# Butylated Hydroxytoluene

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

**Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.**



## Document History and Schedule for the Adoption Process

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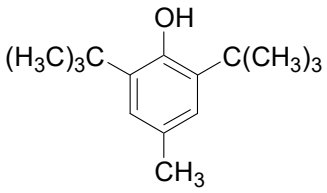
| Further follow-up action as required. | |

# **Butylated Hydroxytoluene**. Page 1698

Change **to:** **Butylated Hydroxytoluene**

BHT




$C_{15}H_{24}O$ Mol. Wt.220.4

Butylated Hydroxytoluene is Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl.

Butylated Hydroxytoluene contains not less than 99.0 per cent and not more than 101.5 per cent of $C_{15}H_{24}O$.

**Category.** Pharmaceutical aid (antioxidant).

**Description.** A white, crystalline powder.

## Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *butylated hydroxytoluene IPRS* or with the reference spectrum of butylated hydroxytoluene.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

## Tests

**Related substances.** Determine by liquid chromatography (2.4.14).

*Test solution.* Dissolve 0.2 g of the substance under examination in the mobile phase and dilute to 100.0 ml in the mobile phase.

*Reference solution.* A 0.0002 per cent w/v solution of *butylated hydroxytoluene IPRS* in the mobile phase.

Chromatographic system
- a stainless steel column15 cm x 3.0 mm, packed with octadecylsilane bonded to porous silica (3 µm) (Such as Luna C18),
- column temperature: 40°,
- mobile phase: a mixture of 65 volumes of *acetonitrile* and 35 volumes of a 5 per cent v/v solution of *glacial acetic acid* in *water*,
- flow rate: 0.75 ml per minute,
- spectrophotometer set at 275 nm,
- injection volume: 10 µl.

| Name | Relative retention time | Correction factor |
|---|---|---|
| p-Cresol or m-cresol* | 0.12 | 0.53 |
| 3-tert-Butyl-4-hydroxyanisole (BHA) | 0.19 | 0.91 |
| 3,5-Di-tert-butyl-4-hydroxybenzoic acid | 0.20 | 0.28 |
| 2-tert-Butyl-4-methylphenol or 2-tert-butyl-5-methylphenol# | 0.27 | 0.59 |
| 3,5-Di-tert-butyl-4-hydroxy benzaldehyde | 0.37 | 0.15 |
| 4,6-Di-tert-butyl-m-cresol | 0.66 | 0.91 |
| 2,6-Di-tert-butyl-phenol | 0.77 | 1.11 |

| | | |
|---|---|---|
| Butylated hydroxytoluene (Retention time: about 10.8 minutes) | 1.0 | --- |

* The *p*-cresol and *m*-cresol peaks are not separated under the method conditions.
# The 2-*tert*-butyl-4-methylphenol and 2-*tert*-butyl-5-methylphenol peaks are not separated under the method conditions.

Inject the reference solution. The test is not valid unless the signal-to-noise ratio of not less than 40.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.1 per cent) and the sum of the areas of all the secondary peaks is not more than 7 times the area of the principal peak in the chromatogram obtained with the reference solution (0.7 per cent).

**Sulphated ash** (2.3.18). Not more than 0.002 per cent, determined on 50 g.

**Assay.** Determine by liquid chromatography (2.4.14), as described under Related substances with the following modification.

*Test solution.* Dissolve 50 mg of the substance under examination in the mobile phase and dilute to 100.0 ml with the mobile phase.

*Reference solution.* A 0.05 per cent w/v solution of *butylated hydroxytoluene IPRS* in the mobile phase.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 1.5 and the relative standard deviation for replicate injections is not more than 0.5 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{15}H_{24}O$.

**Storage.** Store protected from moisture.