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SOP 426
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

NEWCO PHARM HUNGARIA KFT
RÁKÓCZI U. 142 - 146.
7100 SZEKSZÁRD
HUNGARY

Hoogstraten, 08.11.2016

Material

F808100-006994-01 LIGNOCAINE HCl 2% 100 ML

Pharmaceutical Form:

Sterile solution

Batch 25588A16 / Manufacturing Date 05.2016 Expiry date 05.2019

Inspection lot 40000016948 from 10.2016

CERTIFICATION STATEMENT: 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.

Formula: Lidocaine Hydrochloride 20 mg - Adrenaline acid tartrate 0,036 mg - excipients q.s. ad 1 ml

Aspect: clear, colourless to light yellow solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml) (NLT)	%	100,74	100,00	
pH		3,86	3,00	4,00
Relative density		1,008	1,000	1,010
Id: Lidocaine HCl		Complies		
Id: Adrenaline tartrate		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Lidocaine HCl	%	101,50	95,00	105,00
Assay: Adrenaline tartrate	%	99,86	87,50	112,50
Assay: Na methyl p-hydroxybenz	%	101,55	90,00	110,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
27.10.2016 10:57:46

Qualified Person

Conclusion:
Quality test complied