GPO COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Isoniazid BP (Item No. 41010840)	**Spec. No.** : SP-AK30-I4
Reference(s) : BP 2019 p. I-1363 to I-1365	**Rev. No.** : 07
Other Requirements : GPO Specification	**Page** : 1/2

BP 2019

Test Items	Specification	
Description	White or almost white, crystalline powder.	
Solubility	Freely soluble in water, sparingly soluble in ethanol (96%).	
Identification A. Melting point B. Infrared absorption spectrophotometry	 170 °C to 174 °C. Conforms to IR standard spectrum.	
Appearance of solution	Solution S is clear and not more intensely coloured than reference solution BY_7.	
pH	6.0 to 8.0 for solution S.	
Impurity E	Not more than 15 ppm.	
Related substances	Impurity A	: Not more than 0.15%.
	Impurity B	: Not more than 0.15%.
	Unspecified impurity	: Not more than 0.10%.
	Total impurities	: Not more than 0.5%.
Loss on drying	Not more than 0.5%.	
Sulfated ash	Not more than 0.1%.	
Assay	99.0 – 101.0% of Isoniazid ($C_6H_7N_3O$), calculated with reference to the dried substance.	

GPO Specification

Test Items	Specification
Fineness	Pass through sieve No. 60 : not less than 95%.
Tapping volume	5.0 g portion occupies not less than 7 ml and not more than 12 ml when tapped down 20 times at 3-mm drop height and at a rate of 250 drops/minute.

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Siwannee / 01/08/19 Head of Raw Material Standard Section 1	Tasmin / 02/08/19 Director of Raw Material Standard Division	02/08/19 Director of Regulatory Compliance and Documentation Division	Vichien Ruangwongrit (Acting) 06/08/19 Director of Quality Assurance Department	30/10/19

GPO องค์การเภสัชกรรม COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Isoniazid BP (Item No. 41010840)	**Spec. No.** : SP-AK30-I4
Reference(s) : BP 2019 p. I-1363 to I-1365	**Rev. No.** : 07
Other Requirements : GPO Specification	**Page** : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Isoniazid BP (Item No. 41010840).
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-I4.
Storage condition	Preserve in tight, light-resistant containers. Store at 25 °C, excursions permitted between 15 °C and 30 °C.
Retest period	1 year after first testing date.

History

Rev. No.	Description	Effective date
03	เปลี่ยนเป็น BP 2007	13/08/07
04	เปลี่ยนเป็น BP 2011	15/09/11
05	Update spec. เป็น BP 2015 เพื่อให้สอดคล้องกับ Finished product spec. ตาม CR No. 58232 โดยเนื้อหาของ BP 2011 และ BP 2015 เหมือนกัน	30/10/15
06	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน แต่คง spec. เดิม BP 2015	30/10/18
07	Update spec. เป็น BP 2019 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป	30/10/19

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee , 01/08/19 Head of Raw Material Standard Section 1	, 02/08/19 Director of Raw Material Standard Division	02/08/19 Director of Regulatory Compliance and Documentation Division	Vichien Ruengyongroj 06/08/19 Director of Quality Assurance Department	30/10/19