FAGRON IBERICA, S.A.
JosepTapiolas 150
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C.I.F. ES-A-08/199499

kimia farma

Plant Bandung

CERTIFICATE OF ANALYSIS
Finished Product
No. 12080096K

Product Name	:	Quinine Sulphate	Document Code	:	FQC-10-0024/02
Product Code	:	1900006	Issued Date	:	April 2, 2012
Batch No.	:	H12N096B	Analysis Date	:	August 15, 2012
Quantity	:	511.8 kg	Analysis by	:	Dinne, Saldia
Packaging	:	Drum @ 25 kg	Re-test Date	:	August , 2017
Mfg. Date	:	August 15, 2012			

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. Sulphates 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

Bandung, August 29, 2012

QA / QC Manager

kimia farma
PLANT BANDUNG

QC Assistant Manager

(Endang Widiastuti,Pharmacist)

(Diah Sofiyanti,Pharmacist)

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Corresponde al lote de Fagron:
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