

STELLENCE PHARMSCIENCE LIMITED, BANGLORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : BROMAZEPAM BP/EP

Page 1 of 1

Sr.No	TESTS		SPECIFICATIONS	METHOD
1.	CHARACTERS	:	A white or yellowish, crystalline powder,	By visual observation
2.	SOLUBILITY	:	practically insoluble in water, sparingly soluble in alcohol and in methylene chloride.	As per BP
3.	IDENTIFICATION	:	Test A: Specific absorbance: The specific absorbance at 233 nm is 980 to 1080.	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
			Test D: Colour test: A violet colour develops	As per BP
			Test E: Bromide reaction: The solution should give bromide reaction	2.3.1 As per BP
	APPERANCE OF SOLUTION	:	The solution is clear	2.2.1 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 in Vacuum for 4 hours at 80°C)	:	Not more than 0.2 %	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 C₁₄H₁₀BrN₃O. ON DRIED BASIS)	:	99.0 % to 101.0 % by potentiometric titration.	2.2.20 As per BP