



RELEASE CERTIFICATE

Distributor : Altius SRL

CODE :	306236	
PRODUCT :	BORGAL 24% 100ML	RO
BATCH NUMBER :	4MGX	
EXPIRY DATE :	March 2019	
QUANTITY :	2,952 P	
FINAL DECISION :	Accepted the	5/5/2014

I certify that the above batch has been manufactured, analysed, inspected and tested according to the GMP and marketing authorization and is satisfactory for release for sale.

Qualified Person

LARCHER Sandrine

Printed on

May 7, 2014



**Bulletin
d'Analyses**

**Analysis
Certificate**

PRODUIT / PRODUCT : BORGAL 24% 100ML RO
Lot N° / Batch N° : 4MGX
Contrôle N° / Control N° : 542017
CLIENT / CUSTOMER : Altius SRL
Manufacturing date : April 2014
Expiry date : March 2019

Résultats exprimés pour 100 ml / Results expressed for 100 ml of finished product

306236 4MGX

ANALYSES / ANALYSIS	RESULTATS / RESULTS	NORMES / STANDARDS
CHARACTERS		
Appearance	Passed	Clear, light brownish yellow solution (max BY1) practically free from visible particles
pH undiluted	9.7	9.3 to 10.0
pH diluted with water (1/1)	9.0	8.0 to 9.5
Relative Density at 20°C	1.236	1.210 to 1.250
Extractable volume	105 ml	Min. 100 ml
IDENTIFICATIONS		
Sulfadoxine	Passed	Rt of corresponding peak complies
Trimethoprim	Passed	Rt of corresponding peak complies
TESTS		
Sterility	Passed	No growth detectable
RELATED SUBSTANCES		
Sulfadoxin, known single	0.36 %	Max. 0.7 %
Sulfadoxin, known sum	0.66 %	Max. 1 %
Trimethoprim, known single	0.0 %	Max. 0.3 %
Trimethoprim, unknown single	0.0 %	Max. 0.5 %
Trimethoprim, known sum	0.0 %	Max. 0.5 %
Triméthoprim, unknown sum	0 %	Max. 1 %
ASSAYS		
Sulfadoxin	20.3 g	19.0 to 21.0 g
Trimethoprim	4.0 g	3.8 to 4.2 g

DECISION **Accepté**

Date **5/5/2014**


Qualified Person

LARCHER Sandrine

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