HEDINGER 1843 A pure decision.

SPECIFICATION

Butylhydroxytoluene Ph. Eur.* / USP-NF*/ JPE*

Vulkanox® BHT GMP Grade

Testing specifications: Ph. Eur.* / USP-NF* / JPE* / LSM 216

The material meets all requirements of Ph. Eur.*, USP-NF* and JPE* **Product code: 216**

Pharmacopoeia Parameters	Ph. Eur.*		USP-NF*		JPE*	
	Specification	Test method	Specification	Test method	Specification	Test method
Identification	A, C	Ph. Eur.*	conforms	USP-NF*	conforms	JPE*
Appearance of Solution / Clarity and color of solution	conforms	Ph. Eur.*	-	-	conforms	JPE*
Absorbance	-	-	-	-	conforms	JPE*
Sulfate	-	-	-	-	≤ 0.019%	JPE*
Freezing Point	69 – 70 °C	Ph. Eur.*	-	-	-	-
Melting Point	-	-	-	-	69.5 – 72.0 °C	JPE*
p-Cresol	-	-	-	-	conforms	JPE*
Related Substances	≤ 0.5% each	Ph. Eur.*	-	-	-	-
Organic Impurities - Individual impurity - Total impurities	-	-	≤ 0.1% ≤ 0.7%	USP-NF*	-	-
Sulfated Ash / Residue on Ignition	≤ 0.1%	Ph. Eur.*	≤ 0.002%	USP-NF*	≤ 0.05%	JPE*
Heavy Metals	-	-	-	-	≤ 20 ppm	JPE*
Water (Karl Fischer)	-	-	-	-	≤ 0.2%	JPE*/LSM 216
Assay	-	-	99.0 – 101.5%	USP-NF*	-	-

Additional Parameters	Specification	Test method
Assay (GC)	≥ 99.0%	LSM 216
2-tert.-butyl-p-cresol (GC)	≤ 0.5%	LSM 216
p-Cresol (GC)	≤ 0.1%	LSM 216
Any other impurity (GC)	≤ 0.5%	LSM 216

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production at original manufacturer	Requirements defined from a HACCP study
Supply chain	EXCiPACT GMP / GDP
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP]

*current version

Compiled by: 12.01.2024	Approved by: 15.01.2024	Released by: 15.01.2024	Effective:	Supersedes:
Manuel Eliete QA/QC	Dr. Stefan Heß QA-Manager	Dr. Frank Milek Qualified Person (GMP)	19.01.2024	01.07.2023

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Storage: protected from light and moisture, < 50 °C, avoid piling of pallets

Shelf life in originally sealed bags: 36 months from date of manufacture

Manufacturer and manufacturing site: LANXESS Deutschland GmbH, Leverkusen (Germany)

Regulatory Compliance:

The material is manufactured and packaged by LANXESS Deutschland GmbH according to IPEC-PQG GMP Guidelines for Pharmaceutical Excipients. Testing, release and storage is performed by Aug. Hedinger GmbH & Co. KG according to IPEC-PQG GMP Guidelines for Pharmaceutical Excipients.

The material also meets the requirements of current FCC* but is not tested batchwise.

Allergens:
Allergens listed in Regulation (EU) No 1169/2011 Annex II are not used during the manufacture, are not intentionally added or known to be present in the product.

Batch certification:
Every batch is analysed according to all parameters of this specification listed in the table above. The Certificate of Analysis (CoA) provides all results like above including analysis date, manufacturing date, residual solvents statement and elemental impurities statement. All CoAs are signed by a Qualified Person (QP) according to EU-GMP or a responsible QA/QC-Manager.

Elemental impurities (Ph. Eur.* 5.20 / USP* <232> / ICH Q3D*):
At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities were below the level of 30% of the permitted concentrations for parenteral application according to table A.2.2 of the guideline ICH Q3D. More detailed information is available upon request.

Nitrosamines:
Nitrosamines, nitrites, nitrates, nitrosating agents, secondary and tertiary amines, primary amines, amides or ammonium salts are not used in the manufacturing process, are not intentionally added or known to be present in the product. More detailed information is available upon request.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):
Solvents of class 1- 3 except Methanol, *tert*-Butyl alcohol and Toluene are excluded by the manufacturing process. Methanol content complies with ICH limit of 3000 ppm. *tert*-Butyl alcohol content complies with ICH limit of 3500 ppm. Toluene content complies with ICH limit of 890 ppm.

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