METAPHARMACEUTICAL IND SL
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CLORHEXIDINA DIACETATO (EUR. PH.)

PRODUCT CODE: 151318	CAS Nº: 56-95-1	ANALYSIS Nº: 123/24	
MANUFACTURER BATCH:	104240092	CERTIFICATE ID:	42.110
SUPPLIER BATCH:	----	MANUFACTURING DATE:	15/03/2024
METAPH BATCH:	0070524	EXPIRY DATE:	14/03/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, microcrystalline powder	White microcrystalline powder
Identification A	Complies	Complies
Impurity P (chloroaniline)	=< 500 ppm	50 ppm
Related substances		
Sum of impurities I and O	=< 0.4 %	< 0.05 %
Impurity K	=< 0.3 %	0.1 %
Impurity A	=< 0.15 %	Not Detected
Impurity H	=< 0.15 %	0.1 %
Impurity N	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.10 % (#)
Total impurities	=< 0.8 %	0.4 %
Loss on drying	=< 3.5 %	1.8 %
Sulfated ash	=< 0.15 %	< 0.1 %
Assay	98.0 - 101.0 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Unspecified impurities detailed underneath:
RT (52.66 min) = 0.07 %
RT (53.40 min) = 0.09 %

Chlorhexidine Diacetate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.

STORAGE

Keep the containers tightly closed in a well-ventilated place.

Analysis date: 20/06/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000250