ORION

CERTIFICATE OF ANALYSIS

DEXMEDETOMIDINE HYDROCHLORIDE

Product Number: 127203
Batch Number: 1409815
Order Number: 80344299
Customers Purchase Order Number: Order B29-540129-000-CF

Customers Batch Number: 1406301
Date of Manufacture: 23.06.2011
Date of Expiration: 21.06.2016
Storage: Room temp. +15..25°C
Specification: 10009974-01(Mat:127203) 25.03.2010

Manufacturing site: Fermion Oy, Oulu site, Finland

TESTS	METHOD	REQUIREMENTS	RESULTS
Appearance	108870-1	almost white powder white powder	white powder
Identification , IR	100310-1	positive	positive
Identification, chlorides	108870-1	positive	positive
Identification, HPLC	108870-1	positive	positive
Clarity of solution	108870-1	clear	clear
Colour of solution	108870-1	colourless	colourless
Loss on drying	108870-1	nmt 1.0 %	0.9 %
Sulphated ash	108870-1	nmt 0.1 %	nmt 0.1 %
Heavy metals	108870-1	nmt 20 ppm	nmt 20 ppm
pH	108870-1	4.7 - 5.7	5.2
Residual solvents, ethyl acetate	108870-1	nmt 0.3 %	0.0 %
Residual solvents, isopropyl alcohol	108870-1	nmt 0.1 %	0.0 %
Optical purity, levomedetomidine HCl	108870-1	nmt 1.0 %	0.3 %
Organic impurities, any unspecified	108870-1	nmt 0.1 %	0.0 %
Organic impurities, total unspecified	108870-1	nmt 0.3 %	0.0 %
Assay, calculated on dried basis	108870-1	98.0 % - 102.0 %	99.9 %

Orion Corporation

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Orion Corporation. Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland.

Code # H5094
Lot # 08-001-08-00
P.O. 540129
Received date: 08/01/11
B. Agudelo 8/01/11

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TESTS	METHOD	REQUIREMENTS	RESULTS
Assay of chloride, calc. on dried basis	108870-1	14.7 % - 15.3 %	15.0 %
Bacterial endotoxins	100598-1	less than 700 EU/mg	less than 700 EU/mg
Bacterial endotoxins	100596-1	nmt 20 IU/mg	nmt 20 IU/mg
Total combined yeasts/moulds count	113391-2	nmt 100 /g	< 100 /g
Total aerobic microbial count	113391-2	nmt 1000 /g	< 1000 /g

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 22.07.2011 11:28:02 by Niina Järveläinen

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Hospira
Hospira, Inc.
Hwy 301 North
Rocky Mount, NC 27801

CERTIFICATE OF ANALYSIS

Drug Name:	Dexmedetomidine Hydrochloride	**Specification Date:**	02/04/09
Code Number:	HS094	**Date Received:**	08/01/11
Lot Number:	08-001-DP-00	**Date Released:**	08/09/11
Vendor:	Fermion Oy	**Vendor Lot Number:**	1409815
		Testing from:	08/06/00-08/09/11
Vendor Site:	Oulu, Finland	**Retest Date:**	07/31/13

	Test	Specification	Result
A.	Appearance	Almost white to white powder	Almost white to white powder
B.	Dexmedetomidine (HPLC)	Not less than 98.0 % and not more than 102.0% by weight, of C13 H17 N2 C1, on a dried basis	100.8 %
C.	Color of solution	Colorless	Colorless
D.	Clarity of Solution	Clear	Clear
E.	Chloride (titration)	Not less than 14.7 and not more than 15.3 percent by weight, chloride, on a dried basis	15.0%
F.	Identification (IR)	Sample and standard spectra exhibit maxima only at the same wavelengths	Sample and standard spectra exhibit maxima only at the same wavelengths
G.	Identification Chloride	Meets test requirements	Meets test requirements
H.	Identification (chiral HPLC)	Meets test requirements	Meets test requirements
I.	Optical purity (% Levomedetomidine HCl)	Not more than 1.0%	0.3%
J.	Related substance (HPLC)	Single largest not more than 0.10% Total not more than 0.30%	None detected None detected

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Lot Number:	08-001-DP-00	**Date Released:**	08/09/11
Vendor:	Fermion Oy	**Vendor Lot Number:**	1409815
		Testing from:	08/06/00-08/09/11
Vendor Site:	Oulu, Finland	**Retest Date:**	07/31/13

	Test	Specification	Result
K.	pH (0.02% water solution with KCl)	Between 4.7 and 5.7	5.4
L.	Loss on drying	Not more than 1.0 percent	0.8%
M.	Residue on ignition	Not more than 0.10 percent	0.00%
N.	Residual solvents		
	Isopropanol	Not more than 0.10 percent	None detected
	Ethyl Acetate	Not more than 0.30 percent	0.00%
O.	Bacterial Endotoxin	Less than 0.70 EU/mcg	Less than 0.01 EU/mcg
P.	Factor		1.00

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Test	Specification	Result

Hospira, Inc.

N Popovich — Written By — 09/14/11 — Date

B. Arguello — Supervisor's Signature — 09/14/11 — Date