GPO 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 page I-353 to I-354	**Rev. No.** : 06
Other Requirements: -	**Page** : 1/2

BP 2016

Test Parameters	Requirement
Description	An amorphous, impalpable, pink or reddish brown powder.
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 (reaction B) 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 residue weighs not more than 10 mg.
Water-soluble dyes	The filtrate is colourless
Residue on ignition	68.0% to 74.0%.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech, 05/02/20	Tanna Linlawan, 05/02/20	, 06/02/20	Vichien Ruengrongroj, 07/02/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department Acting	

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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	For Identification : 100%. For Other Tests : n plan.
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.

History of changes

Rev. No.	Description	Effective Date
04	Update ข้อกำหนดตาม BP 2011	03/11/11
05	Update ข้อกำหนดตาม BP 2016	26/07/16
06	ทบทวนเอกสาร (ข้อกำหนด Rev. No. 05 และ Rev. No. 06 อ้างอิงตาม BP 2016)	15/03/20

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech, 05/02/20 Head of Raw Material Standard Section 2	Tarnnu Lulwont, 05/02/20 Director of Raw Material Standard Division	, 06/02/20 Director of Drug Registration and Pharmacovigilance Division	Vichien Ruengwongroj, 07/02/20 Director of Quality Assurance Department (Acting)	15/03/20