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Date: 19.01.21

Cust.No: 96888

Certificate of analysisReport-No.: 114830746 - 99 002
Batch: 5686
Article: 82483 Bavachin

Test	Unit	Limit	Testresult
Appearance, SOP 100005		powder	Conform
Color, SOP 100006		white	Conform
Solubility, SOP 105001:			Conform
Ethanol 96 %		soluble	Conform
DMSO		soluble	Conform
Identification (HPLC-HR/MS), SOP 204125		Conform	Conform
Identification (UV spectrum from HPLC-DAD analysis) according to specification, SOP 204311		Conform	Conform
Identification (IR-spectroscopy, Ph.Eur. 10.3, 2.2.24)/USP 43 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
Specific optical rotation, according to Ph.Eur. 10.0, 2.2.7 (optical rotation), PV 305501:			
Laevorotation (minus)	°		19.36

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Test	Unit	Limit	Testresult
Peakpurity, (HPLC), SOP 401367		Conform	Conform
Bavachin (HPLC), method 1 (% AU), SOP 440610	%	>= 98.00	99.76
Residual solvents, (headspace-GC), SOP 805765: Residual solvents	%		0.07
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 December 2020.

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, 19.01.21

Dr. Tina Zöllner
 Manager Reference Substances

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