

Analysenzertifikat vom AZ00015270
Artikel: 06-0160-00 Acid citricum monohydr crist

Seite 1 von 2

Packungstext	25KG
Chargennr.	2018.02.0177
Ext. Chargennr.	UJ804
Qualität	PHEUR
MFD	01.2018
Retest	30.01.2021
Ursprungsland	BE
Freigabedatum	14. Mai 2018

Hersteller

S.A. Citrique Belge N.V.
Pastorijstraat 249
3300 Tienen
Belgien

Reference: PhEur 01/2017: 0456

Characters: A white or almost white, crystalline powder,
colourless crystals or granules, efflorescent.

Not tested for bacterial endotoxins.
Not suitable for application in dialysis solutions.

Storage: In an airtight container.

Residues of metal catalysts or metal reagents according to EMEA/CHMP/SWP/4446/2000 are not likely to be present.

Reason for change: Change to current PhEur according to CC2017.01.001.

Test	Methode	Spezifikation		Soll	Resultat
		Min.	Max.		
Identification					
harmonised with JP and USP					
IR-Spectrophotometry	E2.2.24			complies	complies
Water	E-TEST 1			complies	complies
It complies with the test for water (see Tests).					
TESTS					
Appearance of solution	APPEARAN CE	2)		complies	complies
harmonised with JP and USP					
Readyli carb. subst.	E-TEST			complies	complies
The solution is not more intensely coloured than a mixture of 1 ml of red primary solution and 9 ml of yellow primary solution (2.2.2, Method I).					
harmonised with JP and USP					
Oxalic acid	OXALICACI D	2)	360		<10 ppm
Calculated as anhydrous oxalic acid.					
harmonised with JP and USP					

Analysenzertifikat vom AZ00015270
Artikel: 06-0160-00 Acid citricum monohydr crist

Seite 2 von 2

Packungstext	25KG
Chargennr.	2018.02.0177
Ext. Chargennr.	UJ804
Qualität	PHEUR
MFD	01.2018
Retest	30.01.2021
Ursprungsland	BE
Freigabedatum	14. Mai 2018

Test	Methode	Min.	Spezifikation		Soll	Resultat
				Max.		
Sulphates harmonised with JP and USP	E2.4.13 2)			150		<30 ppm
Water harmonised with JP and USP	E2.5.12	7.5		9.0		8.6 %
Sulphated ash harmonised with JP and USP	E2.4.14 2)			0.1		<=0.1 %
Residual solvents Subject to the PhEur 5.4 (CPMP/ICH/283/95) according to supplier information	E2.4.24 2)				complies	complies

Assay

harmonised with JP and USP

Assay	E-ASSAY 2)	99.5	100.5		100.1 %
-------	------------	------	-------	--	---------

Citric acid monohydrate contains not less than 99.5 per cent and not more than the equivalent of 100.5 per cent of 2-hydroxypropane-1,2,3-tricarboxylic acid, calculated with reference to the anhydrous substance.

Remarks / Hinweise

Origin / Ursprungsland	WE22	Belgien
MFD / Herstellungsdatum	MFD	01.2018
Retest / zu überprüfen ab:	RETEST	30.01.2021

**Wir weisen darauf hin, dass der vorliegende Rohstoff als Hilfsstoff geliefert wird.
Dieser Untersuchungsbericht ist ein Computerausdruck der bei uns verfügbaren Daten und ist auch ohne Unterschrift gültig.**

Herisau, 14. Mai 2018
Hänseler AG FvP / QP
i.v. Moritz Weiss