

Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-518D7BA9-31BC-430D-A3D2-B1ECF28E02FB_1_en-US
DOI: https://doi.org/10.31003/USPNF_M34950_01_01
DOI Ref: 6c0kk

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Gentian Violet Topical Solution

DEFINITION

Gentian Violet Topical Solution contains, in each 100 mL, NLT 0.95 g and NMT 1.05 g of gentian violet ($C_{25}H_{30}ClN_3$).

IDENTIFICATION

- A.**
Sample solution: 1 in 5 dilution in water
Analysis: Add 5 drops of hydrochloric acid. To 5 mL of this solution add tannic acid TS dropwise.
Acceptance criteria: A deep blue precipitate is formed.
- B.**
Sample solution: 1 in 5 dilution in water
Analysis: To the remaining solution from *Identification* test A add 500 mg of zinc dust, and warm the mixture.
Acceptance criteria: Rapid decolorization occurs. Place a drop of the decolorized solution adjacent to a drop of 6 N ammonium hydroxide on a filter paper. A blue color is produced at the zone of contact.

ASSAY

- PROCEDURE**
Sample solution: Pipet 25 mL of Topical Solution into a 300-mL conical flask, add 25 mL of water and 10 mL of hydrochloric acid, displace the air in the flask with carbon dioxide, and pass a stream of carbon dioxide through the flask. Add 50.0 mL of 0.1 N titanium trichloride VS, heat to boiling, and boil gently for 10 min, swirling the liquid occasionally. Cool the solution, and add 5 mL of ammonium thiocyanate solution (1 in 10).
Analysis: Titrate with 0.1 N ferric ammonium sulfate VS until a faint red color is produced. Perform a blank determination. Each mL of 0.1 N titanium trichloride is equivalent to 20.40 mg of gentian violet ($C_{25}H_{30}ClN_3$).
Acceptance criteria: It contains, in each 100 mL, 0.95–1.05 g of gentian violet ($C_{25}H_{30}ClN_3$).

SPECIFIC TESTS

- SOLUTION OF RESIDUE IN ALCOHOL**
Sample: 10 mL
Analysis: Evaporate the *Sample* on a steam bath to dryness.
Acceptance criteria: The residue dissolves completely in 10 mL of alcohol.
- ALCOHOL DETERMINATION (611):** 8.0%–10.0%

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Preserve in tight containers.

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

Topic/Question	Contact	Expert Committee
GENTIAN VIOLET TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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