

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

产品名称 Product Name	苯酰甲硝唑 Metronidazole benzate	批号 Batch No	Z-0141216
生产日期 Manufacture Date	2014.12.16	有效期 Expiration Date	2018.12.15
报告日期 Report Date	2014.12.16	每桶装量 Quantities/DRUM	25kg/Drum
粒径 Particle size	60-100MESH	批量 Batch size	1000KGS
检验项目 ITEMS	质量标准 BP2009 SPECIFICATIONS BP2009		检验结果 RESULTS
性状 Characteristics	白色或微黄色结晶性粉末或薄片 A white or slightly yellowish crystalline powder or flakes		微黄色结晶性粉末 Slightly yellow crystalline powder
鉴别: Identification	A	IR	符合 Complies
	B	UV	符合 Complies
溶解性 Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in acetone, slightly soluble in alcohol		符合 Complies
熔点 Melting point	99°C-102°C		100.5°C-100.8°C
紫外吸收系数 A(1%,1cm)of UV	525-575		547
芳伯胺基反应 Primary aromatic amines Reaction	应呈正反应 Positive reaction		合格 Complies
溶液外观 Appearance of solution	≤对照悬浮液 II, ≤对照溶液 GY ₃ ≤Reference suspension II, ≤Reference solution GY ₃		≤II <GY ₃
酸度 Acidity	向规定溶液中加入 0.02mol/l 的 NaOH ≤0.25ml Add 0.02 M NaOH to the solution ≤0.25ml		合格 Complies
有关物质 Related substances	任一杂质 ≤0.1%, 总杂质 ≤0.2% Any impurity: ≤0.1%, Total: ≤0.2%		甲硝唑: 0 硝化物: 0 苯磺酸: 0 总杂质: 0.10% Metronidazole: 0 2-methyl-5-nitroimidazole-0 Benzoic acid: 0 Total: 0.10%
重金属 Heavy metals	≤20ppm		<20ppm
干燥失重 Loss on drying	≤0.5%		0.21%
硫酸灰份 Sulphated ash	≤0.1%		0.05%
含量 Assay	98.5-101.0%		99.62%
结论 CONCLUSION	本品符合英国药典 2009 版规定 The product complies with BP2009		

Q.C.Manager: 负责



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Kalchem International, Inc
224 South Main Street - Lindsay, OK 73052
Toll Free 888-298-9905 | FAX: 405-756-2373