



## **Wanbury Limited**

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## Certificate of Analysis

Product

: Metformin Hydrochloride BP/ PhEur/USP

Batch No.

: BMS0550213

Mfg. Date

: February - 2013

**Batch Size** 

: 2002.25 kg

Exp. Date

: January - 2018

Qty. Supplied

: 2000.00 kg

Date of Sampling

: March 26, 2013

Qty. Sampled

: 100 g

Date of analysis

: March 27, 2013

Mfg. Lic. No.

: KD-242

01. Appearance White Crystals  02. Solubility Freely soluble in water, slightly soluble in alcohol  03. Identification  A. Melting point  B. IR Spectrum  Concordant  C. By TLC  Conforms  D. Colour test E. Chlorides  D. Colour test E. Chlorides  Positive  O4. Appearance of solution (10% solution in water)  05. Related substances (by HPLC)  a) Impurity A (Cyanoguanidine)  (Complies  A pink colour shoul Should be clear and colourless  Should be clear and colourless  Not more than 0.029  (Crecly C to 226 °C  Concordant  Metformin hydroch standard.  The principal spot in the obtained with the te similar in position, oprincipal spot in the obtained with refere a positive  Noull be clear and colourless  Not more than 0.029  (Cyanoguanidine)  (Cyan		Specifications	Observations	Tests	Sr. No.
slightly soluble in alcohol  acetone and in meth  223°C  B. IR Spectrum  Concordant  C. By TLC  Conforms  Complies  A pink colour should be positive  Should be clear and colourless  Should be clear and  Colourless  Complies  A pink colour should be clear and colourless  Not more than 0.029  Not more than 0.029  Not more than 0.194  Not more than 0.194  Not more than 0.384  Not more than 0.385  Not more than 0.395  Not more th		White Crystals	White Crystals	Appearance	01.
03. Identification A. Melting point B. IR Spectrum  Concordant  Concordant  Concordant  Concordant  Infrared absorption should concordant with Melformin hydroch standard.  The principal spot in the obtained with refere b. Complies Complies Complies Complies Complies Complies A pink colour should be positive  O4. Appearance of solution (10% solution in water) Concordant  Melformin hydroch standard.  The principal spot in the obtained with refere A pink colour should be positive  Should be positive  O5. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity 0.042% C) Total impurities 0.069%  O6. Heavy metals 06. Heavy metals 07. Loss on drying at 105°C for 5 hours  O8. Sulphated ash 0.03% O9. Assay (% on dry basis) 09.6%  Not more than 0.0% N	ally insoluble in	Freely soluble in water, slightly solu in alcohol, practically insoluble in acetone and in methylene chloride.		Solubility	02.
B. IR Spectrum  Concordant  Infrared absorption should concordant v Metformin hydroch standard.  C. By TLC  Conforms  The principal spot in obtained with the te similar in position, oprincipal spot in the obtained with refere  D. Colour test E. Chlorides  Outlies  A pink colour should be positive  Outlies  A pink colour should be positive  Should be clear and colourless  Outlies  Complies A pink colour should be clear and colourless  Outlies  Should be clear and colourless  Outlies  Outlies  Not more than 0.029  Not more than 0.199  Outlies Should be clear and colourless  Outlies	And the second s				03.
should concordant we Metformin hydroch standard.  C. By TLC  Conforms  The principal spot in obtained with the tesimilar in position, oprincipal spot in the obtained with refere D. Colour test E. Chlorides  Other impurity Cyanoguanidine) D. Colour test Complies Positive  Complies A pink colour shoul Should be positive  Should be clear and colourless  Should be clear and Clow solution in water)  Cyanoguanidine) D. Colour test Complies A pink colour shoul Should be clear and colourless  Should be clear and Clow solution in water)  Ob. Related substances (by HPLC) a) Impurity A Cyanoguanidine) D. Oo2% D. Other impurity D. Oo2% D. Oo42% Not more than 0.02% Not more than 0.3% Not more than 0.5% Not more than 0.5					
C. By TLC  Conforms  C. By TLC  Conforms  Conforms  C. By TLC  Conforms  Conformin hydroch  Should be clear and  Colour shoul  Should be clear and  Colourless  Conformin hydroch  A principal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the te  similar in position, oprincipal spot in the  obtained with the  conformation, oprincipal spot in the  obtained with the  should be clear and  colourless  Should be clear and  Colourless  Sho		Infrared absorption spectrum of samp	Concordant	B. IR Spectrum	
C. By TLC  Conforms  C. By TLC  Conforms  The principal spot in obtained with the te similar in position, oprincipal spot in the obtained with refere D. Colour test  E. Chlorides  O4. Appearance of solution (10% solution in water)  O5. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity 0.042% C) Total impurities 0.069%  O6. Heavy metals  D5. Loss on drying at 105°C for 5 hours  O8. Sulphated ash  O9. Assay (% on dry basis)  O6. Principal spot in obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with the te similar in position, oprincipal spot in the obtained with refere to similar in position, oprincipal spot in the obtained with refere to similar in position, oprincipal spot in the obtained with refere to similar in position, oprincipal spot in the obtained with refere to similar in position, oprincipal spot in the obtained with refere to similar in position, oprincipal spot in the obtained with refere to obtained with r	The state of the s			∞	
