

检验报告书

CERTIFICATE OF ANALYSIS

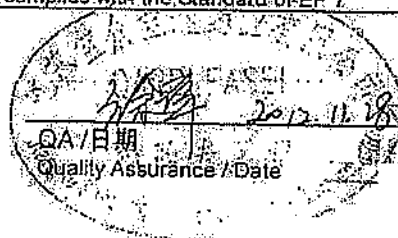
We, JIANGSU BAOZONG & BAODA PHARMACHEM CO. LTD. AS A MANUFACTURER OF FENBENDAZOLE HEREBY CERTIFY THAT THIS BATCH HAS BEEN MANUFACTURED BY US IN FULL COMPLIANCE WITH GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY, GMP NO. 225(2009), VALID TILL 03 NOVEMBER 2014, ISSUED BY MINISTRY OF AGRICULTURE OF P.R.CHINA, ON 04 NOVEMBER, 2009 AS PER WHICH GMP RULES WERE INSPECTED BY CHINESE GMP, AND BATCH PRODUCTION RECORD CHECKED AND APPROVED, NO DEVIATION, NO REWORKING AND REPROCESSING

COA #: FP121128-03

产品名称: Material Name	苯硫咪唑 FENBENDAZOLE	包装: Container	双层塑料袋, 纸板桶 Double-layered plastic bag with fiber drum
批号: Batch #	3031211909	件数: Number of Containers	20 桶 20 drums
数量: Quantity	500kg	报告日期: Date of Release	2012.11.28
生产日期: Mfg. Date	2012.11.11	有效期: Expiry Date	2016.11.10
检验依据: Test in accordance with	EP 7		
检验项目 TEST	标准规定 SPECIFICATION	检验结果 TEST RESULT	
01 外观 Appearance	白色或类白色粉末 A White or almost white powder	类白色粉末 Almost white powder	
02 鉴别 Identification	红外图谱与对照品一致 IR Spectrum of sample complies with RS	与对照图谱一致 Conforms	
03 有关物质 Related substances	杂质(Impurity) A ≤ 0.5% 杂质(Impurity) B ≤ 0.5% 最大未知杂质 Any other impurity (biggest) ≤ 0.5% 总杂质(Total Impurities) ≤ 1.0%	< 0.01% 0.01% 0.04% 0.12%	
04 干燥失重 Loss on drying	≤ 0.5%	0.14%	
05 重金属 Heavy metals	< 20ppm	符合规定 Complies	
06 灼灼残渣 Sulphated ash	≤ 0.3%	0.07%	
07 残留溶剂 Residual solvents	甲醇 (Methanol): ≤ 3000ppm 甲苯 (Toluene): ≤ 890ppm 二甲苯 (Xylene): ≤ 2170ppm 乙酸 (Acetic acid): ≤ 5000ppm 乙醇 (Ethanol): ≤ 5000ppm	1522ppm 835ppm 未检出 (ND) < 1400ppm < 1400ppm	
08 含量 Assay	98.0%~101.0% 按干品计 (on dried substance)	99.7%	
09 储存和运输 Storage & transportation	避光保存 Protected from light	符合要求 Conforms	
结论: CONCLUSION	本品按《欧洲药典 7》检验, 结果符合规定 The product complies with the Standard of EP 7		

通过干燥失重测试

Test as part of Loss on Drying





FAGRON IBERICA, S.A.U. · JOSEP TAPIOLAS,150 · ES-08226 TERRASSA · BARCELONA
Tel 937310722
Fax 937311644
www.fagron.es · www.compoundingmatters.com

Pg. 1
11. Julio 2013

Certificado de Análisis

FENBENDAZOL

PM	299,40
Nº CAS	43210-67-9
Nº Producto	32863-00
Fecha Conclusión	26/06/13
Cod. Fab.	F00226
Nº Lote Fab.	3031211909

Proximo Control Analítico / Retest	28/11/16
Nº Análisis / Analysis Nº	BA-23291
Nº Lote/ Batch No	L13060277
Cod. Muestra / Sample No.	M-029521
Calidad Final	PH.EUR. 7

INCI

Características Polvo blanco o rosado, compactado. Prácticamente insoluble en agua, bastante soluble en dimetilformamida, muy poco soluble en metanol.

White or pinkish powder, compacted. Practically insoluble in water, sparingly soluble in dimethylformamide, very slightly soluble in methanol.

ENSAYOS	ESPECIFICACIONES	RESULTADO	METODO	ANALIZADO POR
* Identificación	A (IR)	Conforme	A0132863-00	Interno
* Sustancias relacionadas	Test Ph.Eur.	Conforme	A0732863-00	Externo
* Pérdida por desecación	< 0.5 %	0,39 %	A0832863-00	Interno
* Riqueza	98.0 - 101.0 %	98,9 %	A1032863-00	Interno
* Metales pesados	< 20 ppm	< 2 ppm	A1232863-00	Externo
* Cenizas sulfúricas	< 0.3 %	0,15 %	A1332863-00	Externo
* Disolventes residuales	Test	Conforme	AEB32863-00	Externo
* Densidad aparente	-	0.635 g/ml	AI32863-00	Externo

Fabricante JIANGSU BAOZONG & BAODA PHARM.
Conservación En envase bien cerrado, protegido de la luz

Puede obtener el CoA original en www.fagron.es

Anna Viñas
Directora Técnica Farmacéutica