



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR METFORMIN HYDROCHLORIDE BP

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 : BP 2001 Page No.1076

Description : White crystals; free from foreign particles.
Complies/Does Not Comply

Solubility : Freely soluble in Water (1 in 1-10); slightly soluble in Alcohol (95) (1 in 100-1000); and practically insoluble in Acetone, in Methylene chloride.(1 in More than 10,000).
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification B,E or A,C,D,E A. Melting point B. IR	BP		. A. 222°C to 226°C B. IR absorption spectrum of test is concordant with reference spectrum of Metformin HCl CRS working.	
2.	Identification (continued) C. TLC	BP		C. The principal spot in chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in chromatogram obtained with the reference solution. D. A pink colour	



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S.No.	Test	Reference	Result	Specification	Remark
	D. Colour reaction E. Reaction of chloride.			develops. E. A curdy, white precipitate is produced. Centrifuge and wash the precipitate with three 1-ml quantities of <i>water</i> . Carry out this operation rapidly in subdued light, disregarding the fact that the supernatant solution may not become perfectly clear. Suspend the precipitate in 2 ml of <i>water</i> and add 1.5 ml of 10M <i>ammonia</i> ; the precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	
3.	Appearance of solution	BP		Solution is clear and colourless.	
4.	Related substances	BP		The area of any peak corresponding to cyanoguanidine is not greater than the area of the peak in the chromatogram obtained with reference solution (a) (0.02 %); the area of any peak, apart from the principal peak and any peak corresponding to cyanoguanidine, is not greater than the area of the principal peak in the chromatogram obtained with reference solution (b)(0.1 %).	
5.	Heavy metals	BP		Not more than 10 ppm	
6.	Loss On Drying	BP		Not More Than 0.5 %	
7.	Sulphated Ash	BP		Not More Than 0.1 %	



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S.No.	Test	Reference	Result	Specification	Remark
8.	Assay as C ₄ H ₁₂ ClN ₅ . (On Dried Basis)	BP		Not Less Than 98.5 % and Not More Than 101.0%	

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 : _____