

CERTIFICATE OF ANALYSIS

Product Name	Telmisartan	Batch No.	200105	Test No.	CP-20021603
Source of product	API department	Batch quantity	220.0kg	Inspected for	Full inspection
Applied by	API department			Expiration date	2024.02
Inspection Reference	USP 40			Date of report	2020.03.17
Test items	Test standards			Test results	
【Identification】					
A	Infrared Absorption<197K>			Conforms	
B	The retention time of the major peak from the Sample solution corresponds to that from the Standard solution,as obtained in the test for Organic Impurities			Conforms	
【ASSAY】					
Related substances	Telmisartan related compound A :≤0.1%			Not detected	
	Telmisartan amide. :≤0.1%			0.03%	
	Telmisartan related compound B :≤0.1%			0.02%	
	Telmisartan diacid :≤0.1%			0.02%	
	Telmisartan tert-butyl ester :≤0.2%			0.03%	
	Telmisartan unknown impurity :≤0.2%			0.03%	
	Any other individual impurity :≤0.1%			0.04%	
	Total impurity :≤1.0%			0.19%	
Loss on drying	≤1.5%			0.1%	
Residue on ignition	≤0.1%			0.04%	
【Content】	98.0%–101.0% on the dried basis			100.3%	
Conclusion: According to usp 40, The test results are in conformity with the regulations.					

Person in charge: Tang Zhonghua

Reviewed by: Peng Xinjiao

Inspected by: LiuYing

