

STELLENCE PHARMSCIENCE LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : TEMAZEPAM BP/EP

Page 1 of 1

Sr.No.	TESTS	SPECIFICATIONS	METHOD
1.	CHARACTERS	: White or almost white, crystalline powder.	By visual observation
2.	SOLUBILITY	: Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in alcohol.	As per BP
3.	IDENTIFICATION	: Test A: IR Spectrum: The sample IR spectrum should be concordant with that of standard	2.2.24 As per BP
4.	IMPURITY A	: Not more than 0.05 %	2.2.25 As per BP
5.	RELATED SUBSTANCES: By HPLC: A Impurity B Impurity C Impurity D Impurity E Impurity F Impurity G Unknown Impurity Total impurity	: Not more than 0.2 % Not more than 0.2 % Not more than 0.2 % Not more than 0.2 % Not mote than 0.2 % Not more than 0.2 % Not more than 0.1 % Not more than 0.5 %	2.2.29 As per BP
5.	LOSS ON DRYING (Determined on 1.0 gm for 4 hours at 100 -105 °C)	: Not more than 0.5 %	2.2.32 As per BP
6.	SULPHATED ASH (Determined on 1.0 g)	: Not more than 0.1 %	2.4.14 As per BP
7.	ASSAY (CONTENT OF C₁₆H₁₃CIN₂O₂. ON DRIED BASIS)	: 99.0 % to 101.0 % by potentiometric titration.	2.2.20 As per BP