

江苏宝众宝达药业有限公司
Jiangsu Baozong & Baoda Pharmachem Co., Ltd.

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(2008), VALID TILL 03 NOVEMBER 2014, ISSUED BY MINISTRY OF AGRICULTURE OF P.R. CHINA ON 04 NOVEMBER, 2008 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	
批号: Batch #		8031211909	包装: Container
数量: Quantity		500kg	双层塑料袋, 纸板桶 Double-layered plastic bag with fiber drum
生产日期: Mfg. Date		2012.11.11	件数: Number of Containers
检验依据: Test in accordance with		EP 7	20桶 20 drums
			报告日期: Date of Release
			2012.11.28
			有效期: Expiry Date
			2016.11.10
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	与要求一致 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



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Corresponde al lote de Fagron:
L13060277
28-10-11
Director Técnico S.