

Lieferposition/Datum  
83028852 000020/24.01.2014

Product Name: UBISTESIN forte

Batch No. 540015  
Expiry Date (MM/YY) 11 / 15  
Cartridge No. 538068  
Manufacturing Date(DD.MM.YYYY) 09.12.2013

Parameters	Unit	Value	lower Limit	upper Limit	Reference
Identity Articaine hydrochloride*	-	OK	-	-	
Identity Epinephrine**	-	OK	-	-	
Epinephrine sulfonic acid	ppm	0,37	-	-	
Articaine hydrochloride	mg/ml	39,2	38,0	≤0,40	
Epinephrine	ppm	10,4	9,9	42,0	
Sodium sulphite	mg/ml	0,55	0,45	10,9	
Articainic acid	ppm	29	-	0,63	
Appearance***	-	OK	-	≤100	
pH	-	3,9	-	-	
Sterility (sterile)	-	OK	3,6	4,4	
Bacterial endotoxins	<28 EU/ml	complies	-	-	
Subvisible particles*****	-	complies	-	-	

\*Rf-value concordant with reference substance

\*\*Retention time concordant with reference substance

\*\*\*clear, not opalescent, colourless liquid

\*\*\*\*\*max. 6000 particles  $\geq 10\mu\text{m}$ ; max. 600 partic.  $\geq 25\mu\text{m}$  per container

The batch was manufactured in accordance with good manufacturing practices and subjected to full quality control tests before release for general sales.

3M Deutschland GmbH  
Qualitymanagement

\* \* \* \* C O N F I D E N T I A L \* \* \*



Vorsitzender des  
Aufsichtsrats:  
Kurt-Henning Wiethoff

Geschäftsführer:  
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