

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-77933A89-0FF6-40D3-92F9-B0C55C32DA93_3_en-US
DOI: https://doi.org/10.31003/USPNF_M38590_03_01
DOI Ref: 111n9

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Hydrogen Peroxide Topical Solution

H₂O₂ 34.01

Hydrogen peroxide CAS RN®: 7722-84-1.

DEFINITION

Hydrogen Peroxide Topical Solution contains, in each 100 mL, NLT 2.5 g and NMT 3.5 g of hydrogen peroxide (H₂O₂). It contains NMT 0.05% of a suitable preservative or preservatives.

IDENTIFICATION

• A.

Sample: 1 mL

Analysis: Shake the *Sample* with 10 mL of water containing 1 drop of 2 N sulfuric acid, and add 2 mL of ether. Subsequently add a drop of potassium dichromate TS.

Acceptance criteria: The addition of potassium dichromate TS produces an evanescent blue color in the water layer, which upon agitation and standing passes into the ether layer.

ASSAY

• PROCEDURE

Sample: 2 mL

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N potassium permanganate VS

Endpoint detection: Visual

Analysis: Pipet the *Sample* into a suitable flask containing 20 mL of water. Add 20 mL of 2 N sulfuric acid, and titrate with *Titrant*. Each mL of 0.1 N potassium permanganate is equivalent to 1.701 mg of hydrogen peroxide (H₂O₂).

Acceptance criteria: 2.5–3.5 g in 100 mL

IMPURITIES

• BARIUM

Sample: 10 mL

Analysis: To the *Sample* add two drops of 2 N sulfuric acid.

Acceptance criteria: No turbidity or precipitate is produced within 10 min.

• LIMIT OF NONVOLATILE RESIDUE

Sample: 20 mL, previously shaken

Analysis: Evaporate the *Sample* on a steam bath to dryness, and dry the residue at 105° for 1 h.

Acceptance criteria: NMT 30 mg of the residue

SPECIFIC TESTS

• ACIDITY

Sample: 25 mL

Analysis: To the *Sample* add phenolphthalein TS, and titrate with 0.10 N sodium hydroxide.

Acceptance criteria: NMT 2.5 mL is required for neutralization.

• LIMIT OF PRESERVATIVE

Sample: 100 mL, well mixed

Diluent: Chloroform and ether (3:2)

Analysis: Extract the *Sample* in a separator with *Diluent*, using 50, 25, and 25 mL, respectively. Evaporate the combined extracts at room temperature in a tared glass dish to dryness, and dry over silica gel for 2 h.

Acceptance criteria: 0.05%; the residue, if any, weighs NMT 50 mg.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, at controlled room temperature.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
HYDROGEN PEROXIDE TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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Current DocID: GUID-77933A89-0FF6-40D3-92F9-B0C55C32DA93_3_en-US

Previous DocID: GUID-77933A89-0FF6-40D3-92F9-B0C55C32DA93_1_en-US

DOI: https://doi.org/10.31003/USPNF_M38590_03_01

DOI ref: [111n9](#)

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