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Compound Clioquinol Topical Powder

DEFINITION

Compound Clioquinol Topical Powder contains NLT 22.5% and NMT 27.5% of clioquinol (C_oH₅ClINO).

Clioquinol	250 g
Lactic Acid	25 g
Zinc Stearate	200 g
Lactose	525 g
To make	1000 g

Mix the Lactic Acid with Lactose. Then add Clioquinol and Zinc Stearate to the mixture, and mix.

IDENTIFICATION

• A.

Sample: A quantity of Topical Powder equivalent to 30 mg of clioquinol

Analysis: Place the *Sample* in a glass-stoppered, 50-mL conical flask, add 20 mL of 1 N sulfuric acid, and shake for 5 min. Filter, and transfer 5 mL of the filtrate to a glass-stoppered test tube. Add 5 drops of potassium dichromate TS and 2 mL of chloroform, and shake well.

Acceptance criteria: A red-violet color develops in the chloroform layer.

ASSAY

Procedure

Standard solution: 5 µg/mL of USP Clioquinol RS in 3 N hydrochloric acid

Sample solution: Transfer a quantity of Topical Powder equivalent to 50 mg of clioquinol to a 200-mL volumetric flask. Add 100 mL of 3 N hydrochloric acid, and shake by mechanical means for 15 min. Dilute with 3 N hydrochloric acid to volume. Filter a portion of the solution. Dilute 4.0 mL of the filtrate with 3 N hydrochloric acid to 200.0 mL, and mix.

Blank: 3 N hydrochloric acid **Instrumental conditions**

Mode: UV

Analytical wavelength: 267 nm

Cell: 1 cm Analysis

Samples: Standard solution and Sample solution

Determine the absorbances of the *Standard solution* and the *Sample solution* at the wavelength of maximum absorbance. Calculate the percentage of clioquinol (C_0H_E CIINO) in the portion of Topical Powder taken:

Result =
$$(A_U/A_S) \times (C_S/C_U) \times 100$$

 A_{ii} = absorbance of the Sample solution

 A_s = absorbance of the Standard solution

C_s = concentration of clioquinol in the Standard solution (µg/mL)

 $C_{\mu\nu}$ = nominal concentration of clioquinol in the Sample solution (µg/mL)

Acceptance criteria: 22.5%-27.5%

ADDITIONAL REQUIREMENTS

• Packaging and Storage: Package in well-closed, light-resistant containers.

• USP Reference Standards (11)

USP Clioquinol RS

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

Topic/Question	Contact	Expert Committee
COMPOUND CLIOQUINOL TOPICAL POWDER	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: <u>Chromatographic Database</u>

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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