



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Deferiprone

Spec. No. : SP-AK30-D29

(Item No. 41021990)

Reference(s): GPO Specification (R&D Institute)

Rev. No. : 04

Other Requirements: -

Page : 1/2

GPO Specification	Description	: White to off-white crystalline powder.
	Identification	: A. Infrared absorption spectrophotometer.
		: B. The retention time of the major peak in the chromatogram of the Sample solution corresponds to that in the chromatogram of the Standard solution, as obtained in the Assay.
	Water content	: Not more than 0.5%.
	Individual impurity	: Not more than 0.1%.
	Total impurities	: Not more than 0.25%.
	Assay	: 98.0% to 102.0% of deferiprone ($C_7H_9NO_2$), calculated on the anhydrous basis.
	Tapping volume	: 5.0-g portion occupies not more than 9.5 ml when tapped down 20 times at 3-mm drop height at a nominal rate of 250 drops/minute.
	Tapped density	: For information.
	Particle size	: For information.
	(By Image Analysis)	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :	Approved by :	Eff. Date
J. Roppadech / 0310219	Turna L. W. / 0310219	Vichin Rungvongroj / 04109119	10/09/19
Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
Standard Section 2	Standard Division	Department (Acting)	



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Deferiprone (Item No. 41021990)	Spec. No. : SP-AK30-D29
Reference(s): GPO Specification (R&D Institute)	Rev. No. : 04
Other Requirements: -	Page : 2/2

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Deferiprone (Item No. 41021990).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-D29.
Storage condition	Store at a condition stated on the label from the manufacturer or store in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	ประกาศใช้ครั้งแรก อ้างอิงตาม GPO Specification (R&D Institute)	29/09/06
02	Update ข้อกำหนดตาม GPO Specification (R&D Institute) เพิ่มหัวข้อทดสอบ Tapped Density และ Particle size (By Image Analysis)	19/10/09
03	ทบทวนข้อกำหนด อ้างอิงตาม GPO Specification (R&D Institute) ซึ่งเหมือนกับ Rev. No. 02	23/06/16
04	ทบทวนข้อกำหนด อ้างอิงตาม GPO Specification (R&D Institute) ซึ่งเหมือนกับ Rev. No. 03	10/09/19

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Noppadech / 03/09/19 Head of Raw Material Standard Section 2	Reviewed by : [Signature] / 03/09/19 Director of Raw Material Standard Division	Approved by : [Signature] / 04/09/19 Director of Regulatory Compliance and Documentation Division	Approved by : [Signature] / 04/09/19 Director of Quality Assurance Department (Aching)	Eff. Date 10/09/19
--	--	--	---	-----------------------