Danilon equidos 1,5g granulátum A.U
Gysz:182411 Lej:22/07/31
Kisz:60x10g Me.:doboz
DR. SZÉKELY KFT. részére

2151 Fót
Keleti Márton u. 19.
Tel:27/537-100
Fax:27/537-100

ESTEVE

Esteve Pharmaceuticals, S.A.
Pharmaceutical Plant

GMP Certificate number: NCF/1842/001/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: 182411

Date of manufacture (according to EMEA/CVMP453/01): 07-2018
Expiry Date: 07-2022

Results of analysis:
See attached Certificate of Analysis (CoA) number: 040000090992, 890000126621

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:

Cristina Colet, Deputy Technical Director

(Qualified Person according Art. 49, Directive 2001 / 83 / EC)

Date: 27 [illegible]

END OF REPORT - Certificate of Manufacture & Batch Release

Esteve Pharmaceuticals, S.A. 08107 - Martorelles (Barcelona), Spain

CERTIFICATE OF ANALYSIS

Date of analysis: 12-11-2018

Product: DANILON EQUI. DCP 60SOBX10G-H+RO+SLO
Date of manufacture: 05-07-2018

Batch: 182411

TEST	SPECIFICATIONS	RESULTS
Description	Yellow granules	Complies
Uniformity of mass		
Units	10 or 30	10
Mean		98,2 %
Standar Deviation		1,2
Acceptance Value	Complies Ph. Eur.	3,3
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	98 %
Minimum		96 %
Complies acceptance criteria	Complies Ph. Eur./USP	Complies
Suxibuzone HPLC		
Identification	Positive	Positive
Assay	95.0 - 105.0 % (0.143 - 0.158 g/g)	97,2 %
Assay/sachet	95.0 - 105.0 % (1.425 - 1.575 g/sachet)	97,4 %
Degradation product		
Phenylbutane	Not more than 1.0 %	0,05 %
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:

C. Colet
Qualified Person

AN: 040000090992,890000126621