

## SPECIFICATION

### Metacresol Ph. Eur.\* / USP\* parenteral grade

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

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

Product code: 024

Parameter	Ph. Eur.*		USP*	
	Specification	Test method	Specification	Test method
Identification	conforms	Ph. Eur.* (2.2.24, FT-IR)	conforms	USP* A (FT-IR) / B (GC)
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/ Organic impurities	conforms	Ph. Eur.*	conforms	USP*
o-cresol	≤ 0.5%	Ph. Eur.*	≤ 0.5%	USP*
p-cresol	≤ 0.5%	Ph. Eur.*	≤ 0.5%	USP*
any other impurity	each ≤ 0.1%	Ph. Eur.*	each ≤ 0.1%	USP*
total	≤ 1.0%	Ph. Eur.*	≤ 1.0%	USP*
Residue on evaporation	≤ 0.1%	Ph. Eur.*	—	—
Assay	—	—	98.0 – 102.0%	USP*

Additional Parameters			
Parameter		Test method	
Absorption (400 - 700 nm)	Max. 0.05	UV-VIS Spectrometry (LSM 024)	
Endotoxins	≤ 0.5 IU/mg	Ph. Eur.* / USP* / JP* (LAL, kinetic-turbidimetric method)	
Parameter	ICH Q3C* Specification	Additional Specification	Test method
Toluene content	≤ 890 ppm	≤ 100 ppm	LSM 024* (GC)

Quality Assurance and Quality Control	
Process/Operation	Standard / Requirement
Production	Requirements defined from a HACCP study
Supply chain	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
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]
Blanketing	Product is blanketed with an argon layer
Primary packaging material	<u>Specified packaging materials from audited suppliers:</u> 100 mL, 1 L, 2.5 L Amber Glass Bottles
Tamper evident sealing	Tamper evident closure with void label
Secure labelling	Full reconciliation of batch-specific labels

\*current version

Effective date: 01.10.2025

Supersedes version from: 01.08.2022

## SPECIFICATION

### Metacresol Ph. Eur.\* / USP\* parenteral grade

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

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

**Product code: 024**

**Storage:** In airtight containers, protected from light, under argon,  
storage temperature: 15 – 25 °C

**Shelf life in originally sealed containers:** 1 L, 2.5 L: 24 months after manufacturing date  
100 mL: 12 months after repackaging date, not more than 24 months  
after manufacturing date

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

**Packaging site:** Aug. Hedinger GmbH & Co. KG, Teutschenthal (Germany)

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

#### Regulatory Compliance

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients\*.

Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Elemental Impurities (ICH Q3D\*), GMO, Nitrosamines and Residual Solvents (ICH Q3C\*) is available upon request.

#### Batch certification:

Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all results including analysis date and date of manufacture. All CoAs are signed by a Qualified Person (QP) according to EU-GMP.

\*current version

Compiled by: 16.05.2025	Approved by: 16.05.2025	Released by: 16.05.2025	Effective:	Supersedes:
Dr. Philipp Hoch Head of QA	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.10.2025	01.08.2022