ESTEVE

LABORATORIOS Dr. ESTEVE, S.A.

c/Sant Martí s/n
08107 Martorelles (Barcelona) SPAIN

CERTIFICATE OF ANALYSIS

Date of analysis: 18-12-2017

Product: DANILON EQUI DCP 60SOBX10G-H+RO+SLO

Batch: 172769

Date of manufacture: 16-05-2017

TEST	SPECIFICATIONS	RESULTS
Description	Yellow granules	Complies
Uniformity of mass	10 or 30	10
Units		98.6 %
Mean		1.1
Standar Deviation	Complies Ph. Eur	2.5
Acceptance Value		
CCF Identification		Positive
Suxibuzone	Positive	Positive
Saccharin sodium		
Quinoline yellow (E-104) (UV)	Positive	Positive
Identification		
Particule size	Less than 10 %	Periodic Test
> 0.21 mm		7 %
Dissolution rate Suxibuzone (UV)	6, 12 or 24	6
Units	Q = 75 % in 45 min	92 %
Mean		89 %
Minimum	Complies Ph. Eur./USP	Complies
Compl es acceptance criteria		
Suxibuzone HPLC	Positive	Positive
Identification	95.0 - 105.0 % (0.143 - 0.158 g/g)	99.1 %
Assay	95.0 - 105.0 % (1.425 - 1.575 g/sachet)	103.6 %
Assay/sachet		
Degradation product	Not more than 1.0 %	< 0.05 %
Phenylbutane	Complies Eur. Ph. 6.3 chapter 5.1.4	Complies
Microbiological purity		

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 Market ng Autorisation.

Signed and dated:

C. Colet
Qualified Person

19 DIC. 20

AN: 040000082150.890000112567

Meoszám:180100301/07/T 7.pld. Kiadva: 18/02/27 Min.biz.:

Danilon equidos 1,5g granulátum A.U
Gysz:172769 Lej:21/05/31
Kisz:60x10g Me.:doboz
DR. SZÉKELY KFT. részére

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

Danilon A.U.

ESTEVE

LABORATORIOS Dr. ESTEVE, S.A.
Pharmaceutical Plant

GMP Certificate number: NCF/1609/001/CAT

CERTIFICATE OF MANUFACTURE AND BATCH RELEASE

Manufacturing site: **LABORATORIOS Dr. ESTEVE, S.A.**
San Marti, s/n - Poligono Industrial
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: 172769

Date of manufacture (according to EMEA/CVMP/453/01) 05-2017

Expiry Date: 05-2021

Results of analysis:
See attached Certificate of Analysis (CoA) number: 040000082150, 8900001 2567

Additional information:

- Destination (Country) Hungary

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:

Gemma Boleda, Deputy Technical Director **Date:**

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

END OF REPORT - Certificate of Manufacture & Batch Release