



CERTIFICATE OF ANALYSES
NAME OF THE PRODUCT : KETOCONAZOLE USP 31

| TEST | OBSERVATION | LIMITS/SPECIFICATION |
|---------------------------------|--------------------------|--|
| DESCRIPTION | WHITE CRYSTALLINE POWDER | WHITE TO OFF WHITE ,CRYSTALLINE POWDER |
| SOLUBILITY | COMPLIES | FREELY SOLUBLE IN DICHLOROMETHANE ,SOLUBLE IN CHLOROFORM AND IN METHANOL,SPARINGLY SOLUBLE IN ETHANOL(95%),PRACTICALLY INSOLUBLE IN WATER AND IN OTHER |
| IDENTIFICATION | COMPLIES | AS PER USP (IR) |
| MELTING RANGE | 149.0°C TO 150.0°C | 148.0°C TO 152.0°C |
| SPECIFIC ROTATION | 0.00° | -1.00° TO +1.00° |
| LOSS ON DRYING | 0.36% | NMT 0.50% |
| RESIDUE ON IGNITION | 0.030% | NMT 0.100% |
| HEAVY METALS | COMPLIES | NMT 0.002% |
| CHROMATOGRAPHIC PURITY (BY TLC) | COMPLIES | 5MN OF INTENSITY OF ANY SECONDARY SPOTS OBTAINED WITH TEST SOLUTION SHOULD NOT MORE INTENSE THAN THE SPOT IN THE CHROMATOGRAM OBTAINED WITH DILUTED STANDARD SOLUTION (NMT 2%) |
| ORGANIC VOLATILE IMPURITY | COMPLIES | AS PER USP |
| ASSAY | 99.62% | 98.0% TO 102.0% W/W ON DRIED BASIS |