

Metacresol Ph. Eur.* / USP* parenteral grade

Testing specifications: Ph. Eur.* / USP* / LSM 024

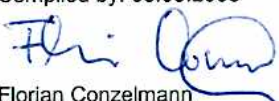
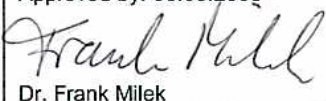
The material meets all requirements of Ph. Eur.* and USP*

Parameter	Ph. Eur.*		USP*	
	Specification	Test method	Specification	Test method
Identification	conforms	Ph. Eur.* (2.2.24, FT-IR)	conforms	USP*
Appearance of solution	conforms	Ph. Eur.* (2.2.1, 2.2.2)	—	—
Clarity of solution	—	—	A+B conform	USP*
Acidity	conforms	Ph. Eur.*	—	—
Related substances	conforms	Ph. Eur.*	—	—
2-methylphenol	≤ 0.5%	Ph. Eur.*	—	—
4-methylphenol	≤ 0.5%	Ph. Eur.*	—	—
any other impurity	≤ 0.1%	Ph. Eur.*	—	—
total	≤ 1.0%	Ph. Eur.*	—	—
Residue on evaporation	≤ 0.1 %	Ph. Eur.*	—	—
Assay	—	—	95.0 – 101.0 %	USP*

Additional Parameter		
Parameter	Specification	Test method
Absorption (400 - 700 nm)	Max. 0.05	UV-VIS Spectrometry (LSM 024)

Quality Assurance and Quality Control	
Process/Operation	Standard / Requirement
Production	Requirements defined from a HACCP study
Supply chain	WHO – GTDP Guidelines for Pharmaceutical Starting Materials
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	Class D (100,000) clean room according to GMP (EU-GMP Part I Annex 1, US cGMP)
Blanketing	Product is blanketed with an argon layer
Primary packaging material	<u>Specified packaging materials from audited suppliers:</u> 1 L, 2.5 L Amber Glass Bottles

*current version

Compiled by: 05.03.2008  Florian Conzelmann Pharmacist, Qualified Person (GMP)	Approved by: 06.03.2008  Dr. Frank Milek Pharmacist, Qualified Person (GMP)	Effective: 01.04.2008	Supersedes: 01.01.2007	Page 1 of 2
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SPECIFICATION

Metacresol Ph. Eur.* / USP* parenteral grade

Testing specifications: Ph. Eur.* / USP* / LSM 024

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

Storage: In airtight containers, protected from light, under Argon, storage temperature > 13 °C is recommended

Expiry Date in originally sealed containers: Manufacturing Date plus 24 months

Manufacturer and manufacturing site: Lanxess AG, D-Leverkusen

Packaging site: Aug. Hedinger GmbH & Co. KG, D-Teutschenthal

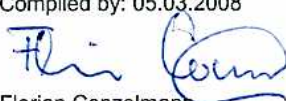
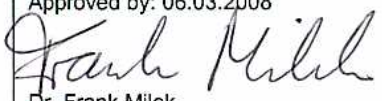
Manufacturer's Article No.: 06311857 [M-Cresol high purity (Hedinger)]

Residual solvents (Ph. Eur.* 5.4 / CPMP/ICH/283/95):

Solvents of class 1- 3 except Toluene are excluded by the manufacturing process. Toluene content complies with ICH limit of 890 ppm, typical content: < 5 ppm: Therefore, the test will not be conducted for every batch.

Every batch is analysed according to all parameters of this specification. The Certificate of analysis (COA) provides all results like above plus analysis date, date of manufacture and residual solvents statement. All COAs are signed by a Qualified Person (QP) according to GMP (Article 49, 2001/83/EEC).

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