



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250395

Product:	
Lot:	250395
Expiry date:	02/08/2026
Reference:	Cumple PhEur11.6
Synonyms:	Sol. acuosa de clorhexidina gluconato 20%.
Formula:	C ₃₄ H ₅₄ Cl ₂ N ₁₀ O ₁₄
Molecular weight:	898 g/mol

Assay	Result	Specification
Identification	Conform (A,B)	
Organoleptic properties	Conform	
Density	1,06 g/ml	1,060-1,070 g/ml
pH	6,1	5,5 - 7,0
Related substances (HPLC)	Conform	
4-chloroaniline	37 ppm	<= 500 ppm
Assay	200 g/l	190 - 210 g/l
Impurity A	< 0,05 %	<= 0,4 %
Impurity B	0,07 %	<= 0,2 %
Impurity F	< 0,05 %	<= 0,2 %
Impurity G	0,07 %	<= 0,3 %
Impurity H	0,23 %	<= 0,5 %
Impurities I+O	< 0,05 %	<= 0,4 %
Impurity J	< 0,05 %	<= 0,4 %
Impurity K	0,06 %	<= 0,4 %
Impurity L	< 0,05 %	<= 0,2 %
Impurity N	0,19 %	<= 1,0 %
Impurity Q	< 0,05 %	<= 0,2 %
Unspecified Impurities	0,05 %	<= 0,10 %
Total impurities	0,67 %	<= 3,0 %

Organoleptic characteristics: Almost colourless or pale-yellowish liquid. Miscible with water, with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/03/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Product	Name	Capacity	Batch
1119902	CLORHEXIDINA DIGLUCONATO 20%	100 g	250395-J-1
1119902	CLORHEXIDINA DIGLUCONATO 20%	100 g	250395-J-2
1119905	CLORHEXIDINA DIGLUCONATO 20%	1 kg	250395-P-1
1119905	CLORHEXIDINA DIGLUCONATO 20%	1 kg	250395-P-2
1200130	CLORHEXIDINA DIGLUCONATO 20%	5 kg	250395-Q-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

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