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Shaklee Quality Control RE: Sports Nutrition Products

1. How many Quality Control tests are done on Physique, Performance, Slim Plan Gold, Multi-Munch, Carbo-Crunch, Basics, and Super Cal Mag Plus?

The number of tests on individual products depends on several factors, but includes raw materials, packaging components, and in-process tests. The number of quality control tests for Super Cal Mag Plus is just over 60, for Physique and Slim Plan Gold, about 100, for Multi-Munch and Carbo Crunch, just over 80, and for Basics, since it contains five individual products, nearly 300.

2. What kinds of things are tested regarding raw ingredients?

Raw materials fall into two categories: (1) Pharmaceutical grade ingredients, and (2), Botanicals, raw agricultural commodities, and other minimally processed, naturally derived ingredients not covered by U.S. Pharmacopoeia/National Formulary (USP/NF) monographs.

Pharmaceutical grade ingredients such as ascorbic acid (Vitamin C), which are purified to USP monograph standards, are tested and certified accordingly. These ingredients are USP/NF grade materials and are suitable for use in any pharmaceutical or dietary supplement product. Quality is extremely high and very consistent, and the FDA routinely inspects for GMP compliance. We test raw material suppliers for all USP/NF monograph tests, plus any additional Shaklee required tests, such as microbiological purity and particle size, to verify the accuracy of the supplier's Certificate of Analysis.

Quality of botanicals, raw agricultural commodities, and other minimally processed, naturally derived ingredients, vary with soil conditions, climate, water and air quality, harvesting techniques, storage conditions and handling procedures. Shaklee's global suppliers of these ingredients must go through a rigorous qualification process, including thorough testing of multiple lots and review of a potential supplier's answers to a multi-page questionnaire by the qualification team, and includes site visits/quality audits. In addition to tests for identity, potency and microbiological purity, the pre-qualification testing may include tests for chemical impurities, such as pesticide residues, organic solvents, heavy metals, arsenic, lead and mercury, as well as "natural" impurities, such as insect fragments, rodent hair, sand, and other foreign material. This qualification process enables Shaklee to establish tight specifications for these raw materials and qualify only the best suppliers who can deliver consistent high quality ingredients.

3. What kinds of test do you run during the processing of ingredients, and how many?

Depending on the product, we conduct some or all of the following in-process tests:

- After blending raw materials, every vitamin and mineral is assayed for potency. After blending pre-mix into bulk product, ingredients are assayed again to ensure quality and potency.
- During tableting, products are tested for hardness, thickness, weight, and inspected for defects.

- After coating, vitamins or minerals included in coating solution are assayed, and the product is inspected for coating defects.
- During packaging, components are verified, tablet count is confirmed, cap torque is measured, label position is ensured, and batch code and expiration date legibility is checked.
- For the products in this paper, the number of in-process tests per batch ranges from approximately 25 to 125 depending upon the product.

4. What kind of tests do you run on the final product?

Each of the label claimed ingredients for potency (vitamins, minerals, etc.) is tested, as are color, odor, appearance and taste against a Master sample. Microbiological evaluation is also conducted. For tablets, the physical characteristics are rechecked (hardness, thickness, average tablet weight and weight variation), as well as disintegration or dissolution. For powdered drink mixes, the physical characteristics are also rechecked for dispersion and solubility. A detailed review of all batch documentation, production and packaging records, quality control records, cleaning and sanitation records is performed to verify that the batch meets all Shaklee specifications.

5. How many suppliers can actually meet Shaklee quality standards?

It is not difficult to find suppliers who can meet Shaklee's requirements for the first category (highly processed pharmaceutical grade ingredients which comply with the monograph of the current USP/NF), though we typically add additional requirements. It is more challenging to find reliable suppliers who can consistently meet Shaklee's requirements for the second category of raw ingredients (botanical, raw agricultural commodities, or other minimally processed, naturally derived ingredients not covered by USP/NF monographs—hence the rigorous qualification process previously described. Our Strategic Sourcing/Purchasing group develops long-term relationships with key suppliers who meet our quality requirements, volume needs, and delivery schedules. While we cannot provide an estimate of the percentage of suppliers that can meet our requirements, suffice it to say, it is relatively low.

6. What Independent 3rd-party tests prove the ingredients of / processes for Shaklee products?

As referenced in question 2, we meet USP/NF and FDA GMP protocols. Some of our products have been tested over the years by independent organizations like ConsumerLab and Consumer Reports. Test results from these organizations have show that our products tested meet their label claims.

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