

CERTIFICATE OF ANALYSIS

PIROXICAM BP 2005/ EP 5

CHARACTERISTICS A WHITE OR SLIGHTLY YELLOW CRYSTALLINE

POWDER

SOLUBILITY PRACTICALLY INSOLUBLE IN

WATER, SOLUBLE IN METHYLENE

CHLORIDE, SLIGHTLY SOLUBLE IN ETHANOL

IDENTIFICATION IR SPECTRUM

RESIDUE ON IGNITION NOT MORE THAN 0.10%

HEAVY METALS NOT MORE THAN ≤20 PPM

WATER NOT MORE THAN 0.5%

LOSS ON DRYING NOT MORE THAN 0.5%

SULPHATED ASH NOT MORE THAN 0.1%

HPLC IMPURITIES

INDIVIDUAL IMPURITIES NOT MORE THAN 0.2%

TOTAL IMPURITIES NOT MORE THAN 0.4%

RESIDUAL SOLVENTS ETHANOL ≤5000 PPM

1,4-DIOXANE : ≤380 PPM

XYLENE : ≤2170PPM

DMF : ≤880 PPM

ACETIC ACID : ≤5000 PPM

TITRATION ASSAY (CALCULATED ON DRIED BASIS) 98.5% -101.0%