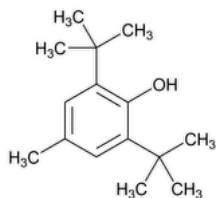


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: NF Monographs
 DocId: GUID-0CFFA0B2-4883-4F4D-8F0F-53D7DC4E0A20_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M11070_05_01
 DOI Ref: 66231

© 2025 USPC
 Do not distribute

Butylated Hydroxytoluene



$C_{15}H_{24}O$ 220.35

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-;
 2,6-Di-*tert*-butyl-*p*-cresol CAS RN®: 128-37-0.

DEFINITION

Butylated Hydroxytoluene contains NLT 99.0% and NMT 101.5% of butylated hydroxytoluene ($C_{15}H_{24}O$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Sample: Undried sample

Acceptance criteria: Meets the requirements

- **B.** The retention time of the butylated hydroxytoluene peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. The chromatographic profile of the *Sample solution* should exhibit only one major peak corresponding to the main compound.

ASSAY

PROCEDURE

Solution A: 5% acetic acid, prepared by diluting 50 mL of [glacial acetic acid](#) in a 1-L flask with [water](#) to volume

Mobile phase: [Acetonitrile](#) and *Solution A* (65:35)

Standard solution: 0.5 mg/mL of [USP Butylated Hydroxytoluene RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Butylated Hydroxytoluene in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 275 nm

Column: 3.0-mm × 15-cm; 3-μm packing [L1](#)

Column temperature: 40°

Flow rate: 0.75 mL/min

Injection volume: 10 μL

Run time: 15 min

System suitability

Sample: *Standard solution*

[NOTE—The retention time of butylated hydroxytoluene is about 10.8 min.]

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of butylated hydroxytoluene ($C_{15}H_{24}O$) in the portion of Butylated Hydroxytoluene taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of butylated hydroxytoluene from the *Sample solution*

r_S = peak area of butylated hydroxytoluene from the *Standard solution*

C_s = concentration of [USP Butylated Hydroxytoluene RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Butylated Hydroxytoluene in the *Sample solution* (mg/mL)

Acceptance criteria: 99.0%–101.5%

IMPURITIES

Change to read:

- [RESIDUE ON IGNITION \(281\)](#).

Sample: 50 g

Analysis: Transfer the *Sample* to a tared crucible, ▲heat gently at a temperature as low as practicable until the *Sample* is thoroughly charred,▲
(NF 1-May-2021) and cool. Moisten the ash with 1 mL of sulfuric acid, and complete the ignition by heating at $800 \pm 25^\circ$ for 15-min periods to constant weight.

Acceptance criteria: NMT 0.002%

• ORGANIC IMPURITIES

Mobile phase and Chromatographic system: Proceed as directed in the Assay, except extend the *Run time* to 20 min.

Standard solution: 2 µg/mL of [USP Butylated Hydroxytoluene RS](#) in *Mobile phase*

Sample solution: 2.0 mg/mL of Butylated Hydroxytoluene in *Mobile phase*

System suitability

Sample: *Standard solution*

[NOTE—The retention time of butylated hydroxytoluene is about 10.8 min.]

Suitability requirements

Signal-to-noise ratio: NLT 40

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the corrected peak area of each individual impurity in the *Sample solution*:

$$\text{Result} = r_u/F$$

r_u = peak area of the individual impurity from the *Sample solution*

F = relative response factor (see [Table 1](#))

Acceptance criteria

Individual impurity: NMT 0.1%; the corrected peak area of each impurity in the *Sample solution* is NMT the area of the principal peak in the *Standard solution*.

Total impurities: NMT 0.7%; the sum of all the corrected peak areas due to impurities in the *Sample solution*, excluding the butylated hydroxytoluene peak area, is NMT 7 times the butylated hydroxytoluene peak area in the *Standard solution*.

Table 1

Name	Relative Retention Time	Relative Response Factor
<i>p</i> -Cresol or <i>m</i> -cresol ^a	0.12	1.9
3- <i>tert</i> -Butyl-4-hydroxyanisole (BHA)	0.19	1.1
3,5-Di- <i>tert</i> -butyl-4-hydroxybenzoic acid	0.20	3.6
2- <i>tert</i> -Butyl-4-methylphenol or 2- <i>tert</i> -butyl-5-methylphenol ^b	0.27	1.7
3,5-Di- <i>tert</i> -butyl-4-hydroxy benzaldehyde	0.37	6.6
4,6-Di- <i>tert</i> -butyl- <i>m</i> -cresol	0.66	1.1
2,6-Di- <i>tert</i> -butyl-phenol	0.77	0.9
Any unspecified impurity	—	