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Certificate of Analysis

Catalogue Number	38138
Product	Ondansetron hydrochloride dihydrate
Lot Number	003483-001-22-23
	1,2,3,9-Tetrahydro-9-methyl-3-[(2-methyl-1 <i>H</i> -imidazol-1-yl)]
CAS Number	103639-04-9
Molecular Formula	C ₁₈ H ₁₉ N ₃ O•HCl•2H ₂ O
Molecular Weight	365.86

Appearance	White to off-white powder
Solubility	Soluble in methanol, sparingly soluble in water and in alcohol, slightly soluble in isopropyl alcohol and dichloromethane, very slightly soluble in acetone, in chloroform and in ethyl acetate
Water Content (Karl Fisher)	9.72%
Yeast and Mold	< 10 cfu/mg
Residual Solvents	2-Propanol : 143.7 ppm Toluene : 40.7 ppm Dimethyl formamide : Not detected
E. Coli	Absent/10g
Microbial Count	< 10 cfu/mg (TBC)
Pseudomonas Aeruginosa	Absent/g
Salmonella	Absent/10g
Staphylococcus Aureus	Absent/g
Related Substances	Ondansetron related compound C and D : Not detected Imidazole, 2-methylimidazole : Not detected Ondansetron, Ondansetron related compound A : Not detected Unknown : 0.057% Total : 0.225%
Residue On Ignition	0.05%
Assay (anhydrous basis)	99.6%
D-Enantiomer	Not detected
Chiral Purity	100% (ee)

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Grade	Meets USP Specification
Storage	Store at 2 - 8 °C
Additional Information	Identification : Test for A : Infrared Spectrum : Conforms to structure Test for B : Passes test Bile-tolerant gram negative bacteria : Absent/g Candida albicans : Absent/g
Remarks	See material safety data sheet for additional information For laboratory use only

The foregoing is a copy of the Certificate of Analysis as provided by our supplier



Bala Kumar
Quality Control Manager