

2664/2018/VET

2018 AUG 21

LABORATORIA



SMEETS

Wilrijk, 28th June 2018

CERTIFICATE OF ANALYSIS

Elanco product name : FLUBENOL PREMIX 50MG/G 25KGX1BAG EU
 Elanco product code : AF066425KEU
 Batch number : 18A08 655
 Manufacturing date : 01.2018
 Smeets product code : F-1961
 Quantity released : 36 x 25kg
 Expiry date : 12.2022

Flubendazole used
 -Quantity : 46.265 kg
 -Elanco batchnumber : C842296
 -Smeets batchnumber : 171222 256

Parameter	Specification	Result
Appearance	White to slightly yellow powder	Pass
Identification flubendazole	HPLC : the retention time of flubendazole in the sample solution must be within 5% of the retention time of flubendazole in the specificity solution	Pass
Identification flubendazole	HPLC-UV : the 3 wavelength maxima of flubendazole must be within ± 2 nm of the wavelength maxima of flubendazole in the reference solution	Pass
Assay flubendazole	95.0% - 105.0% of the stated amount	96.6%
Degradation compounds	Total degradation compounds	$\leq 1.5\%$ <1.5%
	Individual specified degradation compound - R035475	$\leq 0.5\%$ 0.1%
	Individual unspecified degradation compounds	$\leq 1.0\%$ <0.7%
Weight in container	Individual weight \geq nominal	Pass
Loss on drying	Meets the requirements of Ph.Eur. <1037>	$\leq 2.33\%$ 2.01%
Microbiological purity	(Ph.Eur.)	
TAMC	$\leq 10^3$ CFU/g of product	
TYMC	$\leq 10^2$ CFU/g of product	
Specified micro-organisms		NA(*)
Escherichia coli	absent in 1g of product	

(*) Microbiological purity is tested with a frequency in accordance with the Specification Report

Conclusion

The product is conform to the specification SPR-DP-04-012 for the tests mentioned above.

We certify that the product, detailed here above, was manufactured, packed and tested in compliance with the marketing authorisation in the country where the product is to be sold and with the cGMP requirements.

The concerned batch is released for shipment to Elanco.

Ind. Pharm. L. Van Dyck
Qualified Person