



常州齐晖药业有限公司

CHANGZHOU YABANG-QH PHARMACHEM CO., LTD

检验报告书

Certificate of Analysis



报告书号COA #:

C250303-03

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产品名称 Product	甲苯咪唑 Mebendazole	批号 Batch #	65425017
生产日期 Manufacture Date	2025.02.14	复验日期 Retest Date	2027.02.14
数量 Quantity	350.36 KG		
储存条件 Storage Conditions	密闭、避光保存 Kept In Closed Container, Protected From Light		
检验依据 Specification	CURRENT EUROPEAN PHARMACOPOEIA		
检验项目Test Items	检验标准Specifications	检验结果Results	
【性状Characters】			
外观 Appearance	白色至类白色粉末 White or almost white powder	类白色粉末 Almost white powder	
【C晶型含量（红外）】 Assay of Polymorphic C（IR）	≥90.0%	99.2%	
【鉴别（红外）】 Identification(IR)	应与甲苯咪唑对照品图谱一致 Complies with spectrum of mebendazole CRS	符合规定 complies	
【有关物质Related substances】			
总杂质Total Impurities	≤1.0%	0.0%	
单个指定杂质 Individual specified impurities			
杂质A Impurity A	≤0.25%	<0.05%	
杂质B Impurity B	≤0.25%	<0.05%	
杂质C Impurity C	≤0.25%	<0.05%	
杂质D Impurity D	≤0.25%	<0.05%	
杂质E Impurity E	≤0.25%	<0.05%	
杂质F Impurity F	≤0.25%	<0.05%	

地址: 中国 江苏常州市春江镇金龙路18号

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杂质 G Impurity G	≤0.5%	<0.05%	
单个未指定杂质 Individual unspecified impurity	≤0.10%	<0.05%	
【硫酸灰份 Sulphated Ash】	≤0.1%	0.08%	
【残留溶剂 Residual solvent】			
甲醇 Methanol	≤3000ppm	462ppm	
苯 Benzene	≤ 2 ppm	<2ppm	
【干燥失重 Loss on Drying】	≤0.5%	0.07%	
【含量 Assay】	99.0%~101.0% calculated on the dry basis	99.6%	
结论: 检验结果符合现行EP标准 Conclusion: The items tested meet the requirement of CURRENT EUROPEAN PHARMACOPOEIA.			
审核人/日期: 邵文杰 2025.03.03 Reviewed By QA Manager /Date		批准人/日期: 李国栋 2025.03.03 Approved By Quality Director /Date	

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