



Certificate of Analysis

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Name of Product:	Albiotic 330 mg / 100 mg Intramammalis Szuspenzio A.U.V. [Huvepharma Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
7475-100B	10,080	November 2017	November 2019	12 ml Syringe
Active Ingredients:	<ul style="list-style-type: none"> • Methyl Thioliincosamide • Lincomycin Sulfoxide II • Neamine • Lincomycin Base (as hydrochloride) • Neomycin Sulfate 			

Analytical	Results	Specifications
pH	4.8	4.0 - 5.5
Extractable Volume	Conforms	Meets Ph. Eur
Sterility	Conforms	Meets Ph. Eur
Description	Conforms	A clear, colourless to slightly yellow solution, essentially free from visible particulate matter
Colour	Conforms	Not more than Y6
Clarity	Conforms	Not more than reference II
Bacterial Endotoxins	Conforms	Meets Ph. Eur
Methyl Thioliincosamide	NMT 1.5 %	Not more than 1.5 %
Lincomycin Sulfoxide II	NMT 0.4 %	Not more than 0.4 %
Neamine	NMT 2.9 %	Not more than 2.9 %
Lincomycin Base (as hydrochloride)	324 mg/10 ml	313 to 347 mg/10 mL
Neomycin Sulfate	104 mg/10 ml	95 to 105 mg/10 mL
Identification of Lincomycin Hydrochloride (HPLC)	Conforms	Positive
Identification of Neomycin Sulfate (HPLC)	Conforms	Positive
Identification of Neomycin Sulfate (TLC)	Conforms	Positive
Identification of Lincomycin Hydrochloride (TLC)	Conforms	Positive

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 [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Prepared By:
Date:

Nadine Anderson
22-January-2018

Stephen Mitchell
Qualified Person
& Quality Advisor
PASSED

Step A Mitchell
23 JAN 2018