F.LAB.10
Rev.07

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E-mail :

CERTIFICATE OF ANALYSIS
No. 240/102/KN/11/14

Name of Product: Quinine Sulfate EP 8.0

Manufacturer : PT. Sinkona Indonesia Lestari Batch No. : KS.1411010 Mfg. Date : October 31, 2014 Expiry Date : October 31, 2019 Quantity : 500 kgs	**DELIVERED TO:** ARNOLD SUHR NETHERLANDS B.V. STEIJNLAAN 26 1217 JS HIL VERSUM THE NETHERLANDS TEL. : +31 30 2481010 ; FAX. : +31 30 2414636 PURCHASE ORDER NO.: 7140282 DATED 16-10-2014

TEST RESULT ACCORDING TO THE EUROPEAN PHARMACOPOEIA 8.0

No.	TEST	SPECIFICATION	RESULT
1.	Appearance	White or almost white, crystalline powder or fine, colourless needles.	Conform
2.	Solubility	Slightly soluble in water, sparingly soluble in boiling water and in ethanol (96 per cent).	Conform
3.	Identification A. Test Chromatogram TLC	The principal spot sample similar with the reference solution	Conform
	B. Test Bromine and Ammonia	A green colour develops	Conform
	C. Test Fluorescence	An intense blue fluorescence appears which disappear on addition of hydrochloric acid	Conform
	D. Test of sulfates	The solution gives the reaction of sulphates	Conform
4.	Appearance of Solution Solution S (0.5 g in 25 ml 0.1 M hydrochloric acid)	Solution is clear and not more intensely coloured than reference solution GY_6 .	Conform
5.	Acidity pH (1% suspension in water)	5.7 to 6.6	6.15
6.	Specific Optical Rotation. (2%w/v solution in 0.1M HCl)	-237° to -245° Calculated on the dried basis.	-241.68°
7.	Other Cinchona Alkaloids By HPLC A. Dihydroquinine B. Any impurity eluted before quinine C. Any other impurity	 A. Max. 10% B. Max. 5% C. Max. 2.5%	 A. 2.61% B. 1.98% C. 0.00%
8.	Loss on drying (105°C for 3 h)	3.0% to 5.0%	4.60%
9.	Sulfated Ash	Max. 0.10%	0.04%
10.	Assay By non-aqueous titration with 0.1N $HClO_4$	99.0% to 101.0% Calculated on the dried basis.	100.28%
11.	Residual Solvent A. Toluene B. Benzene	 Max. 5 ppm Max. 2 ppm	 0.38 ppm 0.00 ppm

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
IJA109-B06
Director Técnico

Ciater; November 26, 2014

Bangbang Budiman
Assistant Manager of QC