

FAGRION IBERICA, S.A.

Josep Tapiolas 150

08226 Terrassa (Barcelona)

kimia farma**CERTIFICATE OF ANALYSIS****Finished Product****C.I.F. ES-A-08/199499**

Plant Bandung

No. 12080096K

Product Name : **Quinine Sulphate**
Product Code : 1900006
Batch No. : H12N096B
Quantity : 511.8 kg
Packaging : Drum @ 25 kg
Mfg. Date : August 15, 2012

Document Code : FQC-10-0024/02
Issued Date : April 2, 2012
Analysis Date : August 15, 2012
Analysis by : Dinne, Saldia
Re-test Date : August, 2017

NO	TEST	REQUIREMENTS	RESULT	REFERENCE
1	Appearance	White or almost white, crystalline powder or fine, colourless needles.	Conform	BP 2009, Ph Eur 6
2	Solubility	Slightly soluble in water, sparingly soluble in boiling water and in ethanol (96 per cent)	Conform	BP 2009, Ph Eur 6
3	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	BP 2009, Ph Eur 6
	b. Colour Test (Bromine & ammonia reagent)	A green colour develops.	Conform	BP 2009, Ph Eur 6
	c. Fluorescence test	An Intense blue fluorescence appears which disappears almost completely on the addition of hydrochloride acid.	Conform	BP 2009, Ph Eur 6
	d. <u>Sulphates</u> test	The solution gives reaction (a) of sulphate	Conform	BP 2009, Ph Eur 6
	e. pH	5.7 – 6.6	6.33	BP 2009, Ph Eur 6
4	Appearance of Solution	- Solution is clear - Not more intensely coloured than reference solution GY6	Conform Conform	BP 2009, Ph Eur 6 BP 2009, Ph Eur 6 (Method II)
5	pH	5.7 – 6.6	6.33	BP 2009, Ph Eur 6
6	Specific Optical Rotation	-237° to -245°	-241.2°	BP 2009, Ph Eur 6
7	Chloroform-alcohol-insoluble substances	The weight of residue does not exceed 2 mg (0.1%)	0.06%	USP 32

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NO	TEST	REQUIREMENTS	RESULT	REFERENCE
8	Heavy Metals	Not more than 0.001 %	Conform	USP 32(Method II)
9	Other cinchona alkaloids			
	a. Impurity C (Dihydroquinine)	Maximum 10 %	1.36 %	BP 2009, USP 32, Ph Eur 6
	b. Any impurity eluted before Quinine	For each Impurity, maximum 5 %	Quinidine : 0 % Cinchonidine: 0.10%	BP 2009, Ph Eur 6
	c. Any other impurity	For each impurity, maximum 0.2 %	Not detected	BP 2009, Ph Eur 6
	d. Disregard limit	The area of the principal peak in the chromatogram obtained with reference solution (0.2%)	Not detected	BP 2009, Ph Eur 6
10	Loss on drying	3.0 % - 5.0 %	4.51%	BP 2009, Ph Eur 6
11	Water	4.0 - 5.5 %	4.84%	USP 32 (Method I)
12	Sulphated ash / Residue in Ignition	Not more than 0.1 %	0.04%	BP 2009, USP 32, Ph Eur 6
13	Assay (Calculated to the dried substance and to the anhydrous base)	99.0 % - 101.0 %	99.28% (Calculated to the dried substance) 99.62% (Calculated to the anhydrous base)	BP 2009, USP 32, Ph Eur 6

Conclusion : Released

QA / QC Manager

Endang Widiastuti

(Endang Widiastuti, Pharmacist)



Bandung, August 29, 2012

QC Assistant Manager

Diah Sofiyanti

(Diah Sofiyanti, Pharmacist)

Page 2 of 2

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

BBU-B01

2308 B
Director Técnico

Jl. Pajajaran No. 29 - 31
Bandung 40171
Indonesia
Telp. (022) 4204043, 4204044
Fax. (022) 4237079
plantbdg@bdg.centrin.net.id