



METAPHARMACEUTICAL

N DE LOTE:

0141225

16/12/2025

CERTIFICATE OF ANALYSIS

Nº 890000006741

PRODUCT CHLORHEXIDINE DIACETATE EP

Manufacturing Date January 30, 2025

Lot No. 104250037

Expiry date January 29, 2030

TEST	SPECIFICATION	RESULT
Description	White or almost white microcrystalline powder	Conforms
Identification by IR	IR spectrum is concordant with the reference spectrum of the standard	Conforms
Impurity P (chloroaniline)	Less than, or equal to, 500 ppm	52 ppm
Loss on drying	Less than, or equal to, 3.5 %	1.24 %
RELATED SUBSTANCES		
Sum of impurities I and O	Less than, or equal to, 0.4 %	Less than 0.05 %
Impurity K	Less than, or equal to, 0.3 %	0.06 %
Impurity A	Less than, or equal to, 0.15 %	Less than 0.05 %
Impurity H	Less than, or equal to, 0.15 %	0.08 %
Impurity N	Less than, or equal to, 0.15 %	Not Detected
Any unspecified impurity	Less than, or equal to, 0.10 %	Less than 0.05 %
Total impurities	Less than, or equal to, 0.8 %	0.14 %
Sulphated Ash	Less than, or equal to, 0.15 %	Less than 0.05 %
Assay by titration (on dry)	98.0 - 101.0 %	99.5 %

ADDITIONAL INFORMATION

TESTED ACCORDING TO CEP 2018-123 - REV 02

Printing Date: 28/11/25

Reviewed and approved by NURIA GILART (Resp QC Compliance & Documentation Suppo)
2025-10-13

Electronically signed in compliance with 21 CFR Part 11.



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