# FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

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|---|---|---|---|
| **Customer:** | Biogenique | | |
| **Product Name:** | Biogenique Iron Bisglycinate | | |
| **Product Code:** | N/A | | |
| **Product type:** | Capsule | | |
| **Color/Size/Shape** | Clear- Clear size "0" veggie Capsule filled with White powder with black particles powder. | | |
| **Product Packaging:** | Bottles :200cc White HDPE 38/400,<br>CAP: White 38/400 ribbed cap with HIS liner,<br>Silica gel Pillow (0.5gram),<br>Shrink Band 66X28mm, | | |
| **NPN** | 80142870 | | |
| **Storage Conditions:** | Store in cool, dry place. | | |
| **Allergen(s)** | **Yes** □ | **No** ■ | **If yes, list:** |
| **QA Approved By/Date:** |  Jan.12,2026 | | |

| **Ingredients** | | |
|---|---|---|
| **List of Medicinal Ingredients** | **Label Claim (mg)** | **Tolerance limits** |
| Iron (Iron (ii) bisglycinate) | 25.00 | Not Assayed.<br>Product is manufactured quantification by input to contain 25.00 mg of Iron (Iron (ii) bisglycinate) |
| **List of Non-Medicinal Ingredients** | | |
| Hypromellose, Microcrystalline cellulose | | |

| | | | |
|---|---|---|---|
| **Manufacturing Date** | Jan.12,2026 | **Lot #** | 012617 |
| **Expiry Date** | DE-2027 | | |

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| Physical Tests- In-house | | | |
|---|---|---|---|
| **Tests** | **Method** | **Parameter** | **Results** |
| **Appearance** | **Visual** | **Clear- Clear size "0" veggie Capsule filled with White powder with black particles powder** | Clear- Clear size "0" veggie Capsule filled with White powder with black particles powder |
| **Disintegration** | **USP <2040>** | **NMT 45 min** | 06 min |
| **Target Net Content** | **Scale** | **475.00 mg** | 475.00 mg |
| **Weight variation** | **USP <2091>** | **580.0 mg (536.50-623.50) mg** | (536.50-623.50) mg |
| **Locked Length** | **Measurement** | **Size "0": 21.60 ± 0.3 mm** | (21.30 – 21.90) mm |

| Microbial-Tested on Finished Product | | | |
|---|---|---|---|
| **Test** | **Method** | **Parameter** | **Results** |
| **Total Aerobic Microbial Count** | **<USP 2021>** | **NMT 1000 CFU/g** | < 10 CFU/g |
| **Total Yeast & Mold** | **<USP 2021>** | **NMT 100 CFU/g** | <10 CFU/g |
| **Salmonella spp.** | **<USP 2022>** | **Absent in 10g** | Absent |
| **E. Coli** | **<USP 2022>** | **Absent in 10g** | Absent |
| **Staphylococcus aureus** | **<USP 2022>** | **Absent in 10g** | Absent |
| *Microbial tolerance (limits) as per USP<2023> Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements, and USP<1111>Microbiological Examination of Nonsterile Products: Acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use* | | | |

| Heavy Metal-Tested on Finished Product | | | |
|---|---|---|---|
| **Arsenic** | **USP<233>** | **<0.14 µg/kg b.w./day** | < 0.001 µg/kg b.w./day |
| **Cadmium** | **USP<233>** | **< 0.09 µg/ kg b.w./day** | < 0.001 µg/kg b.w./day |
| **Lead** | **USP<233>** | **< 0.14 µg/ kg b.w./day** | < 0.001 µg/kg b.w./day |
| **Mercury** | **USP<233>** | **< 0.29 µg/ kg b.w./day** | < 0.001 µg/kg b.w./day |
| *Tolerance (limits) as per Appendix 3-General finished product specifications for NHP, Quality of NHP Guide* | | | |

| Chemical- Tested on Finished Product | | | |
|---|---|---|---|
| **Test** | **Method** | **Parameter** | **Results** |
| **Residual Solvents (Class III)** | **USP <467>** | **Total: < 5000 ppm (<0.5% v/v)** | 97 ppm (Refer to raw materials COAs) |
| *Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >* | | | |

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| Product Disposition | Released ☑ | Conditional Release ☐ | Rejected ☐ |
|---|---|---|---|
| QA Signature: | | Date: | MAR. 23, 2026 |