



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION
RAW MATERIAL SPECIFICATION

Title : Calamine BP

(Item No. 41020460)

Spec. No. : SP-AK30-C2

Reference(s) : BP 2016 p. I-353 – I-354

Rev. No. : 05

Other Requirements : -

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BP 2016

Description	: An amorphous, impalpable, pink or reddish brown powder; free from grittiness.
Solubility	: Practically insoluble in water. It dissolves with effervescence in hydrochloric acid.
Identification	: A. Yields the reactions characteristic of carbonates. B. It gives reactions of iron salts and zinc salts.
Calcium	: The solution remains clear.
Soluble barium salts	: The solution remains clear.
Lead	: Not more than 150 ppm.
Chloride	: Not more than 0.07%.
Sulfate	: Not more than 0.6%.
Ethanol-soluble dyes	: The filtrate is colourless.
Matter insoluble in hydrochloric acid	: The weight of residue is not more than 10 mg.
Water-soluble dyes	: The filtrate is colourless.
Residue on ignition	: 68.0 % to 74.0 %.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Noppadeeh, 29/06/16 Head of Raw Material Standard Section 2	Reviewed by : Nalee, 29/06/16 Director of Raw Material Standard Division Vichin Rungtongroj, 01/07/16 Director of Regulatory Compliance and Documentation Division	Approved by : A. U. R. R., 12/07/16 Director of Quality Assurance Department	Eff. Date 26/07/16
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Calamine BP (Item No. 41020460).
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-C2.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Rongpadech, 29/07/16 Head of Raw Material Standard Section 2	Reviewed by : N. A. S., 29/07/16 Director of Raw Material Standard Division Vichit, 01/08/16 Director of Regulatory Compliance and Documentation Division	Approved by : A. Y. K., 12/07/16 Director of Quality Assurance Department	Eff. Date 26/07/16
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History of changes

Rev. No.	Description	Reviewed by	Effective Date
04	อ้างอิงตาม BP 2011	ผอ. มาตรฐานวัตถุคิ	03/11/11
05	อ้างอิงตาม BP 2016	ผอ. มาตรฐานวัตถุคิ	26/07/16

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Kloppechey ๑๑๑๑๑๑๑๑ Head of Raw Material Standard Section 2	Reviewed by : ๑๑/๑๑/๑๑ Director of Raw Material Standard Division	Approved by : ๑๑/๑๑/๑๑ Director of Regulatory Compliance and Documentation Division	Eff. Date 26/07/16
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