

28-04-15;09:51 ;MEDIMPEX
 CORTIZEME KULSOLEGGES SZUSZPENZIO 125 ML
 Gysz:4YB7/PC300728 Lej:15/12/31
 Kisz:1X Me.:Darab
 SZÉKELY KFT részére

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

PRODUIT / PRODUCT : CORTIZEME 125ML HU
 Code produit / Code product : 300728
 Lot N° / Batch N° : 4YB7
 Quantité / Quantity : 1,028 P
 Date de fabrication / Manufacturing date : October 2014
 Date de validité / Expiry date : December 2015

Laboratoire / IT batch number: 2308019

Date d'édition / printed on
 March 19, 2015

ANALYSES / ANALYSIS	RESULTATS / RESULTS	NORMES / STANDARDS
CHARACTERS		
Appearance	Passed	Homogeneous fluid white suspension
pH at 20°C	4.2	4.0 to 6.0
Contents	Passed	According to specifications
IDENTIFICATIONS		
Prednisolone	Passed	Identical to the standard
Neomycin	Passed	Identical to the standard
ASSAYS		
Prednisolone	102.6 mg/100ml	95.0 to 105.0 mg/100ml
Neomycin (as sulfate)	521.1 mg/100ml	475.0 to 525.0 mg/100ml
PRESERVATIVES		
Benzyl alcohol	0.53 ml/100ml	0.45 to 0.55 ml/100ml
Sodium hydroxy methane sulfinate	48.8 mg/100ml	20.0 to 110.0 mg/100ml

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 par / Released by

Personne habilitée / Qualified Person

Date de libération / release date : 18/3/2015

LARCHER Sandrine

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Meoszám:150400004MBT

6.pld. Kiadva: 15/04/28

MEDIMPEX GYÓGYSZER ZRT.
 1158 Bp., Rákospalotai határút 2.
 Pantyiné Dr. Balázs Ilona
 Minőségbiztosítási Vezető
 Csak a piros szín hiteles