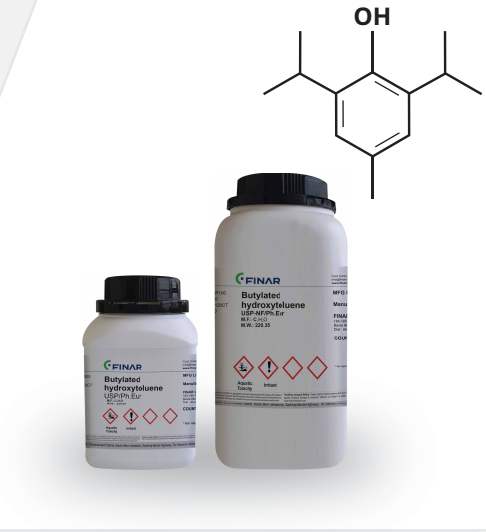
Technical Data Sheet

Butylated Hydroxytoluene

IP, Ph.Eur., USP-NF, CDMF



Applications

Butylated Hydroxytoluene is a commonly used excipient as an antioxidant. The preferred route of application is through Solid oral, Semi-solid, Topical and Parenteral dosage forms.

General Information

Pharmacopeia Status	:	IP, Ph.Eur, USP-NF
CAS No.	:	128-37-0
EC No.	:	204-881-4
Appearance/Description	:	White, crystalline solid, having a faint characteristic odor
Molecular Formula	:	$C_{15}H_{24}O$
Molecular Mass	:	220.40 g/mol

Marketed Formulations

- Vitamin D3 capsules
- Calcitriol tablets
- Vitamin A injections
- Tretinoin gel and more...

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Low Endotoxin suitable for parenteral application
- Control of TAMC & TYMC
- Control of elemental impurities as per ICH Q3D
- Control of Sulfate & Phenol

Pack Mode

- 500 gm & 1kg Plastic container
- 5kg Fiber drum, 25kg, 50kg Plastic container

DMF (Drug Master File)

CDMF registered product (CDE # F20200000189)

Stability and Storage Conditions

Exposure to light, moisture, and heat causes discoloration and a loss of activity. Butylated hydroxytoluene should be stored in a well closed container, protected from light, in a cool and dry place.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Butylated hydroxytoluene may be an irritant to the eyes and skin. Do not inhale and it should be handled in a well-ventilated environment. Gloves and eye protection are recommended. Closed containers may explode owing to pressure build-up when exposed to extreme heat.

Pharmaceutical Specifications

Description	A white to yellowish-white, crystalline solid powder having a faint characteristic odor (IP, Ph.Eur, USP-NF, CDMF)
Solubility	Very soluble in acetone, chloroform and ether. Freely soluble in ethanol (95%), methanol, fixed oils, vegetable oils and fats. Insoluble in water & propylene glycol (IP, USP-NF, Ph.Eur)
Assay (on Anhydrous basis)	99.0% - 101.5% (USP-NF, Ph.Eur)
Identification (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard (IP, USP-NF)
Identification (by Freezing point)	69°C to 70°C (Ph.Eur)
Identification (by chromatogram)	The retention time of the BHT peak of the sample solution corresponds to that of the standard solution as obtained in the assay. The chromatographic profile of sample solution should exhibit only 1 major peak corresponding to the main compound (USP-NF)
Identification (by UV absorbance test)	An absorbance max should be only about 278 nm; absorbance at about 278 nm between 0.40 and 0.45 (IP)
Identification (by UV absorbance test)	The specific absorbance at the maximum (at absorbance maxima 278 nm) is 80 to 90 (Ph.Eur)
Identification (By Chemical test)	A blue color should be produced (IP)
Identification (By Chemical test)	Not more than a faint blue color should be produced (IP)
Identification (By Chemical test)	A blue color develops (Ph.Eur)
Identification (By Chemical test)	A green to blue color should be produced (IP)
Freezing point	69°C - 70°C (IP)
Appearance of Solution	A 10% w/v solution in methanol should be clear and not more intensely colored than reference solution YS5 or BY5 (IP, Ph.Eur)
Related substances (by TLC)	Any secondary spot in the chromatogram obtained with the test solution should not be more intense than the spot in the chromatogram obtained with the reference solution (IP)
Related substances (By TLC)	0.5% max. (Ph.Eur)
Residue on ignition /Sulfated ash	NMT 0.002% (USP-NF)
Organic impurities : p-Cresol or m- cresol	NMT 0.1% (USP-NF)
Organic impurities : 3-tert-Butyl-4Hydroxyanisole (BHA)	NMT 0.1% (USP-NF)
Organic impurities: 3,5-Di-tert-butyl-4-hydroxybenzoic acid	NMT 0.1% (USP-NF)
Organic impurities : 2-tert-Butyl-4-methylphenol or 2-tert-butyl-5-methylphenol	NMT 0.1% (USP-NF)
Organic impurities : 3,5-Di-tert-butyl-4-hydroxybenzaldehyde	NMT 0.1% (USP-NF)
Organic impurities : 4,6-Di-tert-butyl-m-cresol	NMT 0.1% (USP-NF)
Organic impurities : 2,6-Di-tert-butyl-phenol	NMT 0.1% (USP-NF)
Organic impurities : Any unspecified impurity	NMT 0.1% (USP-NF)
Organic impurities : total impurities	NMT 0.7% (USP-NF)
Sulphated ash	NMT 0.1% (IP)
Water	NMT 0.1% (CDMF)
Arsenic	NMT 0.0001% (CDMF)
Sulfate	NMT 0.002% (CDMF)
Free phenol	NMT 0.02% (CDMF)
Particle size	100% must pass through 60 mesh (In-house)
Bacterial endotoxins	NMT 0.5 EU/mg
Total aerobic bacterial count	NMT 100 cfu/g
Total combined yeast and molds count	NMT 10 cfu/g

Regulatory Information

GRAS listed. Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Database (IM and IV injections, nasal sprays, oral capsules and tablets, rectal, topical, and vaginal preparations). Included in the Non-parenteral medicines licensed in the UK and the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN No: UN3077
Transport Hazard class: 9
Packing group: III

See the Material Safety Data Sheet on www.finarchemicals.com

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