WANBURY

Certificate of Analysis			
Product	: Metformin Hydrochloride USP	Batch No.	: MC00350424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 1300 kg	No. of containers	: 26
Customer Name	:		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	223.1°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	Below Quantification Limit	Not more than 0.02 %
	Any other Impurity	Below Quantification Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.22 %	Not more than 0.5 %
7	Residue on ignition	0.06 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.7 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	136 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.003 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	97.4 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	73.7 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	43.1 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.74 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17-04-2024

Works: Wanbury Limited, Doctors Organic Chemicals Division, K. Illindalaparru - 534 217, Iragavaram Mandal, West Godavari District, Andhra Pradesh, India.
Tel: 91-8819-284 249, 284 349, fax: 91-8819-284 350.
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Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis			
Product	: Metformin Hydrochloride USP	Batch No.	: MC00360424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 1300 kg	No. of containers	: 26
Customer Name	: J B KHOKHANI AND CO., INDIA		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	223.2°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	0.001 %	Not more than 0.02 %
	Any other Impurity	Below Detectable Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.23 %	Not more than 0.5 %
7	Residue on ignition	0.04 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.8 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	147 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.003 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	98.6 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	71.5 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	44.1 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.72 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17.04.2024

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Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis			
Product	: Metformin Hydrochloride USP	Batch No.	: MC00370424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 1300 kg	No. of containers	: 26
Customer Name	: J B KHOKHANI AND CO., INDIA		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	224.6°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	Below Detectable Limit	Not more than 0.02 %
	Any other Impurity	Below Detectable Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.21 %	Not more than 0.5 %
7	Residue on ignition	0.04 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.7 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	130 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.003 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	98.4 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	74.9 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	49.1 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.74 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17.04.2024

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Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis			
Product	: Metformin Hydrochloride USP	Batch No.	: MC00380424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 1300 kg	No. of containers	: 26
Customer Name	: J B KHOKHANI AND CO., INDIA		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	224.2°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	Below Detectable Limit	Not more than 0.02 %
	Any other Impurity	Below Detectable Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.22 %	Not more than 0.5 %
7	Residue on ignition	0.04 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.8 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	147 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.003 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	98.3 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	75.4 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	51.1 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.74 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17-04-2024

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Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis			
Product	: Metformin Hydrochloride USP	Batch No.	: MC00390424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 1300 kg	No. of containers	: 26
Customer Name	: J B KHOKHANI AND CO., INDIA		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	223.8°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	0.001 %	Not more than 0.02 %
	Any other Impurity	Below Quantification Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.24 %	Not more than 0.5 %
7	Residue on ignition	0.04 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.9 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	344 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.004 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	97.7 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	76.5 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	54.2 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.72 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17.04.2024

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Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis			
Product	: Metformin Hydrochloride USP	Batch No.	: MC00400424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 1300 kg	No. of containers	: 26
Customer Name	: J B KHOKHANI AND CO., INDIA		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	223.2°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	0.001 %	Not more than 0.02 %
	Any other Impurity	Below Quantification Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.26 %	Not more than 0.5 %
7	Residue on ignition	0.04 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.9 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	328 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.004 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	97.5 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	76.7 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	54.6 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.74 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17.04.2024

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Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis

Product	: Metformin Hydrochloride USP	Batch No.	: MC00410424
Mfg. Date	: Apr, 2024	Exp. Date	: Mar, 2029
Dispatch Quantity	: 200 kg	No. of containers	: 04
Customer Name	: J B KHOKHANI AND CO., INDIA		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White crystalline powder
2	Solubility	Complies	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
3	Identification		
	a) Melting point	223.7°C	222°C to 226°C
	b) IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin Hydrochloride working standard
	c) By TLC	Complies	The principle spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with reference solution.
	d) Color test	Complies	A pink color should develop with alpha Naphthol in the presence of sodium hypobromite
	e) Chloride	Positive	Should be positive
	f) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.
4	Appearance of solution (10 % solution in water)	Clear and colorless	Should be clear and colorless
5	Related substances by HPLC		
	Cyanoguanidine	Below Quantification Limit	Not more than 0.02 %
	Any other Impurity	Below Detectable Limit	Not more than 0.05 %
	Total impurities	0.01 %	Not more than 0.3 %
6	Loss on drying (at 105°C for 5hours.)	0.27 %	Not more than 0.5 %
7	Residue on ignition	0.03 %	Not more than 0.1 %
8	Assay by HPLC (on dried basis)	99.8 %	98.0% to 102.0 %
In-House Tests			
9	Residual solvents by GCHS		
	Methanol	147 ppm	Not more than 1000 ppm
	Xylene	Below Detectable Limit	Not more than 500 ppm
10	Dimethylamine Hydrochloride	0.003 %	Not more than 0.018%
11	Particle size (Sieve)		
	20 mesh	97.7 % passed	Not less than 90 % passes through 20 mesh
	40 mesh	76.1 % passed	Not less than 20 % passes through 40 mesh
	60 mesh	57.1 % passed	Not less than 5 % passes through 60 mesh
12	Bulk Density		
	Un tapped	0.74 g/ml	0.7 to 0.9 g/ml
	Tapped	0.93 g/ml	0.8 to 1.0 g/ml

Remarks: The product complies with USP 43 and in-house / Customer specifications.

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Prepared by:
Sr. Executive-QC
Date: 17/04/2024

Reviewed by:
Dy. Manager-QC
Date: 17/04/2024

Approved by:
Sr. Manager– QA
Date: 17.04.2024

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