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Boric Acid

H_3BO_3 61.83
 Boric acid (H_3BO_3) CAS RN®: 10043-35-3.

DEFINITION

Boric Acid contains NLT 99.5% and NMT 100.5% of boric acid (H_3BO_3), calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Borate:** Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Sample solution: Dissolve 2 g of Boric Acid in 100 mL of a mixture of [glycerin](#) and water (1:1), previously neutralized to [phenolphthalein TS](#).

▲ Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [1 N sodium hydroxide VS](#)

Endpoint detection: Visual ▲ (NF 1-May-2024)

Analysis: Titrate the *Sample solution* with ▲ *Titrant*. ▲ (NF 1-May-2024) Discharge the pink color by the addition of 50 mL of [glycerin](#). ▲ previously ▲ (NF 1-May-2024) neutralized to [phenolphthalein TS](#), and continue the titration until the pink color reappears.

▲ Calculate the percentage of boric acid (H_3BO_3) in the portion of Boric Acid taken:

$$\text{Result} = [(V_s \times N_A \times F) / W] \times 100$$

V_s = volume of *Titrant* consumed by the *Sample solution* (mL)

N_A = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 61.83 mg/mEq

W = weight of Boric Acid (mg)

▲ (NF 1-May-2024)

Acceptance criteria: 99.5%–100.5% on the dried basis

SPECIFIC TESTS

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry over [silica gel](#) for 5 h.

Acceptance criteria: NMT 0.5%

• SOLUBILITY IN ALCOHOL

Sample solution: 1 g in 10 mL of boiling [alcohol](#)

Acceptance criteria: It dissolves completely.

• COMPLETENESS OF SOLUTION

Sample solution: 1 g in 25 mL of water

Acceptance criteria: It produces a clear solution.

Add the following:

- ▲ **BACTERIAL ENDOTOXINS TEST (85):** If labeled for use in preparing injectable dosage forms, it also meets the following requirements. The level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Boric Acid is used can be met. Where the

label states that Boric Acid must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Boric Acid is used can be met.▲ (NF 1-May-2024)

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Change to read:

- **LABELING:** ▲Where Boric Acid is intended for use in the manufacture of injectable dosage forms, it is so labeled. Where Boric Acid must be subjected to further processing during the preparation of injectable dosage forms to ensure acceptable levels of bacterial endotoxins, it is so labeled.▲ (NF 1-May-2024)

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

Topic/Question	Contact	Expert Committee
BORIC ACID	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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