



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR NIMESULIDE

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

Reference : In House

Description : Pale yellow to yellow crystalline powder ; free from foreign particles. Complies/Does Not Comply

Solubility : Soluble in Chloroform, Dichloromethane, Acetone and in 1N Sodium Hydroxide (1 in 10-30);
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1	Identification (IR)	IH		IR absorption spectrum of test is concordant with WRS.	
2.	Residue on ignition	IH		Not More Than 0.1%	
3.	Melting range	IH		Between 147° and 151°C	
4.	Heavy metals	IH		Not more than 10 ppm	
5.	Loss On Drying	IH		Not More Than 1.0 %	
6.	Chromatographic purity	IH		Total impurities Not more than 1.0 %	
7.	Assay as (On Dried Basis)	IH		Not Less Than 98.0 % and No More Than 101.0 %	

Raw Data Reference :

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Hard Book No. : Page No. :

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Results : Sample Conforms / Does Not Conform to Specification

Analyzed By : _____ Date : _____

Checked By : _____ Date : _____

Approved By : _____ Date : _____