

KELA N.V.

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Established in 1941

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

Produkt - Produit - Product <i>LIDOKEL 02 100 ML</i>	NEWCO PHARM HUNGARIA KFT RAKOCZI U. 146 7100 SZEKSZARD Z.Hd: Dr. Varga
Farm. Vorm - Pharm. Form <i>STERILE SOLUTION</i>	
Art. No. F808100	
Batch Nr. MAN: EXP 20922.11 01-2014 01-2017	
	Hoogstraten, 28.02.14

Formula :

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

Tests Performed	Specifications	Results
Appearance	clear colourless solution	clear colourless solution
Theoretical volume	100 ml 250 ml	100 ml
Average volume	98 - 102 %	100,5 %
pH	3,0 - 4,0	3,63
Specific gravity (s.g.)	1,000 - 1,010	1,008
Refractive index	1,335 - 1,345	1,340
Identifications		
Lidocaine HCl	positive	positive
Adrenaline acid tartrate	positive	positive
Assays		
Lidocaine HCl	95 - 105 %	99,7 %
Adrenaline acid tartrate	87,5 - 112,5 %	101,6 %
Assay preservative	90 - 110 %	93,3 %
Special Tests		
Sterility	sterile	sterile
Conclusion		
CONFORM		

BATCH RELEASE CERTIFICATE :

We declare that this batch has been manufactured and packed according to current GMP rules and has been released into the market.

KELA N.V.
N. VAN EEGHEM
Kris Van Buggenhout
Industrial Pharmacist
Cert. Nr. 1562
Ind. Pharm.