



NORMON

Ronda de Valdecarrizo, 6
28760 Tres Cantos. Madrid. España
Tel.: 91 806 52 40
Fax: 91 806 52 56
Fax: 91 806 52 58 Dpto. Técnico
www.normon.es

**CERTIFICADO DE LIBERACIÓN
BATCH RELEASE CERTIFICATE**

D^a Alicia Govantes, Directora Técnica de LABORATORIOS NORMON, S.A., certifica que el producto:

Ms. Alicia Govantes, Technical Manager/Qualified Person of LABORATORIOS NORMON, S.A., certifies that the product:

**CITOCARTIN with adrenalin
40 mg/ml + 10 microgram/ml injectable solution
1861 boxes with 50 cartridges - Batch M3VJ1**

Ha sido fabricada de acuerdo a las Normas de Correcta Fabricación y cumple con lo establecido en el dossier de dicho producto.

Has been manufactured according to the Good Manufacturing Practices and complies with its Dossier.

Los resultados de los controles efectuados sobre este lote son conformes a las especificaciones del Dossier.

Quality control testing complies with the specifications stated in the Dossier.

Tres Cantos, 11th July 2017



NORMON

TECHNICAL MANAGEMENT/Q.P.

Alicia Govantes
Qualified Person

**NORMON**

Ronda de Valdecarrizo, 6
28760 Tres Cantos. Madrid. España
Tel.: +34 91 806 52 40
Fax: +34 91 806 52 58

Certificate of Analysis

ARTICAINE + ADRENALINE (CITOCARTIN) MOLTENI 40MG/ML 10 UG/ML 50

CRT LT

BATCH: M3VJ1

PRODUCT CODE: 4-MOLCIT10ECLT

MANUF. DATE: 19-06-2017

EXPIRY DATE: 06-2019

PHARMA TYPE: Solution for injection

ANALYTICAL METHOD CODE: A-CIT10(PT)/01

SPECIFICATION CODE: E-2-A-CIT10(PT)/00

ANALYTICAL CERTIFICATE CODE: CA-2-A-CIT10(PT)/00

Test	Specification	Result
DESCRIPTION	Complies with macroscopic examination. Cartridge containing a clear and colourless solution, without suspended particles.	Complies
IDENTIFICATION		
Articaine hydrochloride:	Positive for articaine hydrochloride (HPLC).	Positive
Adrenaline:	Positive for adrenaline (HPLC).	Positive
pH	Between 3.4 and 4.0	3.5
AVERAGE EXTRACTABLE VOLUME	>= 1.7 ml	1.7 mL
SLIDING PLUNGER (1)	<= 30 N Fmax	<15 N
SLIDING PLUNGER (2)	2-20 N Freib	<15 N
TEST FOR LEAKAGE	(1) Complies test	Complies
ASSAY (HPLC)		
Articaine HCl (%):	95%-105% of stipulated amount of articaine hydrochloride	104 %
Articaine HCl (mg/ml):	38.0-42.0 mg/ml	41.4 mg/mL
Adrenaline (bitartrate) (µg/ml):	10.5-11.55 µg/ml	11.41 µg/ml
Adrenaline (bitartrate) (%):	105%-115% of stipulated amount of adrenaline (bitartrate)	114 %
ARTICAINE IMPURITIES (HPLC)		
Articaine acid (Imp. B):	<= 0.3%	0.1 %
Single unknown impurity:	<= 0.1%	0.0 %
Total impurities (except Imp. B):	<= 0.5%	0.1 %
SODIUM METABISULPHITE	Positive	Positive
IDENTIFICATION		
SODIUM METABISULPHITE	Each ml of solution contains between 0.40 and 0.55 mg/ml of metabisulphite (80%-110%)	0.42 mg/mL
BACTERIAL ENDOTOXINS	(1) Not more than 28 UE/ml	<= 28 UE/ml
STERILITY	(1) Complies test	Complies
PARTICLES		
(1) Visible:	practically absent	Complies
(1) Subvisible >= 10 µm:	<= 3000 particles/ cartridge	0 p/c
(1) Subvisible >= 25 µm:	<= 300 particles/ cartridge	0 p/c



NORMON

Ronda de Valdecarrizo, 6
28760 Tres Cantos. Madrid. España
Tel.: +34 91 806 52 40
Fax: +34 91 806 52 58

Certificate of Analysis

ARTICAINE + ADRENALINE (CITOCARTIN) MOLTENI 40MG/ML 10 UG/ML 50
CRT LT

BATCH: M3VJ1

MANUF. DATE: 19-06-2017

PHARMA TYPE: Solution for injection

ANALYTICAL METHOD CODE: A-CIT10(PT)/01

ANALYTICAL CERTIFICATE CODE: CA-2-A-CIT10(PT)/00

PRODUCT CODE: 4-MOLCIT10ECLT

EXPIRY DATE: 06-2019

SPECIFICATION CODE: E-2-A-CIT10(PT)/00

(1) Complies with current Eur. Ph.

[Signature]
07/07/17
Approval Quality Unit

DISPOSITIONED BY: Sandra Erenas Cabas

DISPOSITION DATE: 07/07/2017 14:14:20

Date of Issue: 07/07/2017 14:16:28

Supervisor: Ildefonso Peloeche Trinidad, Ana Moreno García

Analyst: IAC, MFPB, VSGR, JMR1, AOM, RRN