



# Certificate of Analysis

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Puurs Batch Number: B02281

Date Generated: 07-2014

Product Name: LINCOCIN FORTE S SS 24X10ML PLAST  
(LINCAMYCIN HYDROCL.+ NEOMYCIN SULPHATE)

Material Number: F000122436

Date of Manufacture: 02-2014

Expiration Date: 01-2016

Specification Name: P9013001003EU

TEST	RESULT	UNIT	LIMITS
CLARITY	MEETS TEST		NMT REFERENCE II
COLOR	MEETS TEST		NMT Y6 AT TIME OF RELEASE, NMT Y3 AT END OF SHELF LIFE
DESCRIPTION	MEETS TEST		A CLEAR, COLORLESS TO SLIGHTLY YELLOW SOLUTION ESSENTIALLY FREE FROM VISIBLE PARTICULATE MATTER
ENDOTOXINS	MEETS TEST		MEETS TEST
EXTRACTABLE VOLUME	10.2	ML	NMT 50 EU/ML
IDENTIFICATION LINCAMYCIN	POSITIVE		MEETS PH EUR REQUIREMENTS
IDENTIFICATION NEOMYCIN	POSITIVE		POSITIVE
LINCAMYCIN BASE	328	MG/10ML	POSITIVE
LINCAMYCIN SULFOXIDE II	< 0.1	%	313 TO 347 MG/10 ML
METHYLTHIOLINCOSAMIDE	< 0.1	%	NMT 1.0 %
NEAMINE	0.4	%	NMT 2.1%
NEOMYCIN BASE	102	MG/10ML	NMT 3.4 %
PH	4.7		95 TO 105 MG/10 ML
STERILITY	MEETS TEST		4.0 TO 5.5
			MEETS PH EUR REQUIREMENTS (MEMBRANE FILTRATION)

BATCH: A10783

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.  
THIS BATCH OF PRODUCT HAS BEEN FABRICATED/MANUFACTURED, INCLUDING PACKAGING AND QUALITY  
CONTROL IN FULL COMPLIANCE WITH THE GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY  
AND WITH THE SPECIFICATIONS IN THE MARKETING AUTHORISATION OF THE IMPORTING COUNTRY:

POLAND - PL

THE BATCH PROCESSING/PACKAGING AND ANALYSIS WERE  
REVIEWED AND FOUND TO BE IN COMPLIANCE WITH GMP.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: Ilse De Keuster Lot Release Local Timestamp: 24-JUL-2014 09:23:19 Server Timestamp:  
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