

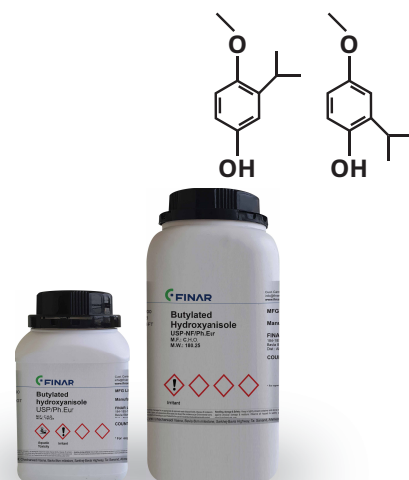


Butylated Hydroxyanisole

Ph.Eur, USP-NF, CDMF

Applications

Butylated Hydroxyanisole 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	: Ph.Eur., USP-NF
CAS No.	: 25013-16-5
EC No.	: 246-563-8
Appearance/Description	: White or yellowish/slightly yellow or slightly pinkish waxy solid or crystalline powder, having a faint, characteristic odor.
Molecular Formula	: C ₁₁ H ₁₆ O ₂
Molecular Mass	: 180.24 g/mol

Marketed Formulations

- Simvastatin tablets
- Vitamin D3 capsules
- Calcitriol tablets
- Vitamin A injections
- Tretinoin gel & many 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

Pack Mode

- 500 gm, 1 kg, 25 kg plastic container
- 5 kg fiber drum

DMF (Drug Master File)

CDMF registered product (CDE # F2020000188)

Stability and Storage Conditions

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

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Butylated hydroxyanisole may be irritant to the eyes, skin. Do not inhale and it should be handled in a well-ventilated environment. Gloves and eye protection are recommended. On combustion, toxic fumes may be given off.

Pharmaceutical Specifications

Appearance/Description	White or yellowish / slightly yellow or slightly pinkish waxy solid or crystalline powder having a faint characteristic odor (USP-NF, CDMF, Ph.Eur)
Solubility	Practically insoluble in water, very soluble in methylene chloride, freely soluble in alcohol, propylene glycol, chloroform, ether and in fatty oils. It dissolves in dilute solutions of alkali hydroxides (Ph.Eur, CDMF, USP-NF)
Assay(HPLC)	NLT 98.5% (USP-NF, CDMF)
Identification (By IR)	To comply the test (USP-NF, CDMF)
Identification (By TLC test)	The principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a) (Ph.Eur, USP-NF)
Identification (by Chromatogram)	The retention time of the main peak of the sample solution corresponds to that of the standard solution and exhibit only one major peak corresponding to butylated hydroxyanisole (USP-NF, CDMF)
Identification (By Chemical test)	After separation, the organic layer is red (Ph.Eur ,CDMF)
Identification (By Chemical test)	A red colour develops (Ph.Eur , CDMF)
Appearance of Solution	Solution is clear and not more intensely coloured than intensity 5 of the range of reference solutions of the most appropriate colour (Ph.Eur, CDMF)
Residue on ignition /Sulfated ash	NMT 0.01% (USP-NF, CDMF)
Related substances By TLC (3-(1,1-Dimethylethyl)-4-methoxyphenol)	NMT 10.0% (Ph.Eur, CDMF)
Related substances By TLC (Hydroquinone)	NMT 0.2% (Ph.Eur, CDMF)
Related substances By TLC (Any other impurity)	NMT 0.5% (Ph.Eur, CDMF)
Sulphated ash	NMT 0.1% (Ph.Eur)

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, sublingual, rectal, topical, and vaginal preparations). Included in Non-parenteral medicines licensed in the UK and the Canadian List of Acceptable Non-medicinal Ingredients.

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

Note : The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

For more information contact : deepaklodhiya@finarchemicals.com

Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN No: UN3077

Transport Hazard class: 9

Packing group: III

Finar Limited

CORPORATE OFFICE & WORKS

184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej
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