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Product Name	Entekor-1 Tablets		B No	KT-242	
Generic Name	Entecavir Tablets I.P. 1.0 mg				
Batch Size	NS	Sampling Date	28/02/2018	M/D	02/2018
Sample Qty	60 Tablets	Analysis Date	28/02/2018	E/D	01/2020
Reporting Date	03/03/2018		A.R. No	IAL/MP/180228007	

S. No	TEST	SPECIFICATION	RESULTS
01.	Description		
02.	Identification (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.
03.	Dissolution (by HPLC)	Not less than 80% (Q) of the labeled amount of Entecavir Monohydrate is dissolved in 45 minutes.	Within 91.12% 97.15%
04.	Related Substances (by HPLC)	Complies	Complies
05.	Average Weight	207 mg \pm 3%	207.16 mg
06.	Uniformity of Content	85% to 115%	Complies
08.	Assay:- Each film coated tablet contains 1 mg of Entecavir Monohydrate	Not less than 90.0% and not more than 110.0% of the labeled amount of Entecavir Monohydrate	0.971 mg (97.1%)

Prepared by	Checked by	Approved by
		