PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR GLICLAZIDE BP

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.:**
Control No./A.R.No.:		**Retest Date:**

Reference : BP 2000 pg 752-753

Description : A white or almost white powder; free from foreign particles.
Complies/ Does Not Comply

Solubility : Practically insoluble in water (1 in More than 10000) ; freely soluble in Dichloromethane (1 in 1-10); sparingly soluble in Acetone(1 in 30-100); slightly soluble in Ethanol (96%)(1 in 1000-10000).
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification IR	BP		The infrared absorption spectrum of test is concordent with the referance spectrum of Gliclazide WS	
2.	Heavy metals	BP		Not More Than 10 ppm	
3.	3- Nitroso-3-azabicyclo[3.3.0] octane	BP		Not More Than 2 ppm	
4.	Related substances	BP		Not More Than 0.02 %	
5.	Loss on drying	BP		Not More Than 0.25 %	
6.	Sulphated Ash	BP		Not More Than 0.1 %	
7.	Assay as $C_{15}H_{21}N_3O_3S$ (On dried Basis)	BP		Not Less Than 99.0 % and Not More Than 101.0 %	

Raw Data Reference:

Analyst Name :

Analyst Name :

Analyst Name :

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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: _____