Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2015
Document Type: USP Monographs
DocId: GUID-F59D2D4E-8D78-476D-92BC-E43FD486F216_3_en-US
DOI: https://doi.org/10.31003/USPNF_M59165_03_01
DOI Ref: l3op2

Oxaprozin Tablets

DEFINITION
Oxaprozin Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of oxaprozin ($C_{18}H_{15}NO_3$).

[Note—Because of light sensitivity, protect all oxaprozin samples and standard solutions from light.]

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Sample solution: 2 mg/mL of oxaprozin in acetone

Developing solvent system: Ethyl acetate and glacial acetic acid (99:1)

Acceptance criteria: Meet the requirements

• **B.** 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**

Solution A: 0.1% Phosphoric acid. Add phosphoric acid, dropwise, to water to obtain a pH of 2.00 ± 0.10.

Mobile phase: Acetonitrile and *Solution A* (45:55)

Standard solution: Dissolve an accurately weighed quantity of USP Oxaprozin RS in acetonitrile to obtain a solution having a concentration of about 12 µg/mL of oxaprozin.

Sample stock solution: Nominally 0.6 mg/mL of oxaprozin prepared as follows. Transfer a suitable amount of oxaprozin from NLT 20 powdered Tablets to an appropriate volumetric flask. Add water to 10% of the final volume, and sonicate for 10 min. Add 40% of the final volume of acetonitrile, and sonicate for 30 min. Shake by mechanical means for an additional 30 min. Add 30% of the final volume of acetonitrile, and sonicate for 10 min. Dilute with acetonitrile to volume. Pass through a suitable filter. Use the filtrate.

Sample solution: Nominally equivalent to 12 µg/mL of oxaprozin from the *Sample stock solution* in acetonitrile

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxaprozin ($C_{18}H_{15}NO_3$) 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 Oxaprozin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.05 M monobasic potassium phosphate buffer, pH 7.4; 1000 mL

Apparatus 2: 75 rpm

Time: 45 min

Detector: UV 286 nm (maximum absorbance)

Standard solution: A known concentration of USP Oxaprozin RS in *Medium*. [Note—A quantity of methanol, not exceeding 5% of the final volume, can be added to help solubilize the USP Reference Standard.]

Sample solution: Filter portions of the solution under test, suitably diluted with *Medium*, if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxaprozin ($C_{18}H_{15}NO_3$) dissolved by using UV absorption from the *Sample solution* in comparison with the *Standard solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of oxaprozin ($C_{18}H_{15}NO_3$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Solution A and **Mobile phase:** Proceed as directed in the *Assay*.

Standard solution: 0.001 mg/mL of USP Oxaprozin RS in acetonitrile

Sample solution: Nominally 1 mg/mL of oxaprozin prepared as follows. Transfer a suitable amount of oxaprozin from NLT 20 powdered Tablets to an appropriate volumetric flask. Add water to 10% of the final volume, and sonicate for 10 min. Add 40% of the final volume of acetonitrile, and sonicate for 30 min. Shake by mechanical means for an additional 30 min. Add 30% of the final volume of acetonitrile, and sonicate for 10 min. Dilute with acetonitrile to volume. Pass through a suitable filter. Use the filtrate.

Chromatographic system: Proceed as directed in the *Assay* except use a column temperature of 20°.

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of benzoin, benzil, and each individual unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of benzoin, benzil, or each individual unspecified degradation product from the *Sample solution*

r_S = peak response of oxaprozin from the *Standard solution*

C_S = concentration of USP Oxaprozin RS in the *Standard solution* (mg/mL)

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

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Benzoin[a]	0.6	0.12	0.2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Oxaprozin	1.0	—	—
Benzil	1.9	0.62	0.2
Any individual unspecified degradation product	—	1.0	0.2

[a] 2-Hydroxy-1,2-diphenylethan-1-one.

SPECIFIC TESTS

• **Water Determination,** *Method Ia*⟨921⟩**:** NMT 3.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Oxaprozin RS

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

Topic/Question	Contact	Expert Committee
OXAPROZIN TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(1)

Current DocID: GUID-F59D2D4E-8D78-476D-92BC-E43FD486F216_3_en-US
Previous DocID: GUID-F59D2D4E-8D78-476D-92BC-E43FD486F216_1_en-US
DOI: https://doi.org/10.31003/USPNF_M59165_03_01
DOI ref: l3op2