

**ESTEVE**

LABORATORIOS Dr. ESTEVE S.A.

c/Sant Martí s/n  
08107 Martorelles (Barcelona) SPAIN**CERTIFICATE OF ANALYSIS**

Date of analysis: 18-12-2017

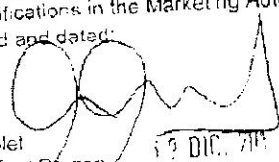
Product: DANILON EQUI DCP 60SOBX10G-H+RO+SLO  
Date of manufacture: 16-05-2017

Batch: 172769

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

Signed and dated:



C. Colet  
Qualified Person

19 DEC 2017

AN: 040000082150.890000112667

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Meoszám: 180100301/07/T

7.pld. Kiadva: 18/02/27

Min.biz.:

Danilon equidos 1,5g granulátum A.U  
Gysz:172769  
Kisz:60x10g  
DR. SZÉKELY KFT. részére

Lej:21/05/31  
Me.:doboz

Danilon A.U.U.

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

**ESTEVE**

LABORATORIOS Dr. ESTEVE, S.A.  
Pharmaceutical Plant

GMP Certificate number: NCF1609/001-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/CVMP453/01) 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 Authorisation, 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 Boieda, Deputy Technical Director**

Date:

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

**END OF REPORT - Certificate of Manufacture & Batch Release**

2017.05.21  
Gemma Boieda  
Deputy Technical Director  
LABORATORIOS Dr. ESTEVE, S.A.  
08107 Martorelles (Barcelona), Spain