WRS N_{21-1}

NRCL
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CADILA PHARMACEUTICALS

CADILA PHARMACEUTICALS LIMITED

1389, Trasad Road, Dholka - 387810

Dist. Ahmedabad, Gujarat, India. Phone : +91-2714-221481/83/84, Fax: +91-2714-221848

CERTIFICATE OF ANALYSIS
QUALITY CONTROL DEPARTMENT

Name of Material	:	**NATEGLINIDE (FORM H) U.S.P.**	A.R. Number	:	RM/DHLK/1501964
Manufacturer /Supplier	:	CADILA PHARMACEUTICALS LTD.	Material Code	:	**NRN111**
Batch Number	:	14NG022	GRN No. / Date	:	4910791576 - 06/06/2015
Date of Manufacturing	:	01/12/2014	Sample Quantity	:	60 g
Date of Expiry / Retest Date	:	30/11/2019	Date of Analysis	:	22/06/2015
Quantity Received	:	84.360 kg	**Specification No. :**		**RMN-061-00**

	TESTS	RESULT	LIMITS
7	Loss on drying	0.31% w/w	Not more than 0.5 % w/w
8	Assay	100.9 %w/w	It should contain not less than 98.0 % w/w and not more than 102.0 % w/w of $C_{19}H_{27}NO_3$, calculated on the dried basis.
* 9	Residual solvents (By GC)		
	Acetonitrile	Not detected	Not more than 410 ppm
	Dichloromethane	21 ppm	Not more than 600 ppm
	Ethyl acetate	Not detected	Not more than 5000 ppm
	Cyclohexane	Not detected	Not more than 3880 ppm
* 10	Particle size [By Malevern analyzer]	0.785 µm	D (0.1) : Not more than 5 µm
		2.07 µm	D (0.5) : Not more than 10 µm
		7.76 µm	D (0.9) : Not more than 20 µm

* Additional Tests

Conclusion: The sample complies to the above specification.

Prepared By :
Date : 09/07/15
(Analyst - Q.C) :

Approved By :
Date : 09/07/15
(Manager - Q.C) :

FORMAT NO : FQC174-04/01

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Date of Expiry / Retest Date	:	30/11/2019	Date of Analysis	:	22/06/2015
Quantity Received	:	84.360 kg	**Specification No. :**		**RMN-061-00**

	TESTS	RESULT	LIMITS
1	Description	White powder.	White or almost white powder.
2	Solubility	Complies	Freely soluble in methanol, methylene chloride and in alcohol, soluble in ether, sparingly soluble in acetonitrile and in octanol practically insoluble in water.
3	Identification	Positive	**By Infrared absorption :** The infrared absorption spectrum of the substance being examined in potassium bromide dispsersion should be concordant with the spectrum obtained from similar preparation of Nateglinide working standard.
		Positive	**By HPLC :** The retention time of the major peak of the sample preparation should correspond to that of the standard preparation, as obtained in the Assay.
		Positive	**X-ray diffraction :** X-ray diffraction pattern of the substance being examined should be concordant with X-ray diffraction pattern of Nateglinide form - H working standard.
4	Residue on ignition	0.06% w/w	Not more than 0.1 % w/w
5	Heavy metals	< 10 ppm	Not more than 10 ppm
6	Impurities		
	Limit of Nateglinide Related Compound A and Other impurities (By HPLC)		

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Quantity Received	:	84.360 kg	**Specification No. :**		**RMN-061-00**

	TESTS	RESULT	LIMITS
	Impurity A1	Not detected	Not more than 0.15 %
	Impurity E2	0.002 %	Not more than 0.15 %
	Trans acid3 (Nateglinide related compound A)	Not detected	Not more than 0.20 %
	Ethyl analog4	0.014 %	Not more than 0.10 %
	IPP impurity5	0.001 %	Not more than 0.10 %
	Ester impurity6	0.007 %	Not more than 0.10 %
	Any other individual impurity	0.013 %	Not more than 0.10 %
	Limit of Nateglinide Related Compound B7 (By HPLC)	Not detected	Not more than 0.20 %
	Limit of Nateglinide Related Compound C and Phenylalanine (By HPLC)		
	Nateglinide cis-isomer8	0.03 %	Not more than 0.20 %
	Nateglinide Related Compound C phenylalanine9	Not detected	Not more than 0.20 %
	Total impurities	0.07 %	The sum of all impurities found in the tests for limit of Nateglinide related compound A and other impurities, Limit of Nateglinide related compound B and Limit of Nateglinide related compound C and Phenylalanine : Not more than 0.50 %

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