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<br>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<br>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<br>(1% suspension in water) | 5.7 to 6.6 | 6.15 |
| 6. | Specific Optical Rotation.<br>(2%w/v solution in 0.1M HCl) | -237° to -245°<br>Calculated on the dried basis. | -241.68° |
| 7. | Other Cinchona Alkaloids By HPLC<br>A. Dihydroquinine<br>B. Any impurity eluted before quinine<br>C. Any other impurity | <br>A. Max. 10%<br>B. Max. 5%<br>C. Max. 2.5% | <br>A. 2.61%<br>B. 1.98%<br>C. 0.00% |
| 8. | Loss on drying<br>(105°C for 3 h) | 3.0% to 5.0% | 4.60% |
| 9. | Sulfated Ash | Max. 0.10% | 0.04% |
| 10. | Assay<br>By non-aqueous titration with 0.1N $HClO_4$ | 99.0% to 101.0%<br>Calculated on the dried basis. | 100.28% |
| 11. | Residual Solvent<br>A. Toluene<br>B. Benzene | <br>Max. 5 ppm<br>Max. 2 ppm | <br>0.38 ppm<br>0.00 ppm |

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
ISA 09-306
Director Técnico

Ciater; November 26, 2014

**Bangbang Budiman**
Assistant Manager of QC

arnold suhr
NETHERLANDS B.V.

# Certificate of Analysis

| | |
|---|---|
| Product : | Quinine Sulfate |
| Product no.: | A079 |
| Quality: | EP 8.0 |
| Batch no.: | KS.1411010 |
| Production date: | 31-10-2014 |
| Expiry date: | 31-10-2019 |
| Quantitiy: | 250 kg |
| Cas number: | 6119-47-7 |
| Your reference: | BI141765 |
| Your article code: | - |

| Item | Specification | Results |
|---|---|---|
| Appearance | White or almost white, crystalline powder or fine, colourless needles | Conform |
| Solubility: | Slightly soluble in water, sparingly soluble in boiling water and in ethanol (96 per cent.) | |
| Identification: | | |
| A) Test chromatogram TLC | The principal spot sample similar with the reference solution | Complies |
| B) Test bromine and ammonia | a green colour develops | Complies |
| C) Test fluorescence | An intense blue fluorescence appears which disappear on addition of hydrochloric acid | Complies |
| D) Test sulfates | The solution gives the reaction of sulphates | Complies |
| Appearance of solution | Solution is clear and not more intensely coloured than reference solution $Y_6$ | Conform |
| pH | 5.7 to 6.6 | 6.15 |
| Specific optical rotation | -237° to -245° calculated on dried basis | -241.68 ° |
| **Other cinchona alkaloids (Chromatogram HPLC):** | | |
| Dihydroquinine | 10 % max. | 2.61 % |
| Any related substance eluted before quinine | 5 % max. | 1.98 % |
| Any other related substance | 2.5 % max. | 0.00 % |
| Loss on drying | 3.0 % to 5.0 % | 4.60 % |
| Sulphated ash | 0.10 % max. | 0.04 % |
| Assay: bynon-aqueous titration with 0.1N HClO4 | 99.0 % to 101.0 % | 100.28 % |
| Residual solvent A. Toluene | Max. 5ppm | 0.38ppm |
| B. Benzene | Max. 2ppm | 0.00ppm |

**AS STATED BY OUR SUPPLIER**