

STELLENCE PHARMSCIENCE LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : NITRAZEPAM BP/EP

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Sr.No.	TESTS		SPECIFICATIONS	METHOD
1.	CHARACTERS	:	A yellow, crystalline powder,.	By visual observation
2.	SOLUBILITY	:	practically insoluble in water, slightly soluble in alcohol..	As per BP
3.	IDENTIFICATION	:	Test A: Melting point: 226°C to 230°C.	2.2.14 As per BP
			Test B: Specific absorbance: The specific absorbance at the maximum is 890 to 950..	2.2.25 As per BP
			Test C: IR Spectrum: The sample IR spectrum should be concordant with that of standard	2.2.24 As per BP
			Test D: Colour test : A red colour should produce on addition of 1 ml of <i>N</i> -(1-Naphthyl)ethylenediamine Dihydrochlorid	As per BP
			Test E: Colour test: A intense yellow colour should produce on addition 0.05 ml dilute sodium hydroxide	As per BP
4.	RELATED SUBSTANCES (By TLC) Aminonitrobenzophenone Nitrazepam impurity A Any individual impurity	:	Not more than 0.1 %. Not more than 0.1 % Not more than 0.1 %	2.2.27 As per BP.
5.	HEAVY METALS	:	Not more than 10 ppm Pb	2.4.8 As per BP
6.	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
7.	SULPHATED ASH (Determined on 1.0 g)	:	Not more than 0.1 %	2.4.14 as per BP
8.	ASSAY (CONTENT OF C₁₅H₁₁N₃O₃. ON DRIED BASIS)	:	99.0 % to 101.0 % by potentiometric titration.	2.2.20 As per BP