

CERTIFICATE OF ANALYSIS

Metacresol Ph. Eur. / USP parenteral grade

m-Kresol hochrein (Hedinger)

Testing specification: Ph.Eur.: 11.0; USP: 2023; LSM 024

The product meets all requirements of the listed pharmacopoeias

Product code (Hedinger): 024

Batch (Hedinger): 024058-06

Batch (Lanxess): CHASMD1208

Parameter / Method	Specification	Result
Identification A Ph.Eur./USP IR	conforms	conforms
Identification B USP GC	conforms	conforms
Clarity of Solution USP (test A)	conforms	conforms
Clarity of Solution USP (test B)	conforms	conforms
Appearance of solution Ph.Eur.	conforms	conforms
Acidity Ph.Eur.	max. 0.5 ml 0.01 M NaOH	0.13 ml
Residue on evaporation Ph.Eur.	max. 0.1 %	0.0000 %
Related substances Ph.Eur. GC		
o-Cresol	max. 0.5 %	0.00 %
p-Cresol	max. 0.5 %	0.36 %
any other impurity	max. 0.1 %	0.04 %
sum of impurities	max. 1.0 %	0.43 %
Organic impurities USP GC		
o-Cresol	max. 0.5 %	0.00 %
p-Cresol	max. 0.5 %	0.36 %
any other impurity	max. 0.1 %	0.04 %
sum of impurities	max. 1.0 %	0.43 %
Assay Metacresol USP GC	98.0 % - 102.0 %	99.8 %

Microbiological Specification

Parameter / Method	Specification	Result
Endotoxins Ph.Eur./USP	max. 0.5 IU/mg	<0.5 IU/mg

Additional Tests

Parameter / Method	Specification	Result
Toluene content GC	max. 100 ppm	<10 ppm
Absorption LSM 024	400 - 700 nm: max. 0.05	0.002

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Manufacturer: LANXESS Deutschland GmbH, Leverkusen, GERMANY

Expiry date in originally sealed containers: 1 L, 2.5 L: manufacturing date plus 24 months;
100 mL: 12 months after repackaging date, not more than 24 months after manufacturing date

Date of repackaging: 03/05/2023

Date of manufacture: 21/10/2022

Supplier: Aug. Hedinger GmbH & Co. KG
06179 Teutschenthal

Analytical release: 26/04/2023

Delivery date: 05/05/2023

Customer: Pharma Ltd.
12345 City, GERMANY

Net quantity: 10 x 1 liter

Customer order no.: 1234567, Hedinger order no.: 7654321

Manufacturing: Lanxess Deutschland GmbH, Leverkusen, Germany, Phone: +49 (0)21430-0

Packaging site: Aug. Hedinger GmbH & Co. KG, D-06179 Teutschenthal, Germany, Phone: + 49 (0)34635 7850

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

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG

– GMP Guidelines for Pharmaceutical Excipients.

Residual solvents [ICH Q3C (current version)]:

The product complies with the requirements of the ICH Q3C Residual Solvents Guideline (current version):

Solvents of class 1-3 except toluene are excluded by the manufacturing process. Toluene content complies with ICH limit of 890 ppm and the additional stricter limit of 100 ppm, typical content: < 10 ppm.

Hereby I confirm that this batch/lot has been analysed according to all listed tests. This CoA is only valid for originally sealed containers and tank trucks of Aug. Hedinger GmbH & Co. KG, Stuttgart labelled with the same batch/lot number. Copies of this CoA are not valid.

Product finally released.

Date:

Elisabeth Bartel, Pharmacist, Qualified Person acc. to EU-GMP