HEDINGER 1843 A pure decision.

SPECIFICATION

Butylhydroxytoluene Ph. Eur.* / USP* (NF)/ JPE* product code: 216

Vulkanox® BHT GMP Grade

Testing specifications: Ph. Eur.* / USP* / JPE* / LSM 216
The material meets all requirements of Ph. Eur.*, USP* and JPE*

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

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

*current version

Compiled by: 16.12.2019	Approved by: 16.12.2019	Released by: 17.12.2019	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.01.2020	01.03.2018

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The material meets all requirements of Ph. Eur.*, USP* and JPE*

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

Shelf life in originally sealed bags: 24 months

Manufacturer and manufacturing site: LANXESS Deutschland GmbH, D-Leverkusen

Regulatory Compliance:

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

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):

Solvents of class 1- 3 except Methanol and Toluene are excluded by the manufacturing process. Methanol content complies with ICH limit of 3000 ppm. Toluene content complies with ICH limit of 890 ppm.

Elemental Impurities (Ph. Eur.* 5.20 / 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.

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 GMP or a responsible QA/QC-Manager.

*current version

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