

STELLENCE PHARMSCIENCE 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 C ₁₄ H ₁₈ N ₂ O ON DRIED BASIS) | : | 99.0 % to 101.0 % by potentiometric titration. | 2.2.20 as per BP |