



Stabilimento di Capua  
RIF. PFS-250 REV. 07/1

## GMP COMPLIANCE CERTIFICATE / SHIPPING AUTHORIZATION

Code	Description:	Batch n°
<b>2103010</b>	<b>Orabloc® 40mg/ml + 0,01 mg/ml artikain, epinefrin 50 x 1.8mL cartridges</b>	<b>0191</b>

Customer Item: NA

Destination Country: Serbia

QC Analysis Ref N°: 700061780

Release Certificate n°: 265/2020

Analysis	Specifications	Results	Methods
Appearance	Cartridges containing a clear, colourless solution, free from visible particles	Conform	CQ/C1B
Extractable volume	≥ 1.8 ml	1.8	CQ/C0G
pH	3.0 – 5.0	3.7	CQ/C4N
Articaine Hydrochloride identity	Positive	Positive	CQ/C2N
Articaine Hydrochloride assay	38.0 – 42.0 mg/ml	40.2	CQ/C2N
Related substances:			
• Impurity A	≤ 0.2 %	< 0.02	CQ/C2N
• Impurity B	≤ 0.4 %	< 0.02	CQ/C2N
• Any single unspecified impurity	≤ 0.10 %	< 0.02	CQ/C2N
• Total of unspecified impurities	≤ 0.5%	< 0.02	CQ/C2N
• Total impurities	≤ 0.7%	< 0.02	CQ/C2N
Epinephrine identity	Positive	Positive	CQ/C0F
Epinephrine assay	9.0 – 11.0 µg/ml	10.6	CQ/C0F
Sodium Metabisulphite identity	Positive	Positive	CQ/C0H
Sodium Metabisulphite assay	0.40 – 0.60 mg/ml	0.44	CQ/C0H
Subvisible particles:			
• ≥ 25 µm diameter	≤ 600 counts/cartridge	6	S115/e.a.-15
• ≥ 10 µm diameter	≤ 6000 counts/cartridge	608	S115/e.a.-15
Sterility	Sterile	Sterile	CQ/B0E
Bacterial Endotoxins	NMT 28 E.U./ml	< 4	CQ/B0D

Further information: NA

Quality Control  
Dr. Mariacarla Crispino

Batch Record Reviewer  
Dr. Valentina Picardi

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Quality Assurance  
Dr. Mariacarla Crispino

Qualified Person  
Dr. Toni Valente

Manufacturing Date  
November 2020

Expiry Date  
November 2022

Release Date  
DECEMBER 16<sup>th</sup> 2020

Sede Legale e Corporate Office:  
Strada Statale Appia 7 bis 46/48  
81043 Capua (CE)  
Phone: +39 0823 62.61.11  
Fax: +39 0823 62.62.28

Capitale Sociale deliberato  
sottoscritti e versati € 3.716.341,74  
P.IVA 04920860964  
R.E.A. n. CE-227340  
Web: www.pierrelgroup.com  
Email: pierrelspa@pierrelgroup.com

Produzione e Logistica (Logistics & Manufacturing):  
Strada Statale Appia 7 bis 46/48  
81043 Capua (CE)  
Phone: +39 0823 62.61.11  
Fax: +39 0823 62.62.28  
Email: manufacturing@pierrelgroup.com