

**BUTILHIDROXITOLUENO (B.H.T.) (EUR. PH.) FARMACEUTICO**

PRODUCT CODE: 0268	CAS Nº: 128-37-0	ANALYSIS Nº: 027/23
MANUFACTURER BATCH: 0002061832	CERTIFICATE ID: 37.248	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/10/2021	
METAPH BATCH: 0030223	RETEST DATE: 01/10/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white, crystalline powder	Complies (*)
Solubility	Practically insoluble in water, very soluble in acetone, freely soluble in alcohol and in vegetable oils	Complies
Identification A	Complies	Complies (*)
Identification C	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y5 or BY5	Complies
Freezing point	69 - 70 °C	70 °C (*)
Related substances	=< 0.5 %	< 0.50 %
Sulfated ash	=< 0.1 %	0.002 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Butylhydroxytoluene is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(\*) Data controlled by Metapharmaceutical Industrial SL.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

**STORAGE**

Store in a cool, dry place, protected from sunlight.

Analysis date: 16/02/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Manufacturer: 40000925