**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/609

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | HAEMOGLOW SYRUP | | REF. NO: NDQD201501047 |
| **DATE RECEIVED:** 27.01.2015 | **LABEL CLAIM:** | Each 15 mL contains; Ferrous Gluconate BP 300 mg, Thiamine Mononitrate BP 5 mg, Riboflavin BP 5 mg, Pyridoxine Hydrochloride BP 1.5 mg, Niacinamide BP 45 mg, Cyanocobalamin(Vitamin B12)BP 15 mcg & Flavoured Syrup base q.s. | |
| **BATCH NO.:** FK155 | **PRESENTATION:** | Brown coloured syrup for oral administration, contained in a 200 mL amber coloured plastic bottle in a unit box. | |
| **MGF. DATE:** Oct. 2014 | **MANUFACTURER:** | FINECURE Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Dec. 2015 | **ADDRESS:** | Shimla Pistaur, Malsa Road, Kichha, Udhamsingh Nagar, Uttarakhand - 263148, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Jos Hansen & Soehne E.A. Ltd, Nairobi, KENYA. | |
| - | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2012 Vol. V App. XVI B | Use the old format, this sample was analysed in march 2015 | Use the old format, this sample was analysed in march 2015 | **COMPLIES** |
| **Identification** | UV HPLC | Ferrous Gluconate; Manufacturer's In-house Method USP 38 NF 33 Vol.4 Page 6313 | Ferrous Gluconate; UV absorption spectra of the sample assay exhibits maxima at wavelength 525 nm corresponding to that in the assay standard preparation. RT of the component Peaks in the assay sample preparation correspond to those in the assay standard preparation | UV absorption spectra exhibited maxima at wavelength 525 nm in both the assay sample and standard preparations. Super-imposable peak at RT; 4.2, 6.2, 9.4 and 15.2 minÃ‚Â± 10% present in the both the assay sample and standard preparations. | **COMPLIES** |
| **Assay** | UV:HPLC | USP 38 NF 33 Vol.4 Page 6313-6315 | Ferrous Gluconate 90.0 - 110.0% 90.0 - 150.0% | Ferrous Gluconate; 90.4% (RSD = 1.6%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV:HPLC | USP 38 NF 33 Vol.4 Page 6313-6315 | Ferrous Gluconate 90.0 - 110.0% 90.0 - 150.0% | Niacinamide; 108.7% (RSD = 0.5%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV:HPLC | USP 38 NF 33 Vol.4 Page 6313-6315 | Ferrous Gluconate 90.0 - 110.0% 90.0 - 150.0% | Pyridoxine HCl; 125.4% (RSD = 0.6%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV:HPLC | USP 38 NF 33 Vol.4 Page 6313-6315 | Ferrous Gluconate 90.0 - 110.0% 90.0 - 150.0% | Thiamine; 128.1% (RSD = 0.5%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV:HPLC | USP 38 NF 33 Vol.4 Page 6313-6315 | Ferrous Gluconate 90.0 - 110.0% 90.0 - 150.0% | Riboflavin;117.0% (RSD = 0.7%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In - house Method | 4.10 - 4.50 | 4.43 | **COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed.

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. F. NAULA |  | DATE:21-12-2015 |
| ANALYST: | DR. K. BOTA |  | DATE:21-12-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:21-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |