GPO COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Fenofibrate USP (micronized) (Item No. 41010698)	**Spec. No.** : SP-AK30-F50
Reference(s) : USP 41 p. 1695 - 1696	**Rev. No.** : 03
Other Requirements : GPO Specification	**Page** : 1/3

USP 41

Test Items	Specification	
Description	White or almost white, crystalline powder.	
Solubility	Very soluble in methylene chloride; slightly soluble in alcohol; practically insoluble in water.	
Identification Infrared absorption <197K>	Conforms to IR standard spectrum.	
Residue on ignition	Not more than 0.1%.	
Chloride	Not more than 0.01%.	
Sulfate	Not more than 0.01%.	
Melting range or temperature	79 °C - 82 °C.	
Acidity	Not more than 0.2 ml is required to change the color of the indicator to pink.	
Loss on drying	Not more than 0.5%.	
Color and Achromicity	The Sample solution is not more intensely colored than the Reference solution.	
Organic impurities	Fenofibrate related compound A	: Not more than 0.1%.
	Fenofibrate related compound B	: Not more than 0.1%.
	(3RS)-3-[4-(4-Chlorobenzoyl)phenoxy]butan-2-one	: Not more than 0.1%.
	Methyl 2-[4-(4-chlorobenzoyl)phenoxy]-2-methyl-propanoate	: Not more than 0.1%.
	Ethyl 2-[4-(4-chlorobenzoyl)phenoxy]-2-methyl-propanoate	: Not more than 0.1%.
	(4-Chlorophenyl)[4-(1-methylethoxy)phenyl]methanone	: Not more than 0.1%.
	Fenofibrate related compound C	: 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 $C_{20}H_{21}ClO_4$, calculated on the dried basis.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

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

Test Items	Specification
Heavy metals	Not more than 20 ppm, Method II.
Particle size - Laser diffraction, Malvern d(0.9)	Not more than 10 µm.

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)	1.520 (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.
9	Measurement background time	≥ 10 seconds.
10	Result units	Volume.

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Fenofibrate USP (micronized) (Item No. 41010698).
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-F50.
Storage condition	Preserve in well-closed, light-resistant containers. Store at room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก อ้างอิง USP 37 ตามที่ยื่นขึ้นทะเบียน	31/03/15
02	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยคงเนื้อหาเดิม USP 37	18/04/18
03	Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป โดยเนื้อหาของ USP 37 และ USP 41 เหมือนกัน	30/11/19

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

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