



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Ferrous Fumarate BP

Spec. No. : SP-AK30-F025

(Item No. 41021550)

Reference(s): BP 2019 page I-1022 to I-1024

Rev. No. : 02

Other Requirements: GPO Specification

Page : 1/2

BP 2019

Test Parameters	Requirement
Description	Fine, reddish-orange or reddish-brown powder.
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96%).
Identification	A. Thin-layer chromatography.
	B. Mix 0.5 g with 1 g of resorcinol. To 0.5 g of the mixture in a crucible add 0.15 mL of sulfuric acid and heat gently. A dark red semi-solid mass is formed. Add the mass, with care, to 100 mL of purified water. An orange-yellow colour develops and the solution shows no fluorescence.
	C. It gives reaction (a) of iron.
Sulfates	Not more than 0.2%.
Arsenic (Method A)	Not more than 5 ppm.
Ferric ion	Not more than 2.0%.
Cadmium	Not more than 10 ppm.
Chromium	Not more than 200 ppm.
Lead	Not more than 20 ppm.
Mercury	Not more than 1 ppm.
Nickel	Not more than 200 ppm.
Zinc	Not more than 500 ppm.
Loss on drying	Not more than 1.0%.
Assay	93.0% to 101.0% of Ferrous Fumarate ($C_4H_2FeO_4$), calculate on the dried substance.

Prepared by: Benjawan Ubongklee, 29/11/21 Head of Raw Material Standard Section 2	Reviewed by: Suwannee, 29/11/21 Director of Raw Material Standard Division	Approved by: (Noting) Tarnie, 02/12/21 Director of Quality Assurance Department	Eff. Date 13/12/21
--	---	--	-----------------------

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Ferrous Fumarate BP (Item No. 41021550)	Spec. No. : SP-AK30-F025
Reference(s): BP 2019 page I-1022 to I-1024	Rev. No. : 02
Other Requirements: GPO Specification	Page : 2/2

GPO Specification

Test Parameter	Requirement
Particle size analysis (by Malvern Mastersizer)	d(0.9) not more than 40 µm.

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Ferrous Fumarate BP (Item No. 41021550).
Sampling plan	For Identification : 100%. For Other Tests : N plan ($\sqrt{N} + 1$).
Testing procedure	Tests to be performed as per current version of WI-AK30-F025.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in airtight containers. Protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด (อ้างอิงตาม BP 2016)	20/09/16
02	Update ข้อกำหนด (อ้างอิงตาม BP 2019) และเพิ่มการทดสอบ Particle size ตาม GPO Specification (R&D Institute)	13/12/21

Prepared by: Benjawan Ubonklee, 29/11/21 Head of Raw Material Standard Section 2	Reviewed by: Gunawanee, 29/11/21 Director of Raw Material Standard Division	Approved by: Tarnie, 02/12/21 Director of Quality Assurance Department	Eff. Date 13/12/21
---	--	---	-----------------------