COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Irbesartan USP (Item No. 41010825)	**Spec. No.** : SP-AK30-I82
Reference(s) : USP 41 p. 2231-2232	**Rev. No.** : 04
Other Requirements : GPO specification	**Page** : 1/3

USP 41

Test Items	Specification	
Description	White to off-white, crystalline powder.	
Solubility	Slightly soluble in alcohol and in methylene chloride; practically insoluble in water.	
Identification A : Infrared Absorption <197K> B : HPLC	Conforms to IR standard spectrum. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	
Water	Not more than 0.5%, Method I.	
Limit of azide	Not more than 10 ppm.	
Organic impurities	Irbesartan related compound A	: Not more than 0.2%.
	Any other impurity	: Not more than 0.1%.
	Total impurities	: Not more than 0.5%.
Assay	98.0% - 102.0% of Irbesartan ($C_{25}H_{28}N_6O$), calculated on the anhydrous basis.	

Prepared by :	Reviewed by :		Approved by :	Eff. Date
24/03/21	26/03/21	26/03/21	26/03/21	01/04/21
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	

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GPO specification

Test Items	Specification	
Heavy metals	Not more than 20 ppm, Method II.	
Particle size by Laser diffraction, Malvern	d (0.9)	: Not more than 10 µm.
Nitrosamines content	N-Nitrosodimethylamine (NDMA)	: Not more than 0.03 ppm.
	N-Nitrosodiethylamine (NDEA)	: Not more than 0.03 ppm.
	N-Nitroso-N-methyl-4-aminobutyric acid (NMBA)	: Not more than 0.03 ppm.

Method Parameters for Particle size Analysis using Malvern Mastersizer 3000.

No.	Parameter	Specification
1	Condition	Dry Dispersion (Air pressure 3 bar).
2	Absorption	0.1 (For slightly colored powders).
3	Particle refractive index (RI)	1.689 (For organic compounds).
4	Weighted residual	< 3%.
5	Obscuration	1-3%.
6	Analysis model	General purpose.
7	Particle shape	Irregular-particles have angular shapes (default).
8	Measurement integration time	≥ 3000 ms/ sample.
9	Measurement background time	≥ 10 seconds.
10	Result units	Volume.

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

Approved source (s)	Refer to current version of Approved Vendor List of Irbesartan USP (Item No. 41010825).
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-I82.
Storage condition	Preserve in tight containers and store at a temperature below 30 °C.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	- First issue, อ้างอิง USP 37 ตามที่ยื่นขึ้นทะเบียน	01/04/15
02	- เอกสารมีอายุครบ 3 ปี จึงทบทวน โดยคง spec. USP 37	30/09/18
03	- เพิ่มข้อกำหนดหัวข้อ Nitrosamines content ตามมติที่ประชุม supplier meeting 2019 (กลุ่มย่อย) ในวันที่ 10 เมษายน 2562 ที่ห้องประชุมฝ่ายประกัน - Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/ BP 2016 ขึ้นไป โดยเนื้อหาของ USP 41 และ USP 37 เหมือนกัน	22/04/19
04	- ปรับเกณฑ์การยอมรับของ Nitrosamine impurities แต่ละรายการ (NDMA, NDEA และ NMBA) ให้มีปริมาณไม่มากเกินกว่า 0.03 ppm ตามประกาศจากสำนักงานคณะกรรมการอาหารและยา	01/04/21

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 24/03/21	JARINEE LERMBOONRAT / 26/03/21	/ 26/03/21	/ 26/03/21	01/04/21
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