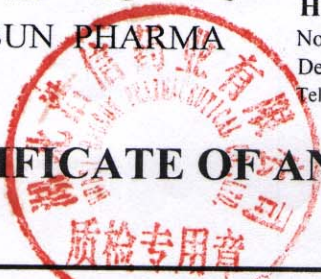




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湖北浩信药业有限公司

Hubei Haosun Pharmaceutical Co., Ltd.
No.20 Juxian Road, Gedian Economic & Technology
Development Area, Hubei, China Post Code: 436070
Tel : +86-711-3811388, 5916663 Fax : +86-711-3813389



CERTIFICATE OF ANALYSIS

Check No.: FP-19-1108001

Product Name:	Granisetron Hydrochloride	Batch No.:	HS1920110701
Quantity:	1118.0g	Manufacturing Date:	2011-7-31
Packing:	500g/tin	Retest Date:	2014-7-30
Test Standard:	USP 34	Report Date:	2011-8-7

Items	Specifications	Results
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Characters

a) Appearance	White or almost white crystalline powder	White crystalline powder
b) Solubility	Freely soluble in water, sparingly soluble in methylene chloride, slightly soluble in methanol	Conform

Identification

a) IR	The sample's IR spectrum is in accordance with that of Granisetron Hydrochloride RS	Conform
b) Chloride	It gives reaction of chlorides	Conform

Appearance of solution	The solution is colorless and clear	Conform
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pH	4.0~6.5	6.1
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Impurity E	Not more than 0.5%	<0.5%
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Related Substances

Impurity A	Not more than 1.0%	0.002%
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Impurity B	Not more than 0.5%	0.006%
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Impurity C	Not more than 0.2%	0.012%
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Impurity D	Not more than 0.1%	<LOD
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Individual unknown impurity	Not more than 0.10%	0.08%
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Total impurities	Not more than 1.0%	0.11%
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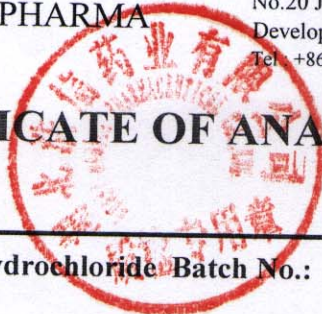
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Items	Specifications	Results
Loss on drying	Not more than 0.5%	0.01%
Residue on ignition	Not more than 0.1%	0.08%
Heavy metals	Not more than 20ppm	<20ppm
Residual solvents		
Ethanol	Not more than 5000ppm	759ppm
Dichloromethane	Not more than 600ppm	<LOD
DMF	Not more than 880ppm	<LOD
Triethylamine	Not more than 10ppm	<LOD
Bacterial endotoxins	Not more than 0.56EU/mg	<0.56EU/mg
Microbial limits		
Bacteria	Not more than 50CFU/g	<10CFU/g
Mould(yeast)	Not more than 50CFU/g	<10CFU/g
Escherichia coli	Absence	Absence
Assay(on dried substance)	97.0%~102.0%	99.7%

Conclusion: Conform to USP 34 standard

QC Manager: 2011年08月07日

Rechecker: 2011年08月07日

Checker: 2011年08月07日
SMP-QA-0031-01