杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Oxfendazole

Batch No.: DR20130320	**Piece:** 500.0kg
Manufacture Date: 2013.03.20	**Expiry Date:** 2018.03.19

TESTS:

Items	Specification	Results
Characteristics	White or almost white powder	Almost white powder
Identification	Practically insoluble in water,slightly soluble in ethanol(96%) and methylene chloride	Conforms
IR Identification	Conforms with reference spectrum	Conforms
Related substances(HPLC)	Total impurities:≤3.0% Impurity A(fenbendazole): ≤1.0% Impurity B(peroxide): ≤2.0% Impurity C: ≤1.0% Impurity D: ≤1.0% Other unspecified impurities:≤0.1%	1.4% 0.43% 0.99% < 0.05% < 0.05% < 0.05%
Loss on drying	≤0.5%	0.2%
Sulphated ash	≤0.2%	0.1%
Assay（dried basis)	97.5%~100.5%	99.6%
In-house specification		
Particle size	90%≤100μm 75%≤25μm 50%≤10μm	90% < 9μm 75% < 7μm 50% < 5μm
Bulk density	——	0.30g/ml
Polymorph	Polymorph-A	——
Residual solvents	Methanol:≤600ppm Ethanol:≤200ppm Methyl formate:≤100ppm	64ppm Absent 14ppm
Microbiological purity	Total aerobic microbial count:≤100CFU/g Total combined mold and yeast count:≤100CFU/g Control bacteria:P.Aeruginosa absent in 10g of product.	< 5CFU/g < 5CFU/g Absent
Conclusion: The results conform with EP7.0.		

杭州东瑞医药科技有限公司 Hangzhou Dawn Ray Pharmaceutical Co.,Ltd. 质检专用章 QUALITY STAMP

Analyst:_____ **Checker:**_____ **QA.Manager:** _____

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