COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Primaquine phosphate USP (Item No. 41011250)	**Spec. No.** : SP-AK30-P28
Reference(s) : USP 41 p. 3430-3431	**Rev. No.** : 05
Other Requirements : GPO Specification	**Page** : 1/2

USP 41

Test Items	Specification	
Description	Orange-red, crystalline powder, odorless.	
Solubility	Soluble in water, insoluble in chloroform and in ether.	
Identification A. Infrared absorption <197K> B. Phosphate Test C. HPLC	 The IR absorption spectrum of sample exhibits the same spectrum as Reference Standard. - With silver nitrate TS, pyrophosphates obtained by ignition yield a white precipitate that is soluble in 2 N nitric acid and in 6 N ammonium hydroxide. - With ammonium molybdate TS, a yellow precipitate that is soluble in 6 N ammonium hydroxide is formed. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	
Loss on drying	Not more than 1.0%.	
Organic impurities	Specified unidentified impurity at RRT 0.24	: Not more than 0.20%.
	Specified unidentified impurity at RRT 0.29	: Not more than 0.60%.
	Primaquine related compound A	: Not more than 2.0%.
	Secaquine	: Not more than 0.80%.
	Any other individual impurities	: Not more than 0.20%.
	Total impurities	: Not more than 3.0%.
Assay	97.0% to 102.0% of primaquine phosphate ($C_{15}H_{21}N_3O \cdot 2H_3PO_4$), calculated on the dried basis.	

GPO Specification

Test Items	Specification
Tapping volume	5.0-g portion occupies between 10 ml and 15 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
Suvannee / 03/04/19 Head of Raw Material Standard Section 1	Tawee / 04/04/19 Director of Raw Material Standard Division	/ 05/04/19 Director of Regulatory Compliance and Documentation Division	Kumgrong / 09/04/19 Director of Quality Assurance Department (Acting)	17/06/19

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Primaquine phosphate USP (Item No. 41011250)	**Spec. No.** : SP-AK30-P28
Reference(s) : USP 41 p. 3430-3431	**Rev. No.** : 05
Other Requirements : GPO Specification	**Page** : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Primaquine phosphate USP (Item No. 41011250)
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-P28.
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
03	Update spec. เป็น USP 34	15/09/14
04	ทบทวนเอกสารเนื่องจากมีอายุครบ 3 ปี ยังคง spec. เดิม USP 34	27/09/17
05	Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/ BP 2016 ขึ้นไป	17/06/19

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 03/04/19	Tawnee Limlumnt / 04/04/19	/ 05/04/19	Vichien Rungrueangrit / 09/04/19	17/06/19
Head of Raw Material Standard Section I	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department Acting	