



**TABRIZ PHARMA**  
Tabriz Chemical and Pharmaceutical Ind.

Date:  
No:  
Comment:

## Quality Control Laboratory

### Certificate of Analysis

**Product: Dimethyl Fumarate**

**Batch No.: DMF97-100**

**Lab No.: QC 441**

**Mfg. date: 05/10/97**

**Ref: In-House; USP41-BP2017**

**Exp. date: 05/10/99**

No.	Chemical Analysis	Specifications	Results
01	Characteristics	White to off white crystalline powder	Conforms
02	Identification A,B	The IR Spectrum of test sample should be concordant with spectrum obtained with that of the reference standard. The retention time of the major peak in the test chromatogram should concordant to that of the reference standard preparation in assay.	Passes the tests
03	Solubility	Soluble in Methanol, Ethyl acetate and Acetone, Practically insoluble in Water.	Conforms
04	Water	Max. 0.5%	0.1%
05	Sulfated Ash	Max.0.1%	0.08%
06	Heavy metals	Max. 10 ppm	< 10 ppm
07	Free Acid	Max. 1.3ml of NaOH 0.1 M	Test solution Consumed 0.1ml of NaOH 0.1M 99.8%
08	Assay(HPLC)	98-102%	99.8%
09	Related impurities by HPLC:		
	Fumaric Acid	Max. 0.15%	N.D
	Monomethyl fumarate	Max. 0.15%	0.11%
	Dimethyl maleate	Max. 0.15%	0.075%
10	Residual Solvents: Methanol	Max.3000 ppm	< 3000 ppm
11	XRD	X-Ray diffraction pattern of the test sample should be concordant with reference standard.	Conform
12	Melting Point	102-105 °C	104 °C

**Date of Sampling: 06/10/97**

**Approved**

**Rejected**

**Date of Analysis: 07/10/97**

*[Signature]*  
**Analyst**

*[Signature]*  
**Q.C. Manager**

*[Signature]*  
**Authorized by**

We hereby certify that this product has been prepared under GMP regulation and tested according & conform to the requirements of In- house Specification. All test methods are according to USP41 and BP2017 .