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SOP 426  
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ÉRKEZETT 2017 JÚL 10.

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

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

Hoogstraten, 26.06.2017

**Material**

F808100-006994-01 LIGNOCAINE HCl 2% 100 ML

Pharmaceutical Form:

Sterile solution

Batch 26852A11 / Manufacturing Date 04.2017 Expiry date 04.2020

Inspection lot 40000023227 from 04.2017

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)	%	101,00	100,00	
pH		3,56	3,00	4,00
Relative density		1,007	1,000	1,010
Id: Lidocaine HCl		Complies		
Id: Adrenaline tartrate		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Lidocaine HCl	%	99,81	95,00	105,00
Assay: Adrenaline tartrate	%	99,63	87,50	112,50
Assay: Na methyl p-hydroxybenz	%	101,95	90,00	110,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
18.05.2017 10:25:03

Qualified Person

Conclusion:  
Quality test complied