

## Chlorhexidine digluconate solution

<b>CODE ARTICLE:</b> 91339	<b>BATCH:</b> 0129226
<b>TEST DATE:</b> 08/07/2024	<b>TEST:</b> QC-00266184
<b>EXPIRY DATE:</b> 05/03/2026	<b>FABRICATION DATE:</b> 05/03/2024
	<b>MR:</b> 897,80
	<b>FORMULA:</b> C22H30Cl2N10·2C6H12
<b>SYNONYMS / BOTANICAL NAME:</b> 1,1'-Hexametilen-bis-[5-(4-clorofe-nil)biguanida], digluconato	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	TRANSPARENT LIQUID				PH.EUR.*
COLOUR	COLOURLESS				PH.EUR.*
<b>IDENTIFICATION</b>					
IDENTIFICATION A (IR SPECTRUM)	PASS				PH.EUR.*
IDENTIFICATION B (TLC)	PASS				PH.EUR.
PH	6,1 -		5,5	7	PH.EUR.*
DENSITY	1,064 G/ML		1,06	1,07	PH.EUR.
<b>RELATED SUBSTANCES (HPLC)</b>					
TOTAL IMPURITIES	0,21 %		-	3	PH.EUR.
UNSPECIFIED IMPURITIES	<0,05 %			0,10	PH.EUR.
IMPURITY A	<0,05 %			0,4	PH.EUR.
IMPURITY B	<0,05 %			0,2	PH.EUR.
IMPURITY F	N.D. %			0,2	PH.EUR.
IMPURITY G	<0,05 %			0,3	PH.EUR.
IMPURITY H	0,16 %		0,0	0,5	PH.EUR.
IMPURITIES I+O	0,05 %		0,0	0,4	PH.EUR.
IMPURITY J	<0,05 %			0,4	PH.EUR.
IMPURITY K	<0,05 %			0,4	PH.EUR.
IMPURITY L	<0,05 %			0,2	PH.EUR.
IMPURITY N	<0,05 %			1	PH.EUR.
IMPURITY Q	<0,05 %			0,2	PH.EUR.
4-CHLOROANILINE	8 ppm		-	100	PH.EUR.
ASSAY	19,5 %		19	21	PH.EUR.
<b>MICROBIOLOGICAL CONTROL</b>					
TOTAL AEROBICS	PASS	cfu/g		1000	Manufacture's Standard
MOLDS AND YEASTS	PASS	cfu/g		100	Manufacture's Standard
BILE-TOLERANT GRAM-NEGATIVE BACTERIA	PASS			Ausencia/g	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard

*NON-sterile*



**Silvia Sancho-Tello Ripoll**  
Technical Director.

**The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE**

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer Batch: 104240082    Manufacturer Code: 56833    Supplier Code: 405110

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