

CERTIFICATE OF ANALYSIS

Material No: 704137
Name: (+)-Pseudoephedrine HCl crsPwd 50kg

Lot No: 18062004

Manufacturing date: 20-Feb-2018
Retest date: 19-Feb-2023
Actual specification: 755-20

Test	Parameter	Specification	Dimension	Result
<u>Characters</u>				
	Appearance	White or almost white crystalline powder		complies
<u>Identification</u>				
	Identification	Must comply		complies
<u>Identity (Raman)</u>				
	Identity (Raman)	Must comply		complies
<u>Melting range</u>				
	Beginning of melting	min. 183.0	°C	185.0
	End of melting	max. 186.0	°C	186.0
	Melting interval	max. 2	°C	1
<u>Specific rotation</u>				
	Specific rotation	61.0 - 62.5	° in dry sub.	62.2
<u>Appearance of solution</u>				
	Appearance of the solution	Must comply		complies
<u>pH value</u>				
	pH value of the solution	5.0 - 6.0		5.2
<u>Acidity or alkalinity</u>				
	Acidity or alkalinity	Must comply		complies
<u>Loss on drying</u>				
	Loss on drying	max. 0.5	%	< 0.1
<u>Residue on ignition</u>				
	Residue on ignition	max. 0.1	%	< 0.1
<u>Content (potentiometric)</u>				
	Content	99.0 - 101.0	% in dry sub	99.1
<u>Related substances</u>				
	(-)-Ephedrine hydrochloride	max. 0.1	%	< 0.1
	Ph.Eur. Impurity A			
	Further impurities	Max. 0.10% each		complies
	Sum of all impurities (other than Impurity A)	max. 0.4	%	< 0.1

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Test	Parameter	Specification	Dimension	Result
<u>residual solvents (GC)</u>				
	Methanol	max. 1000	ppm	75
<u>Particle size (air jet sieving)</u>				
	Below 0.425 mm (No.40)	min. 97	%	100
	Below 0.045 mm (No.325)	max. 60	%	52

Release comment: Result:
(+)-Pseudoephedrine hydrochloride coarse powder meets the test requirements stipulated in the following monographs (current version): "Pseudoephedrine Hydrochloride" of Ph.Eur., USP and JPC.

(+)-Pseudoephedrine hydrochloride coarse powder is manufactured according to current GMP requirements.

Released on: **12-Mar-2018**
Manufacturer: Siegfried PharmaChemikalien Minden GmbH
Karlstr. 15
32423 Minden
Germany

Site Quality Assurance: Dr. Wienken

This certificate of analysis has been signed electronically.

It has been created automatically by the validated Siegfried Laboratory Information Management System (LIMS).

