

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	42,0	≤0,40
Epinephrine	ppm	10,4	9,9	10,9	
Sodium sulphite	mg/ml	0,55	0,45	0,63	
Articainic acid	ppm	29	-	≤100	
Appearance***	-	OK	-	-	
pH	-	3,9	3,6	4,4	
Sterility (sterile)	-	OK	-	-	
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 ≥10µm; max. 600 partic. ■25µm 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

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