

## CERTIFICATE OF ANALYSIS

<b>Product name</b>	Tenofovir Alafenamide Fumarate	<b>Reference standard</b>	In House Standard
<b>Batch No.</b>	DBH251-B15A-221104	<b>Certificate No.</b>	0018
<b>MFG. date</b>	Jun. 17, 2022	<b>Retest date</b>	Jun. 16, 2025
<b>Packing</b>	20.00 kg/drum	<b>Quantity</b>	20.00 kg
<b>ITEMS</b>	<b>SPECIFICATIONS</b>	<b>RESULTS</b>	
<b>Appearance</b>	White to off-white powder	Off-white powder	
<b>Identification</b>	HPLC: The retention time of the major peak in the sample solution corresponds to that of the standard.	Conform	
<b>Solution of clarity</b>	2% sample solution shows the same clarity as that of methanol or its opalescence is not more pronounced than that of the reference suspension.	Conform	
<b>Water</b>	≤0.5%	0.2%	
<b>Related Substances</b>	Isomer 6&1 ≤0.15%	0.01%	
	Impurity1 ≤0.50%	0.03%	
	Impurity2 ≤0.15%	0.01%	
	Impurity3 ≤0.15%	0.02%	
	Impurity4 ≤0.15%	<0.01%	
	Impurity5 ≤0.15%	<0.03%	
	Any other individual impurity ≤ 0.10%	0.04%	
	Total impurities ≤1.0%	0.12%	
<b>Assay</b>	98.0~102.0%, (on the anhydrous and solvent free basis)	99.3%	
<b>Fumaric acid content</b>	9.8~11.8%	10.8%	
<b>Enantiomer</b>	≤0.15%	<0.01%	
<b>Residual Solvents</b>	Methanol ≤3000 ppm	ND	
	Isopropanol ≤5000 ppm	ND	
	Acetonitrile ≤410 ppm	49 ppm	
	Dichloromethane ≤600 ppm	<10.9 ppm	
	Toluene ≤890 ppm	ND	
	Triethylamine ≤320 ppm	ND	

ND=Not detected

CONCLUSION: COMPLIES WITH IN HOUSE STANDARD