C. By TLC  Conforms  The principal spot in obtained with the te similar in position, oprincipal spot in the obtained with refere D. Colour test  E. Chlorides  O4. Appearance of solution (10% solution in water)  O5. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity c) Total impurities  O6. Heavy metals  Complies Positive  Complies A pink colour shoul Should be positive  Should be clear and colourless  O6. Heavy metals Complies A pink colour shoul Should be clear and colourless  O6. Heavy metals Complies A pink colour shoul Should be clear and colourless  O6. Heavy metals Complies A pink colour shoul Should be clear and colourless  O6. Heavy metals Complies A pink colour shoul Should be clear and colourless  Not more than 0.029 Not more than 0.1% Not more than 0.3% Not more than 0.3% Not more than 0.3% Not more than 0.5% hours  O8. Sulphated ash O.03% Not more than 0.4% O9. Assay (% on dry basis) O9.6%	mortue working				
D. Colour test E. Chlorides Positive Should be positive  O4. Appearance of solution (10% solution in water)  O5. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity c) Total impurities  O6. Heavy metals  Cess on drying at 105°C for 5 hours  O8. Sulphated ash  O9. Assay (% on dry basis)  O9. Assay (% on dry basis)  Complies Positive Should be clear and Colourless  O.002%  Not more than 0.029 Not more than 0.1% Not more than 0.3% Not more than 0.4%  O.003%  Not more than 0.4%  O.003%  Not more than 0.4% O.003%  Not more than 0.4% O.003%  Not more than 0.4% O.003%	test solution should be a, colour and size to the	The principal spot in the chromatogr obtained with the test solution should similar in position, colour and size to principal spot in the chromatogram	Conforms	C. By TLC	My. Soor
E. Chlorides Positive Should be positive  O4. Appearance of solution (10% solution in water) colourless  O5. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) 0.002% Not more than 0.02% b) Other impurity 0.042% Not more than 0.1% c) Total impurities 0.069% Not more than 0.3% Not more than 0.9 % Not more		obtained with reference solution.			
04. Appearance of solution (10% solution in water) 05. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity c) Total impurities 0.002% Not more than 0.02% b) Other impurities 0.069% Not more than 0.1% c) Total impurities 0.069% Not more than 0.3% Not more than 0.9 p 07. Loss on drying at 105°C for 5 hours 08. Sulphated ash 0.03% Not more than 0.45%		A pink colour should develop			
(10% solution in water)  Colourless  Related substances (by HPLC)  a) Impurity A  (Cyanoguanidine)  b) Other impurity  c) Total impurities  0.069%  Not more than 0.02%  Not more than 0.1%  Not more than 0.3%  Not more than 0.9%			e epecation	E. Chlorides	
05. Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity c) Total impurities 0.042% Not more than 0.02% Not more than 0.1% c) Total impurities 0.069% Not more than 0.3% Not more than 0.3% Not more than 0.3% Not more than 0.09 Not more than 0.05% hours  08. Sulphated ash 0.03% Not more than 0.5% Not more than 0.5% hours  09. Assay (% on dry basis) 99.6% 98.5% - 101.0%	Should be clear and colourless				
a) Impurity A (Cyanoguanidine) b) Other impurity c) Total impurities 0.069% Not more than 0.1% Not more than 0.3% Not more than 0.9 y hours  08. Sulphated ash 0.03% Not more than 0.5 y hours  09. Assay (% on dry basis) 99.6%		colourless			
(Cyanoguanidine) b) Other impurity c) Total impurities 0.069% Not more than 0.029 Not more than 0.1% Not more than 0.39 Not more than 0.41 Not more than 0.29 Not more than 0.29 Not more than 0.19 Not mor					
b) Other impurity c) Total impurities 0.069% Not more than 0.1% Not more than 0.3% Not more than 0.3% Not more than 0.3% Not more than 0.3% Not more than 0.09 Not more than 0.09 Not more than 0.09 Not more than 0.5% hours  08. Sulphated ash 0.03% Not more than 0.1% 98.5% - 101.0%	2%	Not more than 0.02%	0.002%		
06. Heavy metals  105°C for 5 10.20%  Not more than, 10 ppm		Not more than 0.1%	0.042%		
07.       Loss on drying at 105°C for 5 0.20% hours       Not more than 0.5 % hours         08.       Sulphated ash 0.03% Not more than 0.15 % hours         09.       Assay (% on dry basis) 99.6% 98.5% - 101.0%	% हिंदी	Not more than 0.3%	0.069%	c) Total impurities	
07.       Loss on drying at 105°C for 5 0.20% hours       Not more than 0.5 % hours         08.       Sulphated ash 0.03% Not more than 0.15 % hours         09.       Assay (% on dry basis) 99.6% 98.5% - 101.0%	ppm of HOLA	Not more than, 10 ppm of 1001A	Less than 10 ppm	Heavy metals	06.
09. Assay (% on dry basis) 99.6% 98.5% - 101.0%		Not more than, 05 % 10 5/05/13	0.20%		
09. Assay (% on dry basis) 99.6% 98.5% - 101.0%	18 9971	Not more than on % 9 7 1	0.03%	Sulphated ash	08.
Additional Test		98.5% - 101.0%		Assay (% on dry basis)	09.
10 Residual Solvent		क निर्माण क			
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Esig Marcola Bran	NMT 1000 ppm हाल Carporate B		Residual Solvent	10.
Methanol 278 ppm NMT 1000 ppm [7]  Xylene Not detected NMT 500 ppm	40 23/401 ava E	NMT 1000 ppm [70 55710 et 5	278 ppm		

Remarks: Product Complies with B.P-2011 / PhEur -7th Edition /USP-33/Customer Specifications/COS NO.: R1-CEP 1998-079-Rev. 04 Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Analysed By:

Checked By:

Approved By:

K. V. Gunjal

S. K. Dalvi Analyst

A. D. Gaikwad Asst. Manager QA/QC Asst. Manager QC

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