

Certificate Of Analysis

Analysis Date: 14-09-2022 **Re-test Date:** 14-09-2025

TENOFOVIR DISOPROXIL IMPURITY B

Identification

Chemical Name: (1-Methylethyl) (5RS,8R)-9-(6-amino-9H-purin-9-yl)-5-methoxy-8-

methyl-5-oxo-2,4,7-trioxa-5-?5-phosphanonanoate

CAT No : ALL-TENO-12

CAS No : 1246812-16-7

Molecular Formula : C15H24N5O7P

Molecular Weight : 417.35

NH2 N O O CH3 and epimer at P

Analytical Information

Batch No. : ALL-TENO-12 HPLC Purity : 96.01%

Solubility : USP Diluent / EP Diluent (MEOH) **Potency** : 92.10%

Appearance of Product: Off White Solid Mass: Confirm

Long Term Storage : -20°C **IR Analysis** : Confirm

Weight Loss By TGA : 0.190% 1HNMR : Confirm

Residue Of Ignition : 3.881%

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =

 $[100 - (0.190 + 3.881) \times 96.01]/100 = 92.10\%$

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr.Vipul khadase	
		Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche	
		Director QA&QC	

Attachment : HPLC, Mass, 1H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified