

Fenbendazole

CODE ARTICLE: 11612	BATCH: 0123465	Active pharmaceutical ingredient
TEST DATE: 21/11/2023	TEST: QC-00258813	
EXPIRY DATE: 11/06/2027	FABRICATION DATE: 12/06/2023	MR: 299,30
CAS: [43210-67-9]	FORMULA: C15H13N3O2S	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO	PH.EUR.*
COLOUR	CONFORM	-		WHITE	PH.EUR.*
SOLUBILITY					
INSOLUBLE	CONFORM	-		AGUA	PH.EUR.*
SOLUBLE	CONFORM			MODERADAM ENTE SOLUBLE EN DIMETILFORM AMIDA	PH.EUR.*
SOLUBLE	CONFORM			MUY POCO SOLUBLE EN METANOL	PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
SUSTANCIAS RELACIONADAS					
IMPURITY A	<LQ=0,10% (CONFORME) %			<=0,5 (<=2,5 Area SR B)	PH.EUR.*
IMPURITY B	<LQ=0,10% (CONFORME) %			<=0,5 (<=2,5 Area SR C)	PH.EUR.*
TOTAL IMPURITIES	<LQ=0,10% %			<=1,0	PH.EUR.*
UNSPECIFIED IMPURITIES	<LQ=0,10% (CONFORME) %			<=0,5 (<=2,0 Area SR A)	PH.EUR.*
LOSS ON DRYING	0,1 %			1,0	PH.EUR.*
ASHES	0,2 %			0,3	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,6 %		98	101	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	1117 MG/KG			3000	Manufacture's Standard
TOLUENE	730 MG/KG			890	Manufacture's Standard
XILENO	N.D. MG/KG			2170	Manufacture's Standard
ACETIC ACID	<1000 MG/KG			5000	Manufacture's Standard
ETHANOL	<1000 MG/KG			5000	Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 56453 J. B. & B. PHARMACHEM CO., LTD. (China) Manufacturer Batch: 3032306911 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
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Silvia Sancho-Tello Ripoll
Technical Director.

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