



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223276

Product:	FENBENDAZOLE veterinary use
Lot:	223276
Expiry date:	31/03/2027
Reference:	Cumple PhEur10.7
Synonyms:	Fenbendazol para uso veterinario.
Formula:	C15H13N3O2S
Molecular weight:	299,35 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Loss on drying (3h, 105°C)	0,05 %	<= 1,0 %	
Sulphated ashes	0,19 %	<= 0,3 %	
Assay	100,2 %	98,0-101,0%	
Impurity A	<=0,10 %	<= 0,5 %	
Impurity B	<=0,10 %	<= 0,5 %	
Unspecified Impurities	<=0,10 %	<= 0,5 %	
Total impurities	<=0,10 %	<= 1,0 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Methanol	<3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, sparingly soluble in dimethylformamide, very slightly soluble in methanol, practically insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/06/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00388 ALIVIRA ANIMAL HEALTH LIMITED

Manufacturer batch: ASA003223A

Product	Name	Capacity	Batch
1128644	FENBENDAZOL (Uso Veterinario)	1 kg	223276-P-1
1128644	FENBENDAZOL (Uso Veterinario)	1 kg	223276-P-2
1128644	FENBENDAZOL (Uso Veterinario)	1 kg	223276-P-4

1128645	FENBENDAZOL (Uso Veterinario)	5 kg	223276-Q-1
1128645	FENBENDAZOL (Uso Veterinario)	5 kg	223276-Q-2
1400103	FENBENDAZOL (Uso Veterinario)	250 g	223276-N-1
1400103	FENBENDAZOL (Uso Veterinario)	250 g	223276-N-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

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