Plot No. 43&44, IDA, Phase II -Pashamylaram, Patancheru Mandal, Sangareddy District,
Telangana state, India - 502307

CERTIFICATE OF ANALYSIS

Product Name	:	**TELMISARTAN-Ph.Eur**			
Batch No.	:	TL 019 J 24	Date of Manufacturing	:	October-2024
A.R.No.	:	24 FP 0306	Date of Analysis	:	15.10.2024
Dispatch Qty.	:	15.00Kg	Date of Expiry	:	September-2029
Reference	:	Ph.Eur	Customer Name	:	M/s. F & A Pharma
CEP No.	:	R0-CEP 2018-104-Rev 01			
Storage Condition: Store in well closed containers, protect from moisture at room temperature (15-30°C)					

S.No.	Test	Results	Acceptance criteria
1.0	Appearance	White powder	White or slightly yellowish, crystalline powder.
2.0	Identification by IR	Sample matches with standard	IR spectra of sample should match with IR spectra of working standard.
3.0	Solubility	Practically insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride. It dissolves in 1 M sodium hydroxide.	Practically insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride. It dissolves in 1 M sodium hydroxide.
4.0	Appearance of solution	Complies	The solution is not more intensely coloured than reference solution Y_4.
5.0	Loss on drying	0.20%	Not more than 0.5%
6.0	Sulphated ash	0.05%	Not more than 0.1%
7.0	Related substances by HPLC		
7.1	Impurity-A	Not Detected	Not more than 0.15%
7.2	Impurity-B	Not Detected	Not more than 0.15%
7.3	Impurity-C	0.02%	Not more than 0.2%

Compiled by	:		Checked by	:		Approved by	:	
Date	:	25/10/2024	Date	:	25/10/24	Date	:	25/10/2024

METAPHARMACEUTICAL

N DE LOTE: 0201124 18/11/2024

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S.No.	Test	Results	Acceptance criteria
7.4	Impurity-D	Not Detected	Not more than 0.2%
7.5	Unspecified impurity	0.03%	Not more than 0.10%
7.6	Total impurities	0.07%	Not more than 1.0%
8.0	Assay by Potentiometry (On dried basis)	99.80%w/w	Not less than 99.0% and Not more than 101.0% w/w
9.0	Residual solvents by Headspace GC		
9.1	Methanol	14 ppm	Not more than 3000 ppm
9.2	Acetone	4 ppm	Not more than 5000 ppm
9.3	Isopropyl alcohol	Not Detected	Not more than 5000 ppm
9.4	Dichloromethane	Not Detected	Not more than 600 ppm
9.5	Hexanes	Not Detected	Not more than 290 ppm
9.6	Chloroform	Not Detected	Not more than 60 ppm
Additional Test			
10.0	Assay by HPLC (On dried basis)	100.5%	Not less than 99.0% and Not more than 101.0% w/w

Note:-The Product confirms to the above acceptance criteria.

Compiled by	:		Checked by	:		Approved by	:	
Date	:	25/10/2024	Date	:	25/10/24	Date	:	25/10/2024

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Impurity Name	Chemical Name
Impurity-A	4-methyl-6-(1-methyl-1H-benzimidazole-2-yl)-2-propyl-1H-benzimidazole
Impurity-B	4'-[[7-methyl-5-(methyl-1H-benzimidazole-2-yl)-2-propyl-1H-benzimidazole-1yl]methyl]biphenyl-2-carboxylic acid
Impurity-C	1,1-dimethylethyl 4 '-[[4-methyl-6-(1-methyl-1Hbenzimidazol-2-yl)-2-propyl-1H-benzimidazol-1-yl]methyl]biphenyl-2-carboxylate.
Impurity-D	Unknown structure
Impurity-E*	1-[(2'-carboxybiphenyl-4-yl)methyl]-4-methyl-2- propyl-1H-benzimidazol-6-carboxylic acid
Impurity-F*	4'-[(4-methyl-6-(1-methyl-1H-benzimidazol-2-yl)-2- propyl-1H-benzimidazol-1-yl]methyl]biphenyl-2-carboxamide

*E, F Impurities considered as unspecified impurities as per European Pharmacopoeia 9.7.

COPY QA APPROVED
Date 25.10.24
Signature
F&A PHARMA-Handels-GmbH

Compiled by	:		Checked by	:		Approved by	:	
Date	:	25/10/2024	Date	:	25/10/24	Date	:	25/10/2024