



CERTIFICATE OF ANALYSIS

Name	INTRAMICIN	Batch N°	1083A4
Presentation	250 ml	Manufacturing date	16-JAN-2015
Code list	19332B	Expiry date	16-JUL-2016

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	White cream homogeneous suspension	COMPLIES
Average fill volume :	100 - 110 %	100
pH :	6.0 - 7.0	6.4
Relative density :	1.170 - 1.230	1.203
IDENTIFICATIONS		
Dihydrostreptomycin sulphate (TLC) :	Rf identical to standard	COMPLIES
Procaine benzylpenicillin (HPLC) :	RT identical to standard	COMPLIES
Sodium methyl parahydroxybenzoate : (HPLC)	RT identical to standard	COMPLIES
LIMIT ASSAY		
Sodium hydroxymethane sulfinate :	< ou = 0.40 g % ml	COMPLIES
ASSAYS		
Dihydrostreptomycin (as sulphate): (microbiology)	18.400 - 21.600 MIU % ml	20.611
Procaine benzylpenicillin (HPLC) :	19.000 - 21.000 g % ml	20.251
Sodium methyl parahydroxybenzoate : (HPLC)	0.126 - 0.154 g % ml	0.139
STERILITY		
According to Ph. Eur.	Sterile	COMPLIES

This batch has been tested in reference to the dossier in force and has been found to meet the specification requirements

COMPLIES / NOT COMPLIES

Checked by : **Maureen MAYENC**

Batch Release number **365340**

Batch Release date **6-FEB-2015**

ACCEPTED by

Stéphanie ZEBST
Quality Assurance Manager

The undersigned certifies this is a true copy of the results of tests and assays.

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