COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Ritonavir Premix (Item No. 41033107) (Ritonavir 11.76% w/w)
Spec. No. : SP-AK30-R32
Reference(s) : In-house specification (Mylan Laboratories Ltd's specification)
Rev. No. : 01
Other Requirements : —
Page : 1/2

GPO specification

Test Items	Specification	
Description	White or off-white to creamish colored powder.	
Identification - HPLC - X-ray diffraction	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. X-ray diffractogram of the sample solution should not show any crystalline peak of Ritonavir.	
Water	Not more than 3%.	
Organic impurities	N-deacylvaline ritonavir	: Not more than 0.2%.
	Hydroxyritonavir	: Not more than 0.3%.
	Hydantoin aminoalcohol	: Not more than 2.6%.
	Ritonavir hydroperoxide	: Not more than 0.2%.
	Oxazolidinone derivative	: Not more than 0.2%.
	Any individual unspecified degradation product	: Not more than 0.2%.
	Total impurities	: Not more than 3.5%.
Assay (Each 850 mg of Ritonavir premix contains 100 mg of Ritonavir.)	97.0-103.0% of the labeled amount of Ritonavir ($C_{37}H_{48}N_6O_5S_2$), equivalent to 11.41-12.11% w/w).	
Methylene chloride content	Not more than 588 ppm.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sirinannee / 17/08/17 Head of Raw Material Standard Section 1	Yuwaporn / 17/08/17 Director of Raw Material Standard Division	VARIPIN / 17/08/17 Director of Regulatory Compliance and Documentation Division	Vichien Ruangyuryuj 18/08/17 Director of Quality Assurance Department (Acting)	28/08/17

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Ritonavir Premix (Item No. 41033107).
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-R32.
Storage condition	Do not store above 25°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-79N53011 Revision 03 ที่ทางสถาบันวิจัยฯกำหนดเพื่อยื่นขึ้นทะเบียน โดยอ้างอิง Spec ตามบริษัทผู้ผลิต (Mylan Laboratories Ltd, India)	28/08/17

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Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suranee /17/08/17	Yawaporn /17/08/17	VARIPIN /17/08/17	Vichien Rungmuang 18/08/17	28/08/17
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department (Acting)	