

# KARNATAKA CHEMSYN LIMITED, BANGALORE

## FINISHED PRODUCT SPECIFICATIONS

**NAME OF THE PRODUCT : NITRAZEPAM BP/EP**

**Page 1 of 1**

Sr.No.	TESTS		SPECIFICATIONS	METHOD
1.	<b>CHARACTERS</b>	:	A yellow, crystalline powder,.	By visual observation
2.	<b>SOLUBILITY</b>	:	practically insoluble in water, slightly soluble in alcohol..	As per BP
3.	<b>IDENTIFICATION</b>	:	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.	<b>RELATED SUBSTANCES (By TLC)</b>  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.	<b>HEAVY METALS</b>	:	Not more than 10 ppm Pb	2.4.8 As per BP
6.	<b>LOSS ON DRYING</b>  (Determined on 1.0 gm for 4 hours at 100 -105 °C)	:	Not more than 0.5 %	2.2.32 As per BP
7.	<b>SULPHATED ASH</b>  ( Determined on 1.0 g )	:	Not more than 0.1 %	2.4.14 as per BP
8.	<b>ASSAY (CONTENT OF C<sub>15</sub>H<sub>11</sub>N<sub>3</sub>O<sub>3</sub>. ON DRIED BASIS)</b>	:	99.0 % to 101.0 % by potentiometric titration.	2.2.20 As per BP