COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Quinine dihydrochloride BP (Item No. 41033020) **Spec. No.** : SP-AK30-Q001

Reference(s) : BP 2019 p. II-756 to II-757 **Rev. No.** : 07

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

BP 2019

Test Items	Specification
Description	A white or almost white powder.
Solubility	Very soluble in water, soluble in ethanol (96%).
Identification A. TLC B. Acidity C. Chlorides test	 The principal spot in the chromatogram obtained with solution (1) corresponds in position, colour and size to that in the chromatogram obtained with solution (2). pH of a 3% w/v solution, 2.0 to 3.0. A curdled, white precipitate is formed. This precipitate is soluble in ammonia.
Acidity	pH of a 3% w/v solution, 2.0 to 3.0.
Specific optical rotation	(-223) to (-229), calculated with reference to the dried substance.
Barium	The solution remains clear for at least 15 minutes.
Sulfate	Not more than 0.12%.
Other cinchona alkaloids	Dihydroquinine : Not more than 10%. Any related substance eluting before quinine : Not more than 5%. Any other related substance : Not more than 2.5%
Loss on drying	Not more than 3.0%.
Sulfated ash	Not more than 0.1%.
Assay	99.0 - 101.0% of alkaloid dihydrochlorides, calculated as $C_{20}H_{24}N_2O_2,2HCl$, with reference to the dried substance.

GPO Specification

Test Items	Specification
Expiry date	The expiry date is beyond the date of material receipt at GPO warehouse for at least 4 years.

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suvannee 01/08/19 Head of Raw Material Standard Section I	Tawnie Lundsorn 02/08/19 Director of Raw Material Standard Division	02/08/19 Director of Regulatory Compliance and Documentation Division	Vichian Puangpongpis (Acting) 06/08/19 Director of Quality Assurance Department	15/08/19

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Quinine dihydrochloride BP (Item No. 41033020).
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-Q001.
Storage condition	To be stored in well-closed containers, protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
04	Update spec. เป็น BP 2007	15/10/10
05	Update spec. เป็น BP 2014 อ้างอิง CR No. 58236 โดยเนื้อหาของ BP 2014 เหมือนกับ BP 2007	29/05/15
06	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดย update spec. เป็น BP 2017 โดยเนื้อหาของ BP 2014 และ BP 2017 เหมือนกัน	29/05/18
07	Update spec. เป็น BP 2019 ตามมติที่ประชุม Site transfer	15/08/19

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
01/08/19	02/08/19	02/08/19	06/08/19	15/08/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	