STELLENCE PHARMSCIENCE LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : OLSALAZINE SODIUM BP/EP | **Page 1 of 1**

Sr.No.	TESTS		SPECIFICATIONS	METHOD
1.	**CHARACTERS**	:	A yellow, fine, crystalline powder,	By visual observation
2.	**SOLUBILITY**	:	sparingly soluble in water, soluble in dimethyl sulphoxide, very slightly soluble in methanol.	AS per BP
3.	**IDENTIFICATION**	:	Test A: Ratio of absorbance: The ratio of the absorbance measured at the maximum at 255 nm to that measured at the maximum at 362 nm is 0.53 to 0.56.	2.2.25 as per BP
			Test B: IR Spectrum: The sample IR spectrum should be concordant with that of standard	2.2.24 As per BP
			Test C: TLC: The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a)	2.2.27 As per BP
			Test D: Sodium reaction: It should give reaction of Sodium	2.3.1 As per BP
4.	**ACETATE (By HPLC)**	:	Not more than 1.0 %	2.2.29 As per BP
5.	**METHANESULPHONIC ACID**	:	Not more than 0.3 %	2.2.29 As per BP
6.	**RELATED SUBSTANCES:** **By HPLC: A** Unknown impurity Total impurity	:	 Not more than 1.0 % Not more than 2.0 %	2.2.29 As per BP
7.	**HEAVY METALS**	:	Not more than 10 ppm Pb	2.4.8 As per BP
8.	**LOSS ON DRYING** (Determined on 1.0 gm for 1 hours at 150 ºC)	:	Not more than 2.0 %	2.5.12 As per BP
9.	**ASSAY** (CONTENT OF $C_{14}H_8N_2Na_2O_6$. ON DRIED BASIS)	:	98.0 % to 102.0 % by potentiometric titration.	2.2.20 As per BP