



# ANDHRA ORGANICS LIMITED

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Title	SPECIFICATION	SP No.	FP/SP/TLS/001
		Revision No.	02
Product name	TELMISARTAN IP		
Category	Finished product	Effective date	
Department	Quality Control	Next Review	

## I. SPECIFICATIONS

### TELMISARTAN

S. No.	Test	Specification	Method reference
1.	Description	A white to off-white crystalline powder	IP Monograph
2.	Solubility	Practically insoluble in water, slightly soluble in methanol, Sparingly soluble in dichloromethane.	IP General chapter
3.	Identification by infrared absorption spectrophotometry	The Infrared absorption spectrum of sample is concordant with the spectrum of Telmisartan standard	IP 2.4.6
4.	Appearance of solution	The sample solution is not more intensely coloured than reference solution YS <sub>4</sub>	IP 2.4.1
5.	Loss on drying	Not more than 0.5%w/w	IP 2.4.19
6.	Sulphated ash	Not more than 0.1%w/w	IP 2.3.18
7.	Heavy metals	Not more than 20 ppm	IP 2.3.13
8.	Related substances by HPLC		
	Single maximum impurity	Not more than 0.2%	BP / Ph. Eur. Monograph method
	Total impurities	Not more than 1.0%	
9.	Assay by HPLC (on dried basis)	Not less than 98.0% and Not more than 102.0% w/w	In-house validated method

END OF THE DOCUMENT

Description	Prepared By	Reviewed By	Approved By
Sign & Date			
Department	Quality control	Quality control	Quality assurance

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