Certificate of analysis

Article	4279	Clioquinol, API	
Synonym		Jodchloroxychinolinum	
Synonym		Clioquinol, API	
Batch	24001423		
Specification	Ph.Eur.11.0		
Production date	01.2024	Retest date	01.2027

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
Tests	According to specification	Complies
Acidity or alkalinity	According to specification	Complies
Related substances	According to specification	Complies
Impurity A	Max. 2.0 %	0.9 %
Impurity B	Max. 1.0 %	< 0.1 %
Impurity C	Max. 1.0 %	0.0 %
Each unspecified impurity	Max. 0.10 %	< 0.05 %
Total of all impurities	Max. 3.0 %	1.0 %
Halides	Max. 140 ppm	< 140 ppm
Loss on drying	Max. 0.5 %	0.1 %
Sulphated ash	Max. 0.1 %	0.1 %
Assay	98.0 ... 102.0 %	100.4 %
Correction factor weighing (f, NRF)	1,000	1,001
Complies specification		Yes

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Release date	21.08.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	M/s. Eskay Iodine Pvt. Ltd.		
Manufacturer batch	08053D24		
Manufacturer street	Plot No. 907/2		
Manufacturer city	393 110 Jhagadia, Dist-Bharuch		
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 24001423 complies specification.

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