



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Ferrous Fumarate For Suspension
(Item No. 41021550)

Spec. No. : SP-AK30-F025

Reference(s) : BP 2016 p. I-958 – I-960 [Ferrous Fumarate]

Rev. No. : 01

Other Requirements : -

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BP 2016

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. A dark red semi-solid mass is formed. Add the mass 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	: Maximum 0.2%.
Arsenic (Method A)	: Maximum 5 ppm.
Ferric ion	: Maximum 2.0%.
Cadmium	: Maximum 10 ppm.
Chromium	: Maximum 200 ppm.
Lead	: Maximum 20 ppm.
Mercury	: Maximum 1 ppm.
Nickel	: Maximum 200 ppm.
Zinc	: Maximum 500 ppm.
Loss on drying	: Maximum 1.0%.
Assay	: 93.0% to 101.0% of $C_4H_2FeO_4$ (dried substance).

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

Prepared by : J. Noppadolch, 02/09/16 Head of Raw Material Standard Section 2	Reviewed by : Nalaya, 02/09/16 Director of Raw Material Standard Division Vichin Ruengrongroj, 05/09/16 Director of Regulatory Compliance and Documentation Division	Approved by : Prapanadee A., 06/09/16 (Acting) Director of Quality Assurance Department	Eff. Date 20/09/16
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Ferrous Fumarate BP (Item No. 41021550).
Sampling plan	P plan : For Identification. $\sqrt{N} + 1$ plan : For Other tests.
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 an airtight container, protected from light.
Retest period	1 year after first testing date.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Noppadech, 03/09/16 Head of Raw Material Standard Section 2	Reviewed by : Nalapa, 02/09/16 Director of Raw Material Standard Division Wichin Rungrongroj, 05/09/16 Director of Regulatory Compliance and Documentation Division	Approved by : Prapradu G., 06/09/16 Acting Director of Quality Assurance Department	Eff. Date 20/09/16
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COPY No. 1

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(Item No. 41021550)

Spec. No. : SP-AK30-F025

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History of changes

Rev. No.	Description	Effective Date
01	จัดทำครั้งแรก (อ้างอิงตาม BP 2016)	20/09/16

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Noppadech, 02/09/16 Head of Raw Material Standard Section 2	Reviewed by : Nalaga, 02/09/16 Director of Raw Material Standard Division Nichan, 05/09/16 Director of Regulatory Compliance and Documentation Division	Approved by : Prapanada A., 26/09/16 (Acting) Director of Quality Assurance Department	Eff. Date 20/09/16
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