COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Abacavir Sulfate USP (Item No. 41030010)	**Spec. No.** : SP-AK30-A15
Reference(s) : USP 42 p. 25 - 27	**Rev. No.** : 02
Other Requirements : GPO specification	**Page** : 1/3

USP 42

Test Items	Specification	
Description	White to off-white powder.	
Solubility	Soluble in water.	
Identification		
A. Infrared absorption <197K>	Conforms to IR standard spectrum.	
B. HPLC	The retention time of the major peak of the Sample solution corresponds to that of the System suitability solution, obtained as directed in the test for Organic impurities, Procedure 2.	
C. Sulfate Test	-With barium chloride TS, solutions of sulfates yield a white precipitate that is insoluble in hydrochloric acid and in nitric acid. -With lead acetate TS, neutral solutions of sulfates yield a white precipitate that is soluble in ammonium acetate TS. -Hydrochloric acid produces no precipitate when added to solutions of sulfates (distinction from thiosulfates).	
Water	Not more than 0.5%.	
Residue on ignition	Not more than 0.2%.	
Organic impurities		
- Procedure 1: Related compounds	Descyclopropyl abacavir	: Not more than 0.2%.
	trans-Abacavir	: Not more than 0.2%.
	O-Pyrimidine derivative abacavir	: Not more than 0.2%.
	t-Butyl derivative abacavir	: Not more than 0.2%.
	Any unspecified impurity	: Not more than 0.1%.
	Total impurities	: Not more than 0.8%.
- Procedure 2: Enantiomeric purity	Not more than 0.3% of abacavir enantiomer.	
Assay	97.0% - 102.0% of $(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$ calculated on the anhydrous and solvent-free basis.	

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 25/09/19	Tawinee Limbunmit, 25/09/19	[signature], 27/09/19	Vichien Kuengsongsri, 27/09/19	15/12/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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GPO specification

Test Items	Specification	
Residual solvents	Methanol	: Not more than 200 ppm.
	Ethanol	: Not more than 5000 ppm.
	Isopropyl alcohol	: Not more than 500 ppm.

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Abacavir Sulfate USP (Item No. 41030010).
Sampling plan	1. N Plan ($\sqrt{N} + 1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-A15.
Storage condition	Preserve in well-closed containers. Store at room temperature.
Retest period	1 year after first testing date.

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Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 25/09/19	Tanmia ..., 25/09/19	..., 27/09/19	Vichim Rungruangroj, 27/09/19	15/12/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality (Acting) Assurance Department	

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History of changes

Rev. No.	Description	Effective date
01	First issue, อ้างอิง USP 39 โดยเนื้อหาของ USP 39 และ USP 36 เหมือนกัน และยื่นขึ้นทะเบียนด้วย USP 36	28/08/17
02	Update spec. เป็น USP 42 ตามมติที่ประชุม site change ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป โดยเนื้อหาของ USP 39 และ USP 42 เหมือนกัน	15/12/19

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Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sumaliree, 25/09/19	........, 25/09/19	........, 27/09/19	........, 27/09/19	15/12/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality (Acting) Assurance Department	