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Busulfan Tablets

DEFINITION
Busulfan Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of busulfan ($C_6H_{14}O_6S_2$).

IDENTIFICATION

• **A.**

Sample: A suitable number of Tablets

Analysis: Pulverize the *Sample* and extract the powder with several portions of acetone. Evaporate the combined acetone extracts, with the aid of a current of air, on a steam bath.

Acceptance criteria: The dry residue melts at about 115°.

• **B.**

Sample: 100 mg of the powder obtained in *Identification* test *A*

Analysis: Fuse the *Sample* with 100 mg of potassium nitrate and a pellet of potassium hydroxide weighing 250 mg. Cool, dissolve the residue in water, acidify with 3 N hydrochloric acid, and add a few drops of barium chloride TS.

Acceptance criteria: A white precipitate is formed.

• **C.**

Sample: 100 mg of the powder obtained in *Identification* test *A*

Analysis: Add 10 mL of water and 5 mL of 1 N sodium hydroxide to the *Sample*. Heat until a clear solution is obtained.

Acceptance criteria: An odor characteristic of methanesulfonic acid is perceptible.

• **D.**

Sample solution: Use the solution from *Identification* test *C*.

Analysis: Cool the *Sample solution*, and divide it into two equal portions. To the first portion add 1 drop of potassium permanganate TS. Acidify the second portion of the solution with 2 N sulfuric acid, and add 1 drop of potassium permanganate TS.

Acceptance criteria

For first portion: The purple color changes to violet, then to blue, and finally to emerald-green.

For second portion: The color of the permanganate is not discharged.

ASSAY

• **Procedure**

Guard against accidental inhalation of the fine powder.

Sample solution: Transfer an equivalent to 80 mg of busulfan, from finely powdered Tablets (NLT 40), to a 100-mL beaker. Extract with four 20-mL portions of acetone, each time stirring the mixture well. Allow the insoluble matter to settle, and decant the supernatant through a sintered-glass filter into a 250-mL conical flask. Evaporate the combined acetone extracts to about 10 mL, add phenolphthalein TS, and neutralize with 0.05 N sodium hydroxide. Evaporate to dryness, and add about 30 mL of water. Connect the flask to a reflux air condenser, and boil the mixture gently for NLT 30 min, adding water occasionally to maintain the volume. Cool to room temperature.

Titrimetric system

Mode: Direct titration

Titrant: 0.05 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Add phenolphthalein TS to the *Sample solution*, and titrate with *Titrant*. Each mL of *Titrant* is equivalent to 6.158 mg of the labeled amount of busulfan ($C_6H_{14}O_6S_2$).

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Disintegration** ⟨701⟩

Time: 30 min, the use of disks being omitted

Acceptance criteria: Meet the requirements

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

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

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

Chromatographic Database Information: Chromatographic Database

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