DANILON EQUIDOS 1,5G GRANULÁTUM 60X10GR
Gysz:191200 Lej:22/08/31
Kisz:60X10GR Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
Tel:+36-1-414-6477
Fax:+36-1-414-6479

ESTEVE

Esteve Pharmaceuticals, S.A.
Pharmaceutical Plant

GMP Certificate number: NCF/1911/001/CAT

CERTIFICATE OF MANUFACTURE AND BATCH RELEASE

Manufacturing site: **Esteve Pharmaceuticals, S.A.**
C/ de Sant Martí, 75-97
08107 - Martorelles (Barcelona), Spain

Name of Product , Strength, Dosage form / Pack Size (type) :
Danilon Equidos (Suxibuzone) 1.5 g sachets
/ 60 x 10 g sac.

Packaging Batch Number: 191200

Date of manufacture (according to EMEA/CVMP453/01): 08-2018
Expiry Date: 08-2022

Results of analysis:
See attached Certificate of Analysis (CoA) number: 040000097157, 890000135133

Additional information:

- Destination (Country): Hungary - Romania - Slovenia

Certification:
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, packaged and quality controlled at the above mentioned site in full compliance with the EU GMP requirements and with the specifications of the Marketing Authorisathion, including API origin and quality. The batch processing, packaging and analysis records were reviewed and found to be in compliance with the agreed specifications.

(X) No significant deviations during manufacturing / packaging are reported.
( ) The following significant deviations were reported during manufacturing / packaging and properly investigated.

Signature:

Laura Sobrepere, Deputy Technical Director
(Qualified Person according Art. 49, Directive 2001 / 83 / EC)

Date: 04 JUL. 2019

END OF REPORT - Certificate of Manufacture & Batch Release

Meoszám:190800063MBT 6.pld. Kiadva: 20/01/08

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Rákospalotai határút 2.
Nagyné Kári Éva
Minőségbiztosítási szakasszisztens
Csak a piros szín hiteles

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ESTEVE

Esteve Pharmaceuticals, S.A.
C/ de Sant Martí, 75-97
08107 - Martorelles (Barcelona), Spain

CERTIFICATE OF ANALYSIS

Date of analysis: 17-06-2019

Product: DANILON EQUI. DCP 60SOBX10G-H+RO+SLO
Batch: 191200
Date of manufacture: 17-08-2018

TEST	SPECIFICATIONS	RESULTS
Description	Yellow granules	Complies
Uniformity of mass		
Units	10 or 30	10
Mean		101,2 %
Standar Deviation		0,7
Acceptance Value	Complies Ph. Eur.	1,7
CCF Identification		
Suxibuzone	Positive	Positive
Saccharin sodium	Positive	Positive
Quinoline yellow (E-104) (UV)		
Identification	Positive	Periodic Test
Particule size		
> 0.21 mm	Less than 10 %	5 %
Dissolution rate Suxibuzone (UV)		
Units	6, 12 or 24	6
Mean	Q = 75 % in 45 min	94 %
Minimum		92 %
Complies acceptance criteria	Complies Ph. Eur./USP	Complies
Suxibuzone HPLC		
Identification	Positive	Positive
Assay	95.0 - 105.0 % (0.143 - 0.158 g/g)	97,0 %
Assay/sachet	95.0 - 105.0 % (1.425 - 1.575 g/sachet)	97,4 %
Degradation product		
Phenylbutane	Not more than 1.0 %	0,06 %
Microbiological purity	Complies Eur. Ph. 6.3 chapter 5.1.4	Complies

This is to certify that the product has been manufactured and tested according to current EC Good Manufacturing Practices (GMP) and other rules governing Medicinal Products in the EU at the above mentioned in accordance with the especifications in the Marketing Autorisation.

Signed and dated:

L. Sobrepere 04 JUL. 2019
Qualified Person

AN: 040000097157,890000135133

Meoszám:190800063MBT 6.pld. Kiadva: 20/01/08

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