

## Certificate of analysis



Article	6610	Scopolaminhydrobromid, API	
Synonym		Scopolamini hydrobromidum, Hyoscini hydrobromidum	
Synonym		Hyoscine hydrobromide, API	
Batch	24000160		
Specification	Ph.Eur. 11.0		
Production date	07.2022	Retest date	07.2025

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
IR spectrophotometry	According to specification	Complies
E	According to specification	Complies
Tests	According to specification	Complies
pH-Value	4.0 ... 5.5	4.5
Specific optical rotation	-27 ... -24	-26
Related substances	According to specification	Complies
Impurity A	Max. 0.1 %	0.0 %
Impurity B	Max. 0.5 %	0.0 %
Impurity C	Max. 0.1 %	0.0 %
Impurity D	Max. 0.1 %	0.0 %
Any other impurity	Max. 0.1 %	0.0 %
Total of all impurities	Max. 0.7 %	0.0 %
Water	10.0 ... 13.0 %	12.5 %
Sulphated ash	Max. 0.1 %	0.0 %
Assay	99.0 ... 101.0 %	100.5 %
Correction factor weighing (f, NRF)	1,000	1,002
Complies specification		Yes



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22 ENE 2025

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Specification	Ph.Eur. 11.0	
Production date	07.2022	Retest date 07.2025

Release date	15.01.2024	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Alchem International Private Limited		
Manufacturer batch	255203307001		
Manufacturer street	25/2 Main Mathura Road, Village Kalli		
Manufacturer city	121 004 Faridabad, Haryana		
Manufacturer country	Indien**		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 24000160 complies specification.

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