COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Tenofovir disoproxil fumarate Premix (Item No. 41033720) (Tenofovir disoproxil fumarate 50.63% w/w)	**Spec. No.** : SP-AK30-T37
Reference(s) :	**Rev. No.** : 01
1. In-house specification (Mylan Laboratories Ltd.'s specification) 2. International pharmacopoeia fourth edition	
Other Requirements : —	**Page** : 1/2

GPO specification

Test Items	Specification	
Description	White to off-white, granular powder.	
Identification A. HPLC B. UV absorption	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Related substances by HPLC. The UV absorption spectrum of the Sample solution matches with that of the Standard solution, as obtained in the Assay.	
Water	Not more than 5.0%.	
Related substances	Mono ester impurity	: Not more than 1.5%.
	Tenofovir disoproxil dimer impurity	: Not more than 0.25%.
	Unspecified impurity	: Not more than 0.2%.
	Total impurities	: Not more than 2.5%.
Content of Tenofovir disoproxil fumarate (Each 592.50 mg of premix contains 300 mg of Tenofovir disoproxil fumarate.)	95.0-105.0% of the labeled amount of Tenofovir disoproxil fumarate, equivalent to 48.10 – 53.16% w/w.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 05/01/18 Head of Raw Material Standard Section I	Somthavee, 08/01/18 Director of Raw Material Standard Division	VARIPIN, 8/01/18 Director of Regulatory Compliance and Documentation Division	Vichian (Acting) 10/01/18 Director of Quality Assurance Department	28/01/18

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Tenofovir disoproxil fumaraate Premix (Item No. 41033720).
Sampling plan	P plan : for Identification $\sqrt{N} + 1$: for other tests
Testing procedure	Tests to be performed as per current version of WI-AK30-T37.
Storage condition	Do not store above 30 °C, store in original container.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	First issue, อ้างอิง Spec. : RMS-RA-79N56010 Revision No. 03 ที่ทางสถาบันวิจัยฯ กำหนดเพื่อยื่นขึ้นทะเบียน โดยอ้างอิง Spec. ตามบริษัทผู้ผลิต (Mylan Laboratories Ltd., India) และ International pharmacopoeia fourth edition	28/01/18

Prepared by :	Reviewed by :		Approved by :	Eff. Date
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