

STELLENCE PHARMSCIENCE LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : MIDAZOLAM BP/EP

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Sr.No.	TESTS		SPECIFICATIONS	METHOD
1.	CHARACTERS	:	White or yellowish, crystalline powder.	By visual observation
2.	SOLUBILITY	:	Practically insoluble in water, freely soluble in acetone and in ethanol (96 per cent), soluble in methanol.	As per BP
3.	IDENTIFICATION	:	Test A: Melting point : 161°C to 164°C	2.2.14 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 test solution (b) is similar in position and size to the spot in the chromatogram obtained with reference solution (b)	2.2.27 As per BP
			Test D: Colour test : An addition of 0.1 ml of alizarian solution & 0.1 ml of Zirconyl nitrate solution The test solution is yellow and the blank solution is red.	As per BP
			Test E : Chlorides : The solution should give reactions for chlorides	2.3.1 As per BP
4.	APPERANCE OF SOLUTION	:	The solution is clear and not more intense than reference solution	2.2.1 & 2.2.2 As per BP
5.	RELATED SUBSTANCES: By HPLC: A Impurity B Impurity A Impurity G Unknown Impurity Total impurity	:	Not more than 0.2 % Not more than 0.1 % Not more than 0.1 % Not more than 0.1 % Not mote than 0.3 %	2.2.29 As per BP
	IMPURITY C: (By TLC)	:	Not more than 0.1 %	2.2.27 As per BP

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6.	LOSS ON DRYING (Determined on 1.0 gm for 2 hours at 100 -105 °C)	:	Not more than 0.5 %	2.2.32 As per BP
7.	SULPHATED ASH (Determined on 1.0 g)	:	Not more than 0.1 %	2.4.14 as per BP
8.	ASSAY (CONTENT OF C₁₈H₁₃ClFN₃. ON DRIED BASIS)	:	98.5 % to 101.5 % by potentiometric titration.	2.2.20 As per BP