

B-256, 2nd Floor Naraina Phase-1, New Delhi India-110028
 Email:- Kureasiapharma@gmail.com Ph. +91 11-40234824

Product Name	Tudofovir Tablets		B No	KT-298	
Generic Name	Tenofovir Disoproxil Fumarate Tablets IP 300 mg				
Batch Size	1.0 Lac	Sampling Date	10/06/2018	M/D	06/2018
Sample Qty	40 Tablets	Analysis Date	11/06/2018	E/D	05/2020
Reporting Date	13/06/2018		A.R. No	IAL/MP/180610005	

S. No	TEST	SPECIFICATION	RESULTS
01.	Description	Navy Blue coloured elongated biconvex film coated tablets	Navy Blue coloured elongated biconvex film coated tablets
02.	Identification A (by HPLC)	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the Assay.	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the Assay.
	Identification B	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.
03.	Dissolution (by HPLC)	Not less than 80% (Q) of the labeled amount of Tenofovir Disoproxil Fumarate is dissolved in 45 minutes.	Within 90.48% to 96.31%
04.	Related Substances (by HPLC)	Complies	Complies
05.	Average Weight	1150.0 mg \pm 3%	1151.0 mg
06.	Uniformity of Weight	Within limits	Within limits
07.	Water	Not more than 5.0% w/w	2.48% w/w
08.	Assay:- Each film coated tablet contains 300 mg of Tenofovir Disoproxil Fumarate	Not less than 90.0% and not more than 110.0% of the labeled amount of Tenofovir Disoproxil Fumarate	298.4 mg (99.46%)
Prepared by		Checked by	Approved by
			