



Certificat d'analyse / Analysis certificate
Certificat de libération / Release certificate

PRODUIT / PRODUCT : CORTAVANCE 31ML VBI
 Code produit / Code product : 306991
 Lot N° / Batch N° : 5MH5
 Quantité / Quantity : 2,007 P
 Date de fabrication / Manufacturing date : February 2016
 Date de validité / Expiry date : January 2018

Lot informatique / IT batch number 2302150

Date d'édition / printed on :
 March 23, 2016

ANALYSES / ANALYSIS	RESULTATS / RESULTS	NORMES / STANDARDS
CHARACTERS		
Appearance	Passed	Colorless to yellowish limpid solution with characteristic odour of ether
Appearance of the solution	Passed	Limpid and coloration max. 88
Relative density at 20°C	0.923	0.915 to 0.935
Contents	Passed	According to specifications
IDENTIFICATIONS		
Hydrocortisone aceponate	Passed	Identical to the standard
TESTS		
Single Impurities	0.0 %	Max. 1.0 %
Total Impurities	0.0 %	Max. 2.0 %
Impurity E	0.0 %	Max. 1.0 %
Total aerobic microbial count	<10	Max. 100 UFC/g
Total combined yeasts/moulds count	<10	Max. 10 UFC/g
Pseudomonas aeruginosa	Passed	negative
Staphylococcus aureus	Passed	negative
ASSAYS		
Hydrocortisone aceponate	59.4 mg/100ml	55.5 to 61.3 mg/100ml

Je certifie que les informations ci-dessus sont exactes et authentiques. Ce lot a été fabriqué, y compris l'emballage / étiquetage et le contrôle qualité, sur le site mentionné ci-dessous, en conformité avec les exigences BPF des autorités réglementaires locales et avec les spécifications de l'autorisation de mise sur le marché du pays importateur. Les dossiers de fabrication, de conditionnement et analytiques ont été examinés et jugés conformes aux BPF.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control, at the below mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging, and analysis records have been reviewed and found to be in compliance with GMP.

DECISION : Accepté par / Released by

Personne habilitée / Qualified Person

Date de libération / release date : 22/3/2016

CHAUTARD Audrey