

Certificate of analysis



Article	4052	Ethacridinlactat-Monohydrat, API
Synonym		Aethacridinlactat, Ethacridini lactas monohydricus
Synonym		Ethacridine lactate monohydrate, API
Batch	162734	
Specification	PH.EUR. 8.0	
Expiry date	06.2018	

Test	Specification	Result
Characters	In accordance	Complies
-Appearance	In accordance	Complies
-Solubility	In accordance	Complies
Identification	In accordance	Complies
-IR spectrophotometry	In accordance	Complies
Tests	In accordance	Complies
-pH	5,5 - 7,0	5,9
-Related substances	In accordance	Complies
- Jede Verunreinigung	Je max 0,3 %	Je max 0,05 %
- Sum of all imp.	Max 1 %	0,16 %
-Heavy metals	Max 50 ppm	Max 50 ppm
-Loss on drying	4,5 - 5,5 %	5,4 %
-Sulphated ash	Max 0,1 %	0,00 %
Assay	99,0 - 101,0 %	99,7 %
Correction factor weighing (f, NRF)	*****	1,007
Complies specification	*****	Yes

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Test	Specification	Result
GMP-conform		
Release date	22.11.2016	Head of Quality Control
Manufacturer	Liaoyuan Silver Eagle Pharmaceutical CO. LTD.	Fr. Dr. Haßel.
Manufacturer Batch	A201506004	
Manufacturer City	136200 Jilin Youyo Industry Area of Liaoyuan	
Manufacturer street	No 2 Wealth Northern Road, Youyo Economic Development Zone	
Manufacturer Country	China	

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