|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Product Name:**  XX | **Product Code:**  XX | | **Sizes:**  xx | | **Revision #:**  ss | | **Date Revised:**  xx |
|  | | | | | | | | |
| **TEST** | **METHOD** | | **Acceptance Criteria** | | | | |
| **Physical Appearance:** | Visual | | Include description of color, format (e.g., capsule, powder, softgel), and format size (e.g., #00) | | | | |
| **Dosing Information:** | Count | | Xx per serving  Xx per day | | | | |
| **Organoleptic:** | Taste | | Sweet-Sour-Bitter-Salty-Umami | | | | |
| Odor | | 1 None  2 Faint/Mild  3 Moderate  4 Strong/Overpowering | | | | |
| **Fill Weight** | USP <2091> | | Target Weight (Powder + Shell):  Fill Weight (Powder only): | | | | |
| **Tableting Hardness** | USP <1217> | | **Soft tablets**: 20–40 N (2–4 kp)  **Moderately hard tablets**: 40–80 N (4–8 kp)  **Hard tablets**: 80–160 N (8–16 kp) | | | | |
| **Tableting** **Friability** | USP <1216> | | Cannot exhibit any evidence of cracking, cleaving, or shattering and have less than 1.0% of their weight loss after 100 tumbles. | | | | |
| **Tableting Disintegration** | USP <701> | | Disintegration time of 30 minutes or less | | | | |
| **Bulk Density** |  | |  | | | | |
| **Particle size** |  | |  | | | | |
| **Microbiology**:  Total Aerobic Plate Count  Enterobacteriaceae\*  Combined Yeast and Mold  Salmonella sp.  Escherichia coli  Staphylococcus aureus  \*only required for products containing natural and/or botanical ingredients | USP <62>, <2021>, <2022> | | NMT 10,000 cfu/g  NMT 1,000 cfu/g  NMT 300 cfu/g  Absent / 10g  Absent / 10g  Absent / 10g | | | | |
| **ALLERGEN** | **TEST METHOD** | | | If yes, list source | | | |
| **Peanuts** **and peanut derivatives** | ELISA / PCR or scientifically valid method | | |  | | | |
| **Tree Nuts** (specific type - almonds, walnuts, Brazil nut, cashew, hazelnut, macadamia nut, pecan, pine nut, pistachio) |  | | | |
| **Soybean and soybean products** (soy flour, soy derived vegetable protein, hydrolyzed soy protein, soy lecithin) |  | | | |
| **Milk** **and milk derivatives** |  | | | |
| **Wheat** |  | | | |
| **Gluten** (wheat, rye, barley, oats, spelt, triticale, kamut) or any protein containing part thereof and hybridized strains of these grains. |  | | | |
| **Egg and egg derivatives** |  | | | |
| **Fish and fish products** (specify species – cod, bass, salmon, etc.) |  | | | |
| **Shellfish and shellfish derivatives** (Crustacean Shellfish, specify species – crab, lobster, shrimp, etc.) |  | | | |
| **Sesame** |  | | | |
| **Heavy Metals**  Cadmium  Lead  Mercury  Arsenic | Eurofins AOAC ICP-MS (ICP\_MS\_S:12) Method or appropriate lab using scientifically valid method | USP <2232> | | | | CA Prop 65 | |
| NMT 5mcg/day  NMT 10mcg/day  NMT 15mcg/day  NMT 15mcg/day | | | | NMT 4.1mcg/day  NMT 0.5mcg/day  NMT 0.3mcg/day  NMT 10mcg/day | |
|  | | | | | | | | |
| **FORMULATION** | | | | | | | | |
| **Ingredients** | **Analytical Method:** | | **Acceptable Range**  \* Testing on a skip lot basis as per internal testing protocol. | | | | |
|  |  | | NLT xx mg | | | | |
| **Other Ingredients:** |  | | | | | | |
| **Claims (Vegan, Non-GMO, Hypoallergenic):** |  | | | | | | |
|  | | | | | | | | |
| **Packing Specifications** | | | | | | | | |
| **Bulk Product:** Bulk (Capsules Powder, Softgels and Tablets) packaged in a double lined food grade plastic liner enclosed with a zip tie inside a plastic drum with plastic snap lid. | | | | | | | | |
| **Finished Product:** | **Code**  **(BRH internal only)** | | **Description** | | | | |
| Bottle |  | |  | | | | |
| Cap  \*(*Child-resistant cap for iron products*) |  | |  | | | | |
| Neck Band |  | |  | | | | |
| Label |  | |  | | | | |
| Inserts (i.e., Scoop) |  | |  | | | | |
| Secondary Packaging - Box |  | |  | | | | |
|  | | | | | | | | |
| **Expiration, Storage, and Sampling Plan** | | | | | | | | |
| **Expiration Date:** Based on stability data, **XX** months from date of manufacture | **Expiration Date Format:** EXP MM/YYYY | | | | | | |
| **Sampling Plan:** Per QC-013 | **Storage Conditions:** Temperature between 55 º and 86 º Fahrenheit, humidity at 70% or less. | | | | | | |
| **Storage Time Requiring Retest:** (**assigned expiration date i.e. 24mo, 36mo**) | **Minimum Sample Quantity:** Per QC-013 | | | | | | |
| **Re-Test Sampling Plan:** Per QC-013 | **Re-Test Parameters Required:** Potency and/or Microbiology profile as indicated in QC-013 | | | | | | |
|  | | | | | | | | |
| **Supplier/Manufacturer Site:** | | | | | | | | |
| **Address:** | **Phone:** | | | | | | |
|  | | | | | | | | |
| **Prepared By:** | **Title:** | | **Date:** | | | | |
| **Reviewed By:** | **Title:** | | **Date:** | | | | |
| **These specifications also apply to all private label Blueroot Health® products for contract customers.** | | | | | | | | |