COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Folic acid BP (Item No. 41010715) **Spec. No.** : SP-AK30-F2/1

Reference(s) : BP 2021 p. I-1110 to I-1112 **Rev. No.** : 02

Other Requirements : GPO specification **Page** : 1/2

BP 2021

Test Parameters	Specification Limit	
Description	Yellowish or orange, crystalline powder.	
Solubility	Practically insoluble in water and in most organic solvents. It dissolves in dilute acids and in alkaline solutions.	
Identification A. Specific optical rotation B. Infrared absorption spectrophotometry C. Water	 + 18 to + 22 (anhydrous substance). Conforms to IR standard spectrum. Between 5.0% and 8.5%.	
Related substances	Impurity A	: Not more than 0.5%.
	Impurity D	: Not more than 0.4%.
	Impurities C, E, G : for each impurity	: Not more than 0.3%.
	Impurities H, I : for each impurity	: Not more than 0.15%.
	Unspecified impurities : for each impurity	: Not more than 0.10%.
	Total impurities	: Not more than 1.2%.
Water	Between 5.0% and 8.5%.	
Sulfated ash	Not more than 0.2%, determined on 1.0 g.	
Assay	96.0% - 102.0% of $C_{19}H_{19}N_7O_6$, calculated with reference to the anhydrous substance.	

GPO specification

Test Parameters	Specification Limit	
Residual solvents	Acetone (1)	: Not more than 1000 ppm.

Remark : Residual solvents (1) for DSM Nutritional Products Ltd./Switzerland

Prepared by :	Reviewed by :		Approved by :	Eff. Date
(Acting) Thanyatorn / 03/05/22	Siwanee / 03/05/22	/ 05/05/22	(Acting) Tasanee Lumlerdkrai / 11/05/22	30/06/22
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Folic acid BP (Item No. 41010715).
Sampling plan	1. N Plan ($\sqrt{N}+1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-F2/1.
Storage condition	Preserve in well-closed, light-resistant containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก อ้างอิง BP 2016 ตามตำรับที่ยื่นขึ้นทะเบียน Ferrofolic tablet ของสถาบันวิจัยฯ	31/08/17
02	เอกสารมีอายุมากกว่า 3 ปี จึงทบทวน โดย Update spec. จาก BP 2016 เป็น BP 2021	30/06/22

Prepared by :	Reviewed by :		Approved by :	Eff. Date
(Acting) 03/05/22	03/05/22	05/05/22	(Acting) 11/05/22	30/06/22
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	