

Life 005114



CERTIFICATE OF ANALYSIS

(Yohimbine Hydrochloride EP)

No.	: 333/2014	Date of Issuing	: 16/10/2014
Product Name	: Yohimbine Hydrochloride EP	Batch Number	: 864302502002
Date of Manufacturing	: 10/02/2014	Batch Size	: 9.000 Kgs
Date of Expiry	: 09/02/2019	Dispatch Quantity	: 4.000 Kgs

Analytical Protocol Reference: 8643/E-Rev.02 + Buyer's Req

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Test

Result

Specification

Character

Appearance (Visual test)

White or slightly yellowish crystalline powder.

Slightly yellowish crystalline powder.

Solubility (Visual test)

Sparingly soluble in water

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Practically insoluble in ethanol (96 percent) and in methylene chloride.

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Identification

A. IR Spectrum (IR spectrophotometer)

Infrared absorption spectrophotometry (2.2.24).

Complies with Infrared absorption spectrophotometry.

B. Reaction of Bromides

It gives reaction (a) of chlorides (2.3.1).

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pH (of solution S)

3.5 to 5.5

4.82

Specific optical rotation

(+101 to (+)105

(Calculated on dried substance)

101.9

Related substances (Liquid Chromatography)

Sum of impurities A : NMT 1.0%

0.32%

& G

Impurity F : NMT 0.4%

Less than 0.05%*

Unspecified impurities (for each impurity) : NMT 0.10%

Less than 0.05%*

Total impurities : NMT 2.0%

0.32%

Prepared by

Checked by

Manager Q.C.

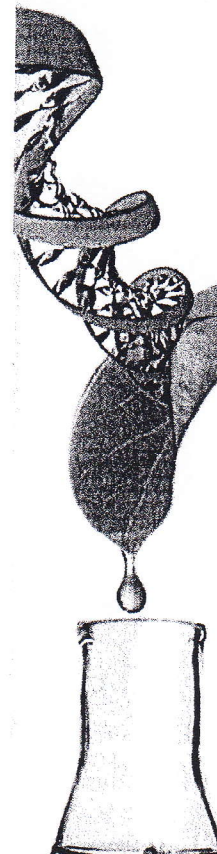
Alchem International Limited

Factory: 25/2, Main Mathura Road, Village Kaili, Ballabgarh, Faridabad – 121 004, Haryana, India

Registered Office: 301, Avalon Apartment, Mangla Puri, Mehrauli-Gurgaon Road, New Delhi – 110 030, India

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<u>Test</u>	<u>Specification</u>	<u>Result</u>
Loss on drying	NMT 0.5%	0.17%
Sulphated Ash	NMT 0.1%	0.06%
Assay	97.0% to 102.0% (Calculated on dried substance)	98.7%
Residual solvents		
Chloroform	: NMT 60 ppm	Less than 10 ppm**
Methanol	: NMT 3000 ppm	808 ppm
Toulene	: NMT 890 ppm	Less than 10 ppm**
Microbiological Control		
Total Viable Bacterial Count	: NMT 1000 cfu/gm	20 cfu/gm
Total Viable Yeast & Moulds	: NMT 100 cfu/gm	Less than 10 cfu/gm
Staphylococcus aureus	: Should be absent/1gm	Absent/1gm
Pseudomonas aeruginosa	: Should be absent/1gm	Absent/1gm
Bile tolerant Gramnegative Bacteria	: Should be absent/1gm	Absent/1gm
Escherichia coli	: Should be absent/1gm	Absent/1gm
Salmonella species	: Should be absent/1gm	Absent/1gm

* Indicates the disregard limit of impurity

** Indicates the limit of detection of residual solvents

Evaluation: Product corresponds with the requirements of current European Pharmacopoeia.

Storage Conditions: Store in a well closed container protected from light below 30°C.

Transportation Temperature: Below 40°C.

Prepared by

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