

PRODUIT / PRODUCT : **BORGAL 24% 100ML RO**
 Code produit / Code product : **306236**
 Lot N° / Batch N° : **5G13**
 Quantité / Quantity : **7,962 P**
 Date de fabrication / Manufacturing date : **October 2015**
 Date de validité / Expiry date : **September 2020**

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

Lot informatique / IT batch number : 2346667

Date d'édition / printed on :

November 16, 2015

ANALYSES / ANALYSIS	RESULTATS / RESULTS	NORMES / STANDARDS
CHARACTERS		
Appearance	Passed	Clear, light brownish yellow solution (max BY1) practically free from visible particles
pH undiluted	9.8	9.3 to 10.0
pH diluted with water (1/1)	8.9	8.0 to 9.5
Relative Density at 20°C	1.236	1.210 to 1.250
Extractable volume	103 ml	Min. 100 ml
IDENTIFICATIONS		
Sulfadoxine	Passed	Rt of corresponding peak complies
Trimethoprim	Passed	Rt of corresponding peak complies
TESTS		
Bacterial count	<5	Max 10 UFC/100 ml
Sterility	Passed	No growth detectable
RELATED SUBSTANCES		
Sulfadoxin, known single	0.2 %	Max. 0.5 %
Sulfadoxin, known sum	0.2 %	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 %
Trimethoprim, unknown sum	0 %	Max. 1 %
ASSAYS		
Sulfadoxin	201 g	190 to 210 g
Trimethoprim	39.6 g	38.0 to 42.0 g

Je certifie que le lot ci-dessus a été fabriqué, analysé et contrôlé selon les BPF et les exigences de l'AMM. Ce lot est conforme pour la mise sur le marché.

I certify that above mentioned product has been manufactured and checked in compliance with the GMP requirements and the specifications in the marketing authorization, and is satisfactory for release for sale.

DECISION : Accepté le / Released by

Personne habilitée / Qualified Person

Date de libération / release date : **13/11/2015**

CHAUTARD Audrey

