PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR NATEGLINIDE

Manufacturer Name :		**Supplier Name :**	
Manufacturer's Batch No.:		**Manufacturer's Batch Size :**	
Manufacturing Date :		**Expiry Date :**	
Quantity received :		**Sample Quantity :**	
Document No.:	**Effective Date. :**	**Change Control No.: N/A**	
Control No./A.R.No. :	**Retest Date :**		

References : In House

Description : White to Off-white powder.
Conforms / Does not conform

Solubility : Soluble in di-chloromethane and methanol.
Conforms / Does not conform

S.No.	Tests	Reference	Results	Specifications
1.	Identification By I.R.	IH		I.R. absorption spectrum of the sample in KBr dispersion is concordant with working standard.
2.	Identification by HPLC	IH		The Retention time of main peak shall match with working standard.
3.	Melting range	IH		136 to 141 °C.
4.	Specific Rotation $[\alpha]_D$ at 25°C	IH		-9.0 to –12°(C=1 %in MeOH)
5.	Loss on drying (at 105° C)	IH		NMT 1.0 %.
6.	Residue on ignition	IH		NMT 0.2 %.
7.	Heavy metals	IH		NMT 20 ppm
8.	Related substances by HPLC i. Impurity-A ii. Impurity-B iii. Impurity-C iv. Impurity-D v. Any highest individual impurity iv. Total impurities	IH		 NMT 0.2 % NMT 0.2 % NMT 0.2 % NMT 0.2 % NMT 0.2 % NMT 1.0 %
9.	Assay by HPLC	IH		Between 98.0% to 102.0%

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR NATEGLINIDE

S.No.	Tests	Reference	Results	Specifications
	(on dried basis)			
10.	Residual solvents i. Methanol ii. Dichloromethane iii. Toluene	IH		NMT 3000ppm. NMT 600ppm. NMT 890 ppm.

Raw Data Reference:

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Hard Book No. : Page No. :

Analyst Hard Book No. : Page No. :

Analyst Hard Book No. : Page No. :

Results : Sample Conforms/Does not Conform to specification

Analyzed By : _____ Date: _____

Checked By : _____ Date: _____

Approved By : _____ Date: _____