

KARNATAKA CHEMSYN LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : PROPYPHENAZONE BP / EP

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Sr.No.	TESTS	SPECIFICATIONS	METHOD
1.	CHARACTERS	: A White or slightly yellowish, crystalline powder.	By visual observation
2.	SOLUBILITY	: Slightly soluble in water, freely soluble in alcohol and in Methylene chloride, soluble in ether.	AS per BP
3.	IDENTIFICATION	: Test A: Melting point: 102°C to 106°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 (By TLC) : The principle spot in the chromatogram obtained with test solution (b) shall be similar in position, size, and colour, to the principle spot in the chromatogram obtained with reference solution (a).	2.2.27 as per BP
		Test D : Colour test : A brownish red colour should appear which becomes yellow on addition of 1 ml of dilute hydrochloric acid.	As per BP
4.	APPEARANCE OF SOLUTION (4 % w/v solution in equal volumes of alcohol and water)	: Should be clear and colourless	2.2.1 and 2.2.2 as per BP
5.	ACIDITY OR ALKALINITY	: Must comply	AS per BP
6.	RELATED SUBSTANCES(BY TLC)	: Any individual impurity : Not more than 0.2 %.	As per BP.
7.	HEAVY METALS	: Not more than 10 ppm	2.4.8 , Test C as per BP.
8	LOSS ON DRYING (Determined on 1.0 gm in Vacuum for 4 hours at 60 °C)	: Not more than 0.5 %	2.2.32 as per BP
9.	SULPHATED ASH (Determined on 0.5 gm)	: Not more than 0.1%.	2.4.14 as per BP
10.	Organic volatile impurities a) Acetone b) IPA	Not more than 750 PPM Not more than 2500 PPM	In house method

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11.	ASSAY (CONTENT OF C₁₄H₁₈N₂O ON DRIED BASIS)	:	99.0 % to 101.0 % by potentiometric titration.	2.2.20 as per BP