

Chlorhexidine digluconate 20%

CODE ARTICLE: 94188	BATCH: 0125817
TEST DATE: 29/02/2024	TEST: QC-00261921
EXPIRY DATE: 18/07/2025	FABRICATION DATE: 19/07/2023
	MR: 897,80
	FORMULA: C22H30Cl2N10·2C6H12
SYNONYMS / BOTANICAL NAME: 1,1'-Hexametilen-bis-[5-(4-clorofe-nil)biguanida], digluconato	
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	TRANSPARENT LIQUID				PH.EUR.*
COLOUR	PALE YELLOW				PH.EUR.*
IDENTIFICATION					
IDENTIFICATION A (IR SPECTRUM)	CONFORM				PH.EUR.*
IDENTIFICATION B (TLC)	CONFORM				PH.EUR.
PH	5,6 -		5,5	7	PH.EUR.*
DENSITY	1,063 G/ML		1,06	1,07	PH.EUR.
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	0,34 %		-	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	0,2 %		0,0	0,5	PH.EUR.
IMPURITIES I+O	0,08 %			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	0,06 %		0,0	1	PH.EUR.
IMPURITY Q	<0,05 %			0,2	PH.EUR.
4-CHLOROANILINE	9 ppm		-	100	PH.EUR.
ASSAY	19,7 %		19	21	PH.EUR.
MICROBIOLOGICAL CONTROL					
TOTAL AEROBICS	CONFORM	cfu/g		1000	Manufacture's Standard
MOLDS AND YEASTS	CONFORM	cfu/g		100	Manufacture's Standard
BILE-TOLERANT GRAM-NEGATIVE BACTERIA	CONFORM			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: 104230255 Manufacturer Code: 56833 Supplier Code: 405110

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