Art.-Nr.: 6610
Charge: 22003532

COPY QA APPROVED
Date 08.11.22
Signature

F&A PHARMA
F. & A. PHARMA-Handels-GmbH
Bonhoefferring 41 • D-46286 Dorsten • Germany
Phone: +49(0)2369-9261947 • Fax: +49(0)2369-9261950

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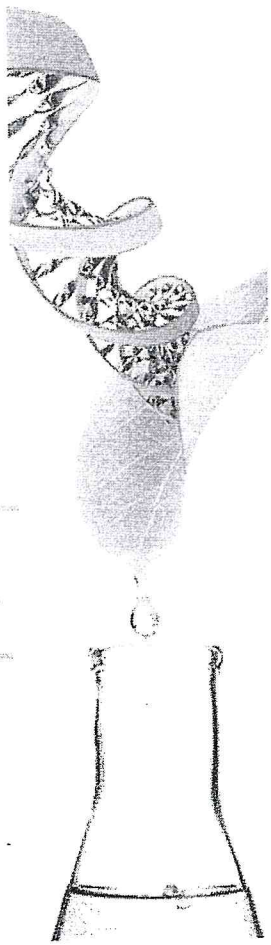
CERTIFICATE OF ANALYSIS

(Hyoscine Hydrobromide EP)

T.C. No.	:	203/2022	Date of Release	:	14/10/2022
Product Name	:	**Hyoscine Hydrobromide EP**	Batch Number	:	**255203307001**
Date of Manufacturing	:	22/07/2022	Batch Size	:	15.130 Kg
Date of Expiry	:	21/07/2027	Dispatch Quantity	:	0.500 Kg

Analytical Protocol Reference: 2552/E-Rev.06+Buyer's Req.

Test	Specification	Result
Character		
	Appearance (Visual test) A white or almost white, crystalline powder or colourless crystals, efflorescent.	White crystalline powder, efflorescent.
	Solubility (Visual test) Freely soluble in water Soluble in ethanol 96%.	Freely soluble in water Soluble in ethanol (96%)
Identification		
A.	**Specific optical rotation** $(\alpha)^{20}_D$ (Polarimeter) It complies with the test for specific optical rotation	Complies with the test for specific optical rotation.
B.	**Infrared Absorption Spectrophotometry** (IR spectrophotometer) IR spectrum of sample should correspond with the IR spectrum of standard.	IR spectrum of sample corresponds with the IR spectrum of standard.
C.	Dissolve about 50 mg in 5 mL of water R and add 5 mL of picric acid solution R drop wise and with shaking. The precipitate, washed with water R and dried at 100 °C to 105 °C for 2 hours, melts (2.2.14) at 188 °C to 193 °C	Melts at 188°C to 192°C.
D.	To about 1 mg add 0.2 mL of fuming nitric acid R and evaporate to dryness on a water-bath. Dissolve the residue in 2 mL acetone R and add 0.1 mL of a 30g/L potassium hydroxide R. in methanol R. A violet colour develops.	A violet colour developed.
E.	**Reaction of Bromides** Its gives reaction (a) of bromides (2.3.1).	Gives reaction (a) of bromides.
pH (of solution S)		
	4.0 to 5.5	4.46
Specific optical rotation $(\alpha)^{20}_D$ (of solution S by Polarimeter)		
	(-)24 to (-)27 (Calculated on anhydrous substance)	(-)26.5
Sulfated ash		
	NMT 0.1%	0.04%



14/10/22
Prepared by

14/10/22
Checked by

14/10/22
Q.C. Incharge

Alchem International Private Limited

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

Registered Office: 201, Empire Plaza, Mehrauli-Gurgaon Road, Sultanpur, New Delhi – 110 030, India

Contact: Telephone – +91-129-426 6000; Fax – +91-129-230 9990, 230 9991, 230 7971

E-mail: contact@alcheminternational.com

Annexure: AIL/COAFP/19/12/17

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Date of Expiry	:	21/07/2027	Dispatch Quantity	:	0.500 Kg

Analytical Protocol Reference: 2552/E-Rev.06+Buyer's Req.

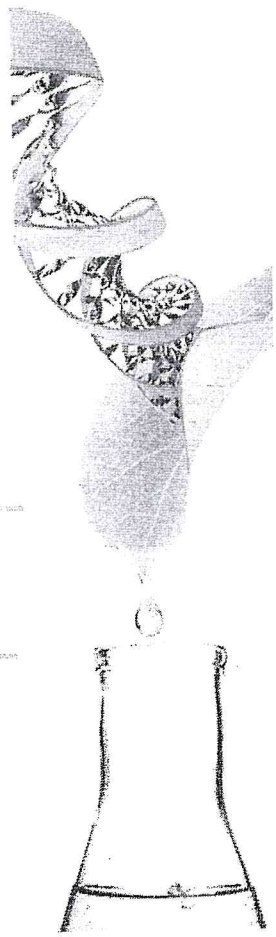
Test	Specification	Result
Water	10.0% to 13.0%	12.2%
Related substances (Liquid Chromatography)		
Impurity A (hyoscyamine)	: NMT 0.1%	Less than 0.05%*
Impurity B (norhyoscine)	: NMT 0.5%	0.07%
Impurity C (apohyoscine)	: NMT 0.1%	Less than 0.05%*
Impurity D (DL-tropic acid)	: NMT 0.1%	Less than 0.05%*
Any other impurity (for each impurity)	: NMT 0.1%	Less than 0.05%*
Total impurities	: NMT 0.7%	0.07%
Residual solvents		
Acetonitrile	: NMT 410 ppm	Less than 10 ppm**
Methanol	: NMT 3000 ppm	Less than 10 ppm**
Methylene Chloride	: NMT 600 ppm	Less than 10 ppm**
Assay	99.0% to 101.0% (Calculated on anhydrous substance)	100.4%
Microbiological Control		
Total Viable Bacterial Count	: NMT 1000 cfu/g	25 cfu/g
Total Viable Yeast & Moulds	: NMT 100 cfu/g	Nil cfu/g
Staphylococcus aureus	: Should be absent/g	Absent/g
Pseudomonas aeruginosa	: Should be absent/g	Absent/g
Bile Tolerant gram negative bacteria	: Should be absent/g	Absent/g
Escherichia coli	: Should be absent/g	Absent/g
Salmonella species	: Should be absent/g	Absent/g

* Indicates the disregard limit of impurity
** Indicates the limit of detection of residual solvent

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.



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