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Contact:

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Date: 30.11.18

Cust.No: 96888

Certificate of analysis

Report-No.: ~~67197084~~ 99-002
Batch: 5292
Article: 82921 Cevadine

Test	Unit	Limit	Testresult
Appearance, SOP 100005		powder	Conform
Color, SOP 100006		white	Conform
Solubility, SOP 105001:			Conform
Methanol		soluble	Conform
Ethanol 96 %		soluble	Conform
Chloroform		soluble	Conform
Identification (UV spectrum from HPLC-DAD analysis) according to specification, SOP 204311		Conform	Conform
Identification (IR-spectroscopy, Ph.Eur. 9.0, 2.2.24)/USP 39 NF 34 <197>), SOP 206000		Conform	Conform
Identification (1H-NMR-spectroscopy), (outsourced), SOP 206010		Conform	Conform
Identification (13C-NMR-spectroscopy), (outsourced), SOP 206020		Conform	Conform
Water content, (micro determination, coulometric titration), Ph.Eur. 9.4., 2.5.32, SOP 304291: Mean value	%		0.4
Peakpurity, (HPLC), SOP 401367		Conform	Conform

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Test	Unit	Limit	Testresult
Cevadine (HPLC), method 1 (% AU), SOP 440532	%	>= 95.00	98.21
Residual solvents, (headspace-GC), SOP 805765: Residual solvents	%		0.13
Inorganic impurities, (ICP-MS), for reference substances, SOP 811701:			
Sodium	%		< 0.1
Potassium	%		< 0.1
Magnesium	%		< 0.1
Calcium	%		< 0.1
Aluminium	%		< 0.1
Phosphorus	%		< 0.1
Sulfur	%		< 0.1
Content*, SOP 890000	%		98

Assessment:

The above mentioned reference substance meets the specification.

*The absolute content is calculated considering the chromatographic purity, and if available, the content of water, residual solvents and inorganic impurities according to the following formula:
 Content = (100% - water content (%) - residual solvents (%) - inorganic impurities (%)) x chromatographic purity (%) / 100.

The chromatographic purity is checked regularly: the last analysis has been performed in November 2018.

The reference substance cannot be documented with an expiry date. The pack is closed and is recommended to be stored as indicated. The unopened product is guaranteed to fulfill the specifications of this analytical report for a period of 60 months. Once opened we can no longer guarantee the stability of the material.

Vestenbergsgreuth, 30.11.18

Dr. Jan Glaser

This is a computer print and valid without signature. A signed certificate of analysis can be taken on request.