

Certificate of Analysis

NN

Material VWRB568-50KG

Material description Urea

Grade Ph.Eur./USP/BP/JP/ENDOTOXIN TESTED

 Lot
 18H075201

 Expiration Date
 2022 May 31

 CAS Number
 57-13-6

 Molecular formula
 NH2CONH2

 Molecular mass
 60.06

 Date of manufacture
 2017 May 29

 Made in
 Germany

Storage Store between 15 °C and 30 °C.

Supplier 10395

Additional information

Characteristics	Specifications	Measured values
Appearance	White powder	White powder
JP specifications:		
Assay [JP]	Min. 99.0 %	Min. 99.0 %
Identification 1	Passes test JP	Passes test JP
Identification 2	Passes test JP	Passes test JP
Ethanol-insoluble substances [JP]	Max. 2.0 mg	0.9 mg
Melting point [JP]	132.5> 134.5 °C	133.7 °C
Heavy metals (as Pb) [JP]	Max. 20 ppm	Max. 20 ppm
Residue on ignition [JP]	Max. 0.1 %	< 0.1 %
CI (Chloride) [JP]	Max. 0.007 %	Max. 0.007 %
SO4 (Sulphate) [JP]	Max. 0.010 %	Max. 0.010 %
Ph.Eur./BP specifications:		
Assay (on dried substance) [Ph.Eur./BP]	98.5> 101.5 %	100.2 %
Identif. A (melting point) [Ph.Eur./BP]	132> 135 °C	134 °C
Identification B (IR)	Passes test Ph.Eur./BP	Passes test Ph.Eur./BP
Appearance of solution	Passes test Ph.Eur./BP	Passes test Ph.Eur./BP
Alkalinity	Passes test Ph.Eur./BP	Passes test Ph.Eur./BP
Biuret [Ph.Eur./BP]	Max. 0.1 %	Max. 0.1 %
Loss on drying [Ph.Eur./BP]	Max. 1.0 %	0.2 %
Sulphated ash [Ph.Eur./BP]	Max. 0.1 %	< 0.1 %
NH4 (Ammonium) [Ph.Eur./BP]	Max. 500 ppm	Max. 500 ppm
USP specifications:	•	
Assay [USP]	98.0> 102.0 %	101.0 %
Identification A	Passes test USP	Passes test USP
Identification B	Passes test USP	Passes test USP
Alcohol-insoluble matter [USP]	Max. 0.04 %	Max. 0.04 %
Heavy metals (as Pb) [USP]	Max. 0.002 %	Max. 0.002 %
Residue on ignition [USP]	Max. 0.1 %	< 0.1 %
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For further manufacturing use only. Not for use as an Active Pharmaceutical Ingredient.



Certificate of Analysis

A		

Characteristics	Specifications	Measured values
Organic impurities:		
Urea related compound A [USP]	Max. 0.1 %	< 0.1 %
Any individual unspecified impurity[USP]	Max. 0.1 %	Max. 0.1 %
Total impurities [USP]	Max. 2.0 %	0.1 %
Bacterial endotoxins	Max. 2.5 EU/g	Passes test

Signature

We certify that this batch conforms to the specifications listed above.

This document has been produced electronically and is valid without a signature.

Anand Matta, Head of Laboratory - Aurora VWR Chemicals, LLC, 220 Lena Dr., Aurora, OH 44202, USA

Additional information

No Class 1, 2, 3 or other residual solvents are present. Manufacturer's date of examination is listed as date of manufacture.