



## TECHNICAL DATA SHEET

0421-TDS-ENG-2024

CLORHEXIDINA DIGLUCONATO 20 % (EUR. PH.)		
DESCRIPTION DCI: CHLORHEXIDINE DIGLUCONATE		DESCRIPTION DOE: CLORHEXIDINA DIGLUCONATO
CAS Nº: 18472-51-0	EC Nº: 242-354-0	AEMPS CODE: 656DG
MOL. WEIGHT: 897,76	MOL. FORMULA: C34H54Cl2N10O14	ARTICLE CODE: 0421

ATTRIBUTES	SHOULD BE
Appearance	Almost colourless or pale-yellowish liquid
Solubility	Miscible with water, with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96 %)
Identification A	Complies
Identification B	Complies
Relative density	1.06 - 1.07
pH	5.5 - 7.0
Impurity P (chloroaniline)	=< 500 ppm
Related substances	
Impurity N	=< 1.0 %
Impurity H	=< 0.5 %
Impurity A	=< 0.4 %
Impurity J	=< 0.4 %
Impurity K	=< 0.4 %
Sum impurities I and O	=< 0.4 %
Impurity G	=< 0.3 %
Impurity B	=< 0.2 %
Impurity F	=< 0.2 %
Impurity L	=< 0.2 %
Impurity Q	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 3.0 %
Assay	199 - 210 g/L

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the container tightly closed. Store in a fresh an cool place. Protect from light.

### REMARKS

Chlorhexidine Digluconate 20% 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,



## TECHNICAL DATA SHEET

0421-TDS-ENG-2024

CLORHEXIDINA DIGLUCONATO 20 % (EUR. PH.)		
DESCRIPTION DCI: CHLORHEXIDINE DIGLUCONATE		DESCRIPTION DOE: CLORHEXIDINA DIGLUCONATO
CAS Nº: 18472-51-0	EC Nº: 242-354-0	AEMPS CODE: 656DG
MOL. WEIGHT: 897,76	MOL. FORMULA: C <sub>34</sub> H <sub>54</sub> Cl <sub>2</sub> N <sub>10</sub> O <sub>14</sub>	ARTICLE CODE: 0421

which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.