



TECHNICAL DATA SHEET

151318-TDS-ENG-2024

CLORHEXIDINA DIACETATO (EUR. PH.)		
DESCRIPTION DCI: CHLORHEXIDINE ACETATE		DESCRIPTION DOE: CLORHEXIDINA ACETATO
CAS Nº: 56-95-1	EC Nº: 200-302-4	AEMPS CODE: 656AC
MOL. WEIGHT: 625,57	MOL. FORMULA: C ₂₆ H ₃₈ Cl ₂ N ₁₀ O ₄	ARTICLE CODE: 151318

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, microcrystalline powder
Solubility	Sparingly soluble in water, soluble in ethanol (96 %), slightly soluble in glycerol and in propylene glycol
Identification A	Complies
Impurity P (chloroaniline)	=< 500 ppm
Related substances	
Sum of impurities I and O	=< 0.4 %
Impurity K	=< 0.3 %
Impurity A	=< 0.15 %
Impurity H	=< 0.15 %
Impurity N	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.8 %
Loss on drying	=< 3.5 %
Sulfated ash	=< 0.15 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.

The above information does not exempt from the obligation to identify the product before use.