

Document Code : FQC-10-0037/03
Issued Date Document : January 10, 2013



Plant Bandung

CERTIFICATE OF ANALYSIS

Finished Product

No. 13050051K

Product Name : Quinine Hydrochloride Analysis Date : May 22, 2013
Product Code : 1900013 Analysis by : Jajang, Saldia
Batch No. : E13N047B Re-test Date : May, 2018
Quantity : 510.1 kg
Packaging : Drum @ 25 kg
Mfg. Date : May 22, 2013

No.	TEST	REQUIREMENTS	RESULT
1	Appearance	White or almost white or colourless, fine, silky needles, often in clusters.	Conform
2	Odor, Taste	Odorless, very bitter	Conform
3	Solubility	Soluble in water, freely soluble in ethanol (96 per cent)	Conform
4	Identification A TLC	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	Conform
	B Colour Test (Bromine & ammonia reagent)	A green colour develops.	Conform
	C Fluorescence test	An intense blue fluorescence appears which disappears almost completely on the addition of hydrochloride acid.	Conform
	D <u>Chlorides</u> test	The solution gives the reaction of chlorides	Conform
	E pH	6.0 – 6.8	6.13
5	Appearance of Solution	• Solution is clear • Not more intensely coloured than reference solution Y6.	Conform Conform
6	pH	6.0 – 6.8	6.13

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No.	TEST	REQUIREMENTS	RESULT
7	Specific Optical Rotation	- 245° to -258° - 247° to -252° (FCC V)	-248.8° -248.0°
8	Sulphate	Not more than 500 ppm (0.05%)	Conform
9	Barium	Any opalescence in the solution is not more than that in a mixture of test solution and distilled water.	Conform
10	Other cinchona alkaloids		
	a. Impurity C (Dihydroquinine)	Maximum 10 %	2.40%
	b. Any Impurity eluted before Quinine	For each impurity, maximum 5 %	Quinidine : 0% Cinchonidine : 0.24%
	c. Any other impurity	For each impurity, maximum 0.2 %	Not detected
	d. Disregard limit	The area of the principal peak in the chromatogram obtained with reference solution (0.2%)	Not detected
	e. Other cinchona alkaloid (Procedure FCC V)	Passes test	Conform
11	Loss on drying	6.0 % - 10.0 % Not more than 10.0% (FCC V)	7.85%
12	Sulphated ash/ Residue on Ignation	Not more than 0.1 % Not more than 0.15% (FCC V)	0.05%
13	Heavy Metal	Not more than 10 ppm	Conform
14	Readily Carbonizable	Not more intensely colored than matching fluid M.	Conform
15	Assay (Calculated to the dried substance)	99.0 % - 101.0 % 99.0 % -101,5 % (FCC V)	99.73% 100.36%

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Product Name : Quinine Hydrochloride Analysis Date : May 22, 2013
Product Code : 1900013 Analysis by : Jajang, Saldia
Batch No. : E13N047B Re-test Date : May, 2018
Quantity : 510.10 kg
Packaging : Drum @ 25 kg
Mfg. Date : May 22, 2013

No.	TEST	REQUIREMENTS	RESULT
16	Chloroform – Alcohol Insoluble Substances	Passes test	Conform
17	Evaluation of Insolubles	No excessive physical matter and no detrimental or obnoxious matter	Conform

Reference : BP. 2009, *Ph Eur* 7, FCC V

Conclusion : Released

QA Manager

(Endang Widiastuti, Pharmacist)

Date : May 24. 2013



Bandung, May 23, 2013

QC Assistant Manager

(Diah Sofiyanti, Pharmacist)



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