Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-4754D852-CB98-4047-B9D8-6A7355B2DDA4_2_en-US
DOI: https://doi.org/10.31003/USPNF_M36950_02_01
DOI Ref: o7fay

Hexachlorophene Cleansing Emulsion

DEFINITION

Hexachlorophene Cleansing Emulsion is Hexachlorophene in a suitable aqueous vehicle. It contains NLT 90.0% and NMT 110.0% of the labeled amount of hexachlorophene ($C_{13}H_6Cl_6O_2$). It contains no coloring agents.

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Diluent: Chloroform and methanol (1:1)

Standard solution: 6 mg/mL of USP Hexachlorophene RS in *Diluent*

Sample solution: Place a volume of Cleansing Emulsion, equivalent to 150 mg of hexachlorophene, in a glass-stoppered, 25-mL graduated cylinder. Dilute with *Diluent* to volume, and allow to stand for 5 min.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin–Layer Chromatography*.)

Adsorbent: 0.25-mm layer of silica gel

Application volume: 10 µL

Developing solvent system: Toluene and glacial acetic acid (9:1)

Spray reagent: Dilute nitric acid (1 in 5)

Analysis: Develop in the *Developing solvent system* until the solvent front has moved 10 cm above the point of application. Remove the plate, mark the solvent front, and evaporate the solvent in a current of warm air. Spray the plate with *Spray reagent*, and warm on a hot plate until yellow spots appear.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Standard stock solution: 1 mg/mL of USP Hexachlorophene RS in methanol

Standard solution: 0.03 mg/mL of USP Hexachlorophene RS prepared as follows. Pipet 3 mL of *Standard stock solution* into a 100-mL volumetric flask. Add 1 mL of dilute hydrochloric acid (1 in 10), and add methanol to volume.

Sample stock solution: Nominally 0.3 mg/mL of hexachlorophene in methanol. Filter the solution through paper, taking adequate precautions to prevent evaporation.

Sample solution: 0.03 mg/mL of hexachlorophene prepared as follows. Pipet a 10-mL aliquot of the *Sample stock solution* into a 100-mL volumetric flask. Add 1 mL of dilute hydrochloric acid (1 in 10), and add methanol to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: UV 299 nm

Cell: 1 cm

Blank: Methanol and hydrochloric acid (99:1)

Analysis: Concomitantly determine the absorbances of the *Sample solution* and the *Standard solution*.

Calculate the percentage of the labeled amount of hexachlorophene ($C_{13}H_6Cl_6O_2$) in the portion of Cleansing Emulsion taken:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

• **pH ⟨791⟩**

Analysis: Place 20 mL of well-shaken Cleansing Emulsion and 10 mL of water in a glass-stoppered, 50-mL graduated cylinder, and determine the pH in a suitable pH meter, using a glass electrode and preferably a sleeve-type calomel electrode.

Acceptance criteria: 5.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant, nonmetallic containers.

• **USP Reference Standards ⟨11⟩**

USP Hexachlorophene RS

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

Topic/Question	Contact	Expert Committee
HEXACHLOROPHENE CLEANSING EMULSION	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

Current DocID: GUID-4754D852-CB98-4047-B9D8-6A7355B2DDA4_2_en-US
Previous DocID: GUID-4754D852-CB98-4047-B9D8-6A7355B2DDA4_1_en-US
DOI: https://doi.org/10.31003/USPNF_M36950_02_01
DOI ref: o7fay