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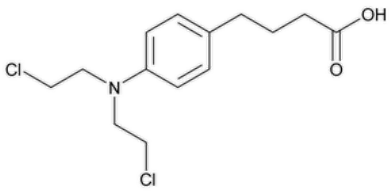
Chlorambucil



$C_{14}H_{19}Cl_2NO_2$ 304.21

Benzenebutanoic acid, 4-[bis(2-chloroethyl)amino]-;

4-[*p*-[Bis(2-chloroethyl)amino]phenyl]butyric acid CAS RN®: 305-03-3; UNII: 18D0SL7309.

DEFINITION

Chlorambucil contains NLT 98.0% and NMT 101.0% of chlorambucil ($C_{14}H_{19}Cl_2NO_2$), calculated on the anhydrous basis.

[**Caution—**Great care should be taken to prevent inhaling particles of Chlorambucil and exposing the skin to it.]

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197S**▲ (CN 1-May-2020)

Sample solution: 8 mg/mL in carbon disulfide

Cell: 1 mm

Acceptance criteria: Meets the requirements

• **B.**

Sample solution: Dissolve 50 mg of Chlorambucil in 5 mL of acetone, and dilute with water to 10 mL.

Analysis: To the *Sample solution* add 1 drop of 2 N sulfuric acid, then add 4 drops of silver nitrate TS.

Acceptance criteria: No opalescence is observed immediately (absence of chloride ion). Warm the solution on a steam bath: opalescence develops (presence of ionizable chlorine).

ASSAY

• **Procedure**

Sample: 200 mg of Chlorambucil

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 10 mL of acetone, add 10 mL of water, and titrate with *Titrant*, using phenolphthalein TS as the indicator. Each mL of 0.1 N sodium hydroxide is equivalent to 30.42 mg of chlorambucil ($C_{14}H_{19}Cl_2NO_2$).

Acceptance criteria: 98.0%–101.0% on the anhydrous basis

SPECIFIC TESTS

• **Melting Range or Temperature** ⟨741⟩**:** 65°–69°

• **Water Determination,** *Method I*⟨921⟩**:** NMT 0.5%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Chlorambucil RS

Topic/Question	Contact	Expert Committee
CHLORAMBUCIL	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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