

FINISHED PRODUCT: CERTIFICATE OF ANALYSIS			
DEPARTMENT : QUALITY CONTROL			
Ref .SOP No	QCS/017	Format No. : QC/017/F/02	

Name of product	Clioquinol EP	Date of Manufacture	Jan - 2024
Batch Number	08053D24	Date of Expiry	Dec - 2028
A.R. Number	ESKAY/2024/01674	Batch Size	350 KG
Date of Release	10/05/2024	Date of Sampling	10/05/2024
Mfg. Lic No	G/25/2008		

Sr. No.	Test	Observation	Specification
1	Appearance	Light yellow powder	Almost white, light yellow, brownish yellow or yellowish-grey powder.
2	Solubility	Complies	Practically insoluble in water, sparingly soluble in methylene chloride, very slightly soluble or slightly soluble in ethanol (96%)
3	Identification (A)	Complies	(A)UV: To be comply.
4	Identification (B)	Complies	(B) IR: To be comply
5	Identification (C)	Complies	(C) When heated, violet fumes are produced
6	Identification (D)	Complies	(D) A dark green colour developed
7	Acidity or alkalinity	0.3 ml of 0.01M sodium hydroxide is required.	NMT 0.5 ml of 0.01M sodium hydroxide is required to change the colour of the indicator to pink.
8	Halides	Complies	NMT 140 ppm, expressed as chlorides.
9	Loss On Drying Determined on 1.0g by drying in a desiccator at a pressure not exceeding 0.7kPa for 24 hours	0.31	NMT 0.5 %
10	Related Substances by HPLC 1)	0.94	1) Impurity A: NMT 2.0%
11	Related Substances by HPLC 2)	0.04	2) Impurity B: NMT 1.0%
12	Related Substances by HPLC 3)	0.02	3) Impurity C: NMT 1.0%
13	Related Substances by HPLC 4)	0.05	4) Unspecified impurities: NMT 0.1%
14	Related Substances by HPLC 5)	1.07	5) Total of nominal impurities NMT 3.0%
15	Sulphated ash	0.08	NMT 0.1%.



Factory : Plot No. 907/2, Jhagadia GIDC Estate, Jhagadia, Dist. Bharuch - 393 110, Gujarat, India.
Tel : +91 9979909072, email : sunilgsharda@sk1932.com Website : www.sk1932.com
Office : 3-A, Shirsagar Estate, Dr. Annie Besant Road, Worli, Mumbai- 400 018, India.
Tel : +(91-22) 6622 7575 Fax : +(91-22) 6622 7600 E-Mail : eskay@sk1932.com

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Sr. No.	Test	Observation	Specification
16	Assay on dried basis	99.70	98.0 to 102.0%
17	Particle Size	15.064	99% < 25 µm
18	Total count of Bacteria	10	Max.1000 CFU/g
19	Total count of moulds and yeasts	Absent	Max.100 CFU/g
20	Search and identification of Pathogens	Absence of all Pathogens	Absence of Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa in 1 gm and absence of Salmonella sp. in 10 gm

Remarks: Product complies as per above specification.

Signature	Prepared By Sanjana Purohit	Checked by Amar Patel	Approved by Sanjay Thakor
Date	10/05/2024 (Quality Control)	10/05/2024 (Quality Control)	10/05/2024 (Quality Assurance)

This certificate has been generated electronically and is valid without signature.