kimia farma

CERTIFICATE OF ANALYSIS
Finished Product
No. 12100127K

Plant Bandung

Product Name	:	**Quinine Hydrochloride**	Document Code	:	FQC-10-0037/02
Product Code	:	1900013	Issued Date	:	April 20, 2012
Batch No.	:	J12N127B	Analysis Date	:	October 30, 2012
Quantity	:	514.2 kg	Analysis by	:	Jajang, Saidia
Packaging	:	Drum @ 25 kg	Re-test Date	:	October , 2017
Mfg. Date	:	October 30, 2012			

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 Chlorides test	The solution gives the reaction of chlorides	Conform
	E pH	6.0 – 6.8	6.55
5	Appearance of Solution	- Solution is clear - Not more intensely coloured than reference solution Y6.	Conform Conform
6	pH	6.0 – 6.8	6.55

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No.	TEST	REQUIREMENTS	RESULT
7	Specific Optical Rotation	- 245° to -258° ***- 247° to -252° (FCC V)***	-249.5° -248.7°
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 %	2.68%
	b. Any impurity eluted before Quinine	For each impurity, maximum 5 %	Quinidine : 0% Cinchonidine : 0.25%
	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)***	6.26%
12	Sulphated ash/ ***Residue on ignation***	Not more than 0.1 % ***Not more than 0.15% (FCC V)***	0.02%
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)***	100.26% 99.97%

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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 6, ***FCC V***
Conclusion : Released

Bandung, October 31, 2012

QA Manager

kimia farma PLANT BANDUNG

(Endang Widiastuti,Pharmacist)

QC Assistant Manager

(Diah Sofiyanti,Pharmacist)

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