**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/610

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | HAEMOGLOW SYRUP | | REF. NO: NDQD201501046 |
| **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, Cyanocoblamine BP (Vitamin B12) 15 mcg and Flavoured Syrup base q.s. | |
| **BATCH NO.:** FK155 | **PRESENTATION:** | Brown coloured syrup for oral administration, contained in a 100 mL amber coloured plastic bottle, packed 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 | B.P. 2012 Vol. V App. XVI B | < 5 x 102 Colony Forming Units (CFU) per mL | < 100 CFU per mL | **COMPLIES** |
| **Identification** | UV HPLC | Thiamine Mononitrate, Riboflavin, Pyridoxine Hydrochloride, Niacinamide and Cyanocobalamin:USP 38 NF 33 Vol.4 Page 6313-6315 | Ferrous 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 min ÃƒÆ’Ã¢â‚¬Å¡Ãƒâ€šÃ‚Â± 10% present in both the assay sample and standard preparations. | **COMPLIES** |
| **Assay** | UV HPLC | Ferrous Gluconate Manufacturer's In House Method USP 38 NF 33 Vol.4 Page 6313-6315 | 90.0 - 110.0% 90.0 - 150.0% | Ferrous Gluconate 96.6% (RSD = 1.3%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV HPLC | Ferrous Gluconate Manufacturer's In House Method USP 38 NF 33 Vol.4 Page 6313-6315 | 90.0 - 110.0% 90.0 - 150.0% | Niacinamide 111.3% (RSD = 0.4%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV HPLC | Ferrous Gluconate Manufacturer's In House Method USP 38 NF 33 Vol.4 Page 6313-6315 | 90.0 - 110.0% 90.0 - 150.0% | Pyridoxine HCl 118.0% (RSD = 0.5%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV HPLC | Ferrous Gluconate Manufacturer's In House Method USP 38 NF 33 Vol.4 Page 6313-6315 | 90.0 - 110.0% 90.0 - 150.0% | Thiamine 114.9% (RSD = 0.2%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | UV HPLC | Ferrous Gluconate Manufacturer's In House Method USP 38 NF 33 Vol.4 Page 6313-6315 | 90.0 - 110.0% 90.0 - 150.0% | Riboflavin 117.0% (RSD = 1.1%; n = 9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In - house Method | 4.10 - 4.50 | 4.33 | **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 |