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Date: 10.12.19

Cust.No: 96888

Certificate of analysis

Report-No.: ~~95157688~~ 99-002
Batch: 5693
Article: 82515 Denudatine

Test	Unit	Limit	Testresult
Appearance, SOP 100005		powder	Conform
Color, SOP 100006		white	Conform
Solubility, SOP 105001: Methanol		soluble	Conform Conform
Identification (HPLC-HR/MS), SOP 204125		Conform	Conform
Identification (IR-spectroscopy, Ph.Eur. 9.0, 2.2.24)/USP 42 NF 37 <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. 10.0., 2.5.32, SOP 304291: Mean value	%		< 0.2
Denudatine (HPLC), method 1 (% AU), SOP 440652	%	>= 95.00	99.75
Residual solvents, (headspace-GC), SOP 805765: Residual solvents	%		< 0.05

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Test	Unit	Limit	Testresult
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	%		100

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 2019.

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.

Vestenbergsreuth, 10.12.19

Dr. Jan Glaser
Manager Reference Substances

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