

STELLENCE PHARMSCIENCE LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : LORAZEPAM BP/EP

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Sr.No	TESTS		SPECIFICATIONS	METHOD
1.	CHARACTERS	:	A white or almost white, crystalline powder	By visual observation
2.	SOLUBILITY	:	Practically insoluble in water, sparingly soluble in alcohol, sparingly soluble or slightly soluble in methylene chloride.	As per BP
3.	IDENTIFICATION	:	Test A: Specific absorbance: The specific absorbance at 230 nm is 1070 to 1170.	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: The principal spot in the chromatogram obtained with test solution (b) is similar in position and size to the spot in the chromatogram obtained with reference solution (a)	2.2.27 As per BP
4.	RELATED SUBSTANCES(BY TLC) Any individual impurity	:	Not more than 0.2 %.	2.2.27 As per BP.
5.	LOSS ON DRYING (Determined on 1.0 gm for 1 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 C₁₅H₁₀Cl₂N₂O₂. ON DRIED BASIS)	:	98.5 % to 102.0 % by potentiometric titration.	2.2.20 As per BP