Siegfried

Siegfried PharmaChemikalien
Minden GmbH
Karlstrasse 15
32423 Minden
Germany
+49 571 391 0

Certificate of Analysis

Material No:	**704128**		
Name:	**(-)-Ephedrine HCl Pwd 25kg**		
Lot No:	**21482182**	Manufacturing date:	03-Dec-2021
CAS No.	50-98-6	Retest date:	03-Dec-2026
Formula:	-	Specification date:	09-Dec-2021
Molecular Weight:	-		

Test	Method	Specification	Result
Characters	Visual	Appearance: White or almost white, crystalline powder or colourless crystals	Complies
Identity HPLC RT time	Inhouse	Identity HPLC (RT time): RT of the major peak in the HPLC corresponds to that which is specified in the HPLC method	Complies
Identity (Raman)	Inhouse	Identity (Raman): In accordance with the reference spectrum	Complies
Melting Range	USP	Min 217 °C Beginning of Melting	220 °C
	USP	Max 220 °C End of Melting	220 °C
Specific rotation	Ph.Eur.	Specific Rotation: -33.5° - -35.5°	-34.5 ° in dry sub.
Appearance of solution	Ph.Eur.	Appearance of solution: Clear and colourless	Complies
Acidity or alkalinity	Ph.Eur.	Acidity or alkalinity: Must comply	Complies
Sulfate	Ph.Eur.	< 100 ppm Sulfate	<100 ppm
Loss on Drying	Ph.Eur.	Max 0.5 % Loss on Drying	<0.1 %
Residue on Ignition	Ph. Eur., USP	Max 0.1 % Residue on ignition	<0.1 %
Content (potentiometric)	Ph.Eur.	99.0 - 100.5 % in dry sub. Content	100.0 % in dry sub.
Related Substances (HPLC)	Ph. Eur.	Max 0.2 % Imp A (Phenylacetylcarbinol)	<0.05 %
	Ph. Eur.	Max 0.5 % Sum of all impurities	<0.05 %
	Ph. Eur.	Impurities: Max. 0.10% each	Complies
Ordinary Impurities	USP	Max 2.0 % Sum of all impurites: USP method (DC) is covered by related substances (HPLC)	<0.1 %
Residual solvent (GC)	Inhouse	Max 200 ppm Toluene	n.b. ppm
Particle Size (Sieve)	Inhouse	Min 100 % Below 0.300 mm (No.50)	100 %

Siegfried PharmaChemikalien
Minden GmbH
Karlstrasse 15
32423 Minden
Germany
+49 571 391 0

Certificate of Analysis

Material No:	**704128**		
Name:	**(-)-Ephedrine HCl Pwd 25kg**		
Lot No:	**21482182**	Manufacturing date:	03-Dec-2021
CAS No.	50-98-6	Retest date:	03-Dec-2026
Formula:	-	Specification date:	09-Dec-2021
Molecular Weight:	-		

Release comment: **meets specification**

Note:
Siegfrieds identification tests replace the Ph. Eur./USP tests based on general notice of Ph. Eur./USP.
The test for toluene is not performed routinely since all of the batches tested previously were under 80 ppm.
Related substances (HPLC): Any impurity at a level greater than (>0.05%) the reporting threshold is reported with RRT and corresponding quantitative result. If no impurities with relative retention time (RRT) are listed, then no impurities are present above the reporting threshold.

Result:
(-)-Ephedrine hydrochloride meets the requirements of Ph.Eur., USP and of this specification.
This batch was manufactured in accordance to the current applicable regulatory dossiers.

(-)-Ephedrine hydrochloride is manufactured according to current GMP requirements.

Released On:	29-Dec-2021 12:20 (UTC+01:00) on behalf of Siegfried PharmaChemikalien
Released By:	Stefan Wienken -

This certificate of analysis is signed electronically.
It has been created automatically by the validated Siegfried Laboratory Information Management System (LIMS)