TRANSGENE BIOTEK LIMITED

Plot No. 68, 69 & 70, Anrich, IDA Bollaram,
Medak dt – 502 325, HYDERABAD, INDIA

CERTIFICATE OF ANALYSIS

PRODUCT : **TACROLIMUS**

BATCH NO :

QUANTITY :

Q C REF NO :

DATE :

DATE OF MFG :

DATE OF EXP :

S.NO.	NAME OF THE PARAMETER	RESULT	SPECIFICATION
1	DESCRIPTION		White crystalline powder
2	SOLUBILITY		Freely soluble in Ethyl acetate and in Acetonitrile, sparingly soluble in n-hexane. Insoluble in water.
3	MELTING RANGE		127 – 129°C
4	SPECIFIC OPTICAL ROTATION @ 20°C		- 84.9 TO – 83.9 Degrees
5	RELATED SUBSTANCES		NMT 2.0 %
6	WATER CONTENT		NMT 3.0%
7	PURITY (ON DRY)		NLT 98.0%
8	HEAVY METALS		NMT 20 ppm
9	TOTAL ISOMERS OF TACROLIMUS		NMT 5.0%
10	CHROMATOGRAPHIC PURITY, LARGEST INDIVIDUAL IMPURITY		NMT 0.7%

TBL

Analyzed by

Checked by