



ANDHRA ORGANICS LIMITED

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Title	FINISHED PRODUCT SPECIFICATION FOR SULPHADIAZINE IP	SP No.	FP/SP/SDZ/002
		Revision No.	01
Department	Quality Control	Effective date	
Supersedes	FP/SP/SDZ/002; Rev.00	Dated: 22.02.2020	Next Review

I. SPECIFICATIONS

SULPHADIAZINE

S. No.	Test	Specification	Method reference
1.	Description	White, yellowish white or pinkish white crystals or crystalline powder; almost odourless.	IP General chapter monograph
2.	Solubility	Slightly soluble in acetone, very slightly soluble in ethanol (95%), practically insoluble in chloroform and in water. It dissolves in solutions of alkali hydroxides and in dilute mineral acids.	IP general chapter 2.4.26
3.	Identification		
3.1.	By Infrared absorption spectrophotometry	The infrared absorption Spectrum of sample is concordant with the spectrum of Sulphadiazine RS or Working standard.	IP 2.4.6 (or) <197A>
3.2.	By TLC	The principal spot in the chromatogram obtained with reference solution-(a) should be similar in position and size with the chromatogram obtained with reference solution-(c).	IP 2.3.7
4.	Appearance of solution	The solution is not more intensely colored than reference solution YS5, BYS5 or GYS5.	IP 2.4.1
5.	Acidity	Not more than 0.2 ml of 0.1M sodium hydroxide is required to change the color of the solution	IP Monograph
6.	Related substances by TLC	Not more than 0.5%	IP Monograph
7.	Heavy metals	Not more than 20 ppm	IP 2.3.13
8.	Sulphated ash	Not more than 0.1%	IP 2.3.18
9.	Loss on drying	Not more than 0.5%	IP 2.4.19
10.	Assay (on dried basis)	Not less than 99.0% and Not more than 101.0% w/w	IP 2.3.31

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Description	Prepared By	Reviewed By	Approved By
Sign & Date			
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Desg. & Dept.	Sr. Executive-QC	Sr. Manager- QC	Manager- QA