

**ESTEVE**

LABORATORIOS DR. ESTEVE, S.A.

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

**CERTIFICATE OF ANALYSIS**

Date of analysis: 12-05-2014

Product: DANILON EQUI. DCP 60SDBX10G-H+RO+SLO

Batch: 140966

Date of manufacture: 07-10-2013

TEST	SPECIFICATIONS	RESULTS
Description	Yellow granules	Complies
Uniformity of mass		
Units	10 or 30	10
Mean		102.4 %
Standard Deviation		1,2
Acceptance Value	Complies Ph. Eur.	3,8
CCF Identification		
Suxibuzone	Positive	Positive
Saccharin sodium	Positive	Positive
Quinoline yellow (E-104) (UV)		
Identification	Positive	Periodic Test
Particulate size		
> 0.21 mm	Less than 10 %	8 %
Dissolution rate Suxibuzone (UV)		
Units	8, 12 or 24	8
Mean	Q = 75 % in 45 min	95 %
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)	100,1 %
Assay/sachet	95.0 - 105.0 % (1.425 - 1.575 g/sachet)	100,3 %
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 specifications in the Marketing Authorisation.

Signed:

E. Rodón

Qualified Person



AN: 04000046785,890000063088

**CERTIFICATE OF MANUFACTURE AND BATCH RELEASE**

Manufacturing site: **Laboratorios Dr. ESTEVE S.A.**  
**San Martí, s/n - Polígono Industrial**  
**08107 - Martorelles (Barcelona), SPAIN**

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

Packaging Batch Number: **140908**

Date of manufacture (according to ENEACVMP45301): **10-2013** ✓

Expiry Date: **10-2017**

**Results of analysis:**

See attached Certificate of Analysis (CoA) number: **040000046765,890000063068**

**Additional Information:**

- Destination (Country): **Hungary**

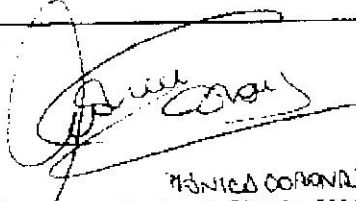
**Certification:**

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 deviations were reported during manufacturing / packaging and properly investigated.

Signature:



MÓNICA CORONAS

Date: **11.03.19**

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

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