FO_6$).

IMPURITIES

- **Organic Impurities**

Buffer A, Buffer B, Solution A, Solution B, Mobile phase, Diluent, Standard solution, System suitability solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each degradation product in the portion of Nasal Spray taken:

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

r_I = peak response of each degradation product from the *Sample solution*

r_U = peak response of triamcinolone acetonide from the *Sample solution*

Acceptance criteria: See *Table 4*. Disregard any peak below 0.05%.

Table 4

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Triamcinolone acetonide ketoacid derivative[a]	0.4	0.3
Triamcinolone acetonide related compound C	0.83	2.8
Triamcinolone acetonide related compound B	0.91	0.4
Triamcinolone acetonide	1.0	—
Any other individual degradation product	—	0.1
Total degradation products	—	3.4

[a] 9-Fluoro-11-hydroxy-16,17-[(1-methylethylidene)bis(oxy)]-(11β,16α)-3,20-dioxopregna-1,4-diene-21-oic acid.

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 4.5–6.0
- **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** It meets the requirements of the tests for absence of *Staphylococcus aureus*, *Escherichia coli*, *Salmonella* species, and