

CERTIFICATE OF ANALYSIS

Product: Darunavir Ethanolate[CAS:635728-49-3]

Batch No: 20160701

Manufacturing Date: July 2016

Expiry Date: July 2018

Quantity: 12.4 Kgs

| Items | Specifications | Results |
|----------------------------|---|---------|
| Description | White or almost white crystalline powder. | Conform |
| Solubility | Freely soluble in acetone and ethyl acetate, practically insoluble in water | Conform |
| Identification | IR | Conform |
| | HPLC RT | Conform |
| Specific rotation | -5°~+5° (1 % w/v in methanol 20°C) | 0° |
| Water (by KF) | ≤1.5% | 0.56% |
| Related substances | Difuranyl impurity≤0.15% | 0.07% |
| | Other Individual impurity≤0.08% | 0.065% |
| | Total impurities≤0.3% | 0.24% |
| Sulphated ash | ≤0.1% | 0.02% |
| Heavy Metals | ≤0.001% | Conform |
| Ethanol | 6.5~8.3% | 7.1% |
| Residual solvents | Ethyl acetate≤0.5% | 0.01% |
| | Isopropyl alcohol≤0.5% | N.D |
| | Methanol≤0.3% | 0.003% |
| | N-methyl-2-pyrrolidone≤0.053% | N.D |
| Microbiological purity | Total number of aerobic bacteria ≤ 1000 CFU in 1g | Conform |
| | Total number of mould and yeast≤ 100 CFU in 1g | Conform |
| | Absence of Escherichia coli in 1g | Conform |
| Assay | 98.0%~102.0% | 99.8% |
| Partical size distribution | D(90) = 50-250 μm | Conform |
| | D(50) = 20-80 μm | Conform |
| | D(10) = less 20 μm | Conform |

Conclusion:It Complies with the Enterprise's Standard.