

FENBENDAZOL FOR VETERINARY USE (EUR. PH.)

PRODUCT CODE: 001956	CAS Nº: 43210-67-9	ANALYSIS Nº: 066/22
MANUFACTURER BATCH: LASA/L2/841/11/21	CERTIFICATE ID: 34.251	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/11/2021	
METAPH BATCH: 0100322	EXPIRY DATE: 30/10/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	Almost white powder
Solubility	Practically insoluble in water, sparingly soluble in dimethylformamide, very slightly soluble in methanol	Complies (*)
Identification	Complies	Complies
Related substances		
Impurity A	=< 0.5 %	Not Detected
Impurity B	=< 0.5 %	< 0.05 %
Unspecified impurities	=< 0.5 %	< 0.05 %
Total impurities	=< 1.0 %	< 0.05 %
Heavy metals	=< 10 ppm	< 20 ppm
Loss on drying	=< 1.0 %	0.06 %
Sulfated ash	=< 0.3 %	0.06 %
Assay	98.0 - 101.0 %	99.4 %
Residual solvents		(*) (**)
Methanol	=< 3000 ppm	< 3000 ppm
Acetone	=< 5000 ppm	< 5000 ppm
Toluene	=< 890 ppm	< 890 ppm
Particle size		(*)
< 20 µm	=< 98 %	< 98 %

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Fenbendazole for Veterinary Use is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Preserve in well-closed, light-resistant containers.

Analysis date: 26/05/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40001098

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