



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233428

Product:	FENBENDAZOLE veterinary use
Lot:	233428
Expiry date:	11/06/2027
Reference:	Cumple PhEur11.2
Synonyms:	Fenbendazol para uso veterinario.
Formula:	C15H13N3O2S
Molecular weight:	299,3 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,06 %	<= 1,0 %	
Sulphated ashes	0,00 %	<= 0,3 %	
Assay	100,2 %	98,0-101,0%	
Impurity A	0,001 %	<= 0,5 %	
Impurity B	0,01 %	<= 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	#
Nitrosamine impurities	NA	NA	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Acetic acid	< 5000 ppm	<= 5000 ppm	#
Residual solvent: xylene	< 2170 ppm	<= 2170 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: 27/09/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00167 JIANGSU BAOZONG & BAODA PHARMACHEM, CO. LTD

Manufacturer batch: 3032306911

Product	Name	Capacity	Batch
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1128644	FENBENDAZOL (Uso Veterinario)	1 kg	233428-P-1
1128644	FENBENDAZOL (Uso Veterinario)	1 kg	233428-P-2
1128644	FENBENDAZOL (Uso Veterinario)	1 kg	233428-P-3
1128645	FENBENDAZOL (Uso Veterinario)	5 kg	233428-Q-1
1128645	FENBENDAZOL (Uso Veterinario)	5 kg	233428-Q-2
1128645	FENBENDAZOL (Uso Veterinario)	5 kg	233428-Q-3
1400103	FENBENDAZOL (Uso Veterinario)	250 g	233428-N-1
1400103	FENBENDAZOL (Uso Veterinario)	250 g	233428-N-2
1400103	FENBENDAZOL (Uso Veterinario)	250 g	233428-N-3

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

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