

Hallochem Group

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product	Telmisartan	Batch No.	TMS20240401
Manuf. Date	20024-04-03	Exp. Date	2027-04-02
Batch Quantity	100Kgs	Test Standard	EP10

TEST	SPECIFICATIONS	RESULTS
Appearance	A white or slight yellow crystalline powder	White crystalline powder
Solubility	Complies	Complies
IR Identification	Should correspond to the RS infrared absorption	conform
Appearance of solution	Should meet the requirement	conform
Related substances	Impurity A $\leq 0.15\%$ Impurity B $\leq 0.15\%$ Impurity C $\leq 0.2\%$ Impurity D $\leq 0.2\%$ Unspecified Ims $\leq 0.1\%$ Total $\leq 1.0\%$	0.05% 0.02% 0.03% 0.05% 0.06% 0.30%
methanol	$\leq 0.3\%$	Not detected
ethanol	$\leq 0.5\%$	0.031%
Methylene dichloride	$\leq 0.06\%$	Not detected
n-hexane	$\leq 0.029\%$	Not detected
Acetic acid ethyl ester	$\leq 0.5\%$	Not detected
Toluene	$\leq 0.089\%$	0.025%
Acetic acid	$\leq 0.5\%$	0.036%
Loss on drying	$\leq 0.5\%$	0.20%
Sulphated ash	$\leq 0.1\%$	conform
Melting point	261- 263°C	261.1-262.2°C
Assay	99.0 – 101.0%	99.9%

Conclusion: The product complies with the requirements of EP10

Quality Manager:

朱永军

Rechecker:

易洪斌

Analyst:

刘松

地址: 中国重庆市垫江县新民镇渝巫路 138 号, 邮编: 408302

Add: No.138, YuWu Road, XinMin Town, DianJiang, ChongQing, China

电话/Tel: +86-23-67030808, 74578888

传真/Fax: +86-23-67030809, 74577298

Http :// www.hallochem.com

HALLOCHEM

