COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Glipizide USP (Item No. 41010789)	**Spec. No.** : SP-AK30-G89
Reference(s) : USP 41 p. 1949 – 1951	**Rev. No.** : 02
Other Requirements : GPO specification	**Page** : 1/3

USP 41

Test Items	Specification	
Description	White to off-white powder.	
Solubility	Freely soluble in dimethylformamide; soluble in 0.1 N sodium hydroxide; slightly soluble in methylene chloride.	
Identification		
A. Infrared Absorption <197K>	Conforms to the IR standard spectrum.	
B. Ultraviolet Absorption <197U>	The UV absorption spectra of the Test solution and Standard solution exhibit maxima and minima at the same wavelengths.	
C. HPLC	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	
Loss on drying	Not more than 1.0%.	
Residue on ignition	Not more than 0.4%.	
Related compounds	**Test 1** (Limit of methyl-N-4-[2-(5-methylpyrazine-2-carboxamido)ethyl] benzenesulfonyl carbamate):	
	Methyl-N-4-[2-(5-methylpyrazine-2-carboxamido) ethyl] benzenesulfonyl carbamate impurity	: Not more than 0.5%.
	Any other individual impurity	: Not more than 0.5%.
	Test 2 (Limit of Related compounds A, B and C):	
	Glipizide related compound A	: Not more than 0.5%.
	Glipizide related compound B	: Not more than 0.5%.
	Glipizide related compound C	: Not more than 0.5%.
	Total impurities (Test 1 + Test 2)	: Not more than 1.5%.
Assay	98.0% - 102.0% of $C_{21}H_{27}N_5O_4S$, calculated on the dried basis.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 24/09/19	25/09/19	, 26/09/19	, 27/09/19	30/11/19
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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GPO specification

Test Items	Specification
Heavy metals	Not more than 0.005%, Method II.
Particle size by Laser diffraction, Malvern	d(0.9) : Not more than 20 µm.

Method Parameters for Particle size Analysis using Malvern Mastersizer 3000

No.	Parameter	Specification
1	Condition	Dry Dispersion (Air pressure 3.5 bar).
2	Absorption	0.1 (For slightly colored powders).
3	Particle refractive index (RI)	1.520 (For organic compounds).
4	Weighted residual	< 2%.
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 and measure 10 times/ sample.
9	Measurement background time	≥ 10 seconds.
10	Result units	Volume.

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COPY No. 1

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Glipizide USP (Item No. 41010789)	**Spec. No.** : SP-AK30-G89
Reference(s) : USP 41 p. 1949 – 1951	**Rev. No.** : 02
Other Requirements : GPO specification	**Page** : 3/3

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Glipizide USP (Item No. 41010789).
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-G89.
Storage condition	Preserve in tight containers, protected from light. Store at room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรกเป็น USP 38	25/08/16
02	Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป โดยเนื้อหาของ USP 38 และ USP 41 เหมือนกัน	30/11/19

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
24/09/19	25/09/19	26/09/19	27/09/19	30/11/19
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)	