



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### ANALYTICAL SPECIFICATION FOR METFORMIN HYDROCHLORIDE IP

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

**Reference:** IP 1996 Page No. 469

**Description:** White crystalline powder, hygroscopic ; free from foreign particles.  
Complies/Does Not Comply

**Solubility:** Freely soluble in Water ( 1 in 1-10); slightly soluble in Ethanol (95) (1 in 100-1000); and practically insoluble in Acetone, in Chloroform, in Dichloromethane and in Ether. (1 in More than 10,000).  
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification A. IR  B. Colour reaction	IP		A. IR absorption spectrum of test is concordant with reference spectrum of Metformin HCl WRS.  B. An orange colour is produced which darkens on keeping.	
2.	Identification  C. Colour reaction  D. Melting point			C. A wine red colour develops within 3 minutes.  D. Melts Between 222° and 226°	
3.	Related substances	IP		In the chromatogram obtained with solution (1) the area of any	



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S.No.	Test	Reference	Result	Specification	Remark
				peak corresponding to Dicyandiamide is not greater than that obtained with solution (3) and the area of any other secondary peak is not greater than that obtained with solution (2).	
4.	Heavy metals	IP		Not more than 20 ppm	
5.	Sulphated Ash	IP		Not More Than 0.1 %	
6.	Loss On Drying	IP		Not More Than 0.5 %	
7.	Assay as C <sub>4</sub> H <sub>11</sub> N <sub>5</sub> ·HCl (On Dried Basis)	IP		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 :** \_\_\_\_\_