



Certificate of analysis

Product name: Tenofovir disoproxil fumarate

Cas number: 202138-50-9

Molecular Formula: $C_{19}H_{30}N_5O_{10}P$

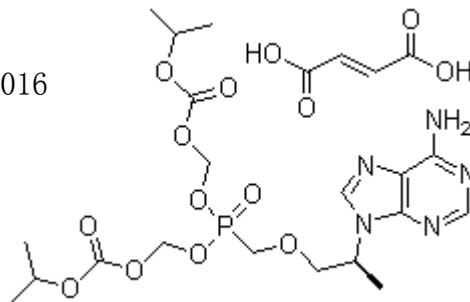
Molecular Weight: 635.51

Date of production: Apr. 18, 2016

Batch NO: 20160418

Exp Date: Apr. 17, 2018

Chemical structure:



Items	Specifications	Results
Appearance	White or slight white powder	white powder
Water	$\leq 1.0\%$	0.31%
Identification	The same as Ref, Standard	Conforms
Clarity and color of solution (1% sample in solution in methanol)	Should not more intense than the reference	Conforms
Solubility	Soluble in water:methanol(1:1)	Conforms
Sulphated ash	$\leq 0.5\%$	0.06%
Heavy metal	≤ 10 PPM	Conforms
Fumaric acid	17.5%~19.0%	18.3%
Enantiomeric purity	S-isomer $\leq 1.0\%$	0.01%
Related substances	Impurity A (Mone-pom PMPA) $\leq 0.8\%$	0.26%
	PMPA $\leq 0.15\%$	0.02%
	Impurity B $\leq 0.15\%$	Conforms
	Impurity C $\leq 0.15\%$	Conforms
	Specified unidentified impurity at RRT1.05 $\leq 0.15\%$	Conforms
	Chloromethyl isopropyl casbonate $\leq 0.10\%$	0.003%
	Unspecified impurity $\leq 0.10\%$	0.06%
Residual solvents	Total impurity $\leq 2.50\%$	0.63%
	Isopropyl alcohol ≤ 3000 ppm	Conforms
	Dichloromethane ≤ 300 ppm	Conforms
	Isopropyl acetate ≤ 4000 ppm	Conforms
	N-methyl pyrrolidone ≤ 480 ppm	Conforms
Polymorphic identity	Total residual solvents ≤ 7780 ppm	Conforms
	By differential scanning calorimetry	Conforms
Assay	By X-ray powder diffraction	Conforms
		98%~102%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F

