

# 30 STEPS

## to the Birth of a Sorvana™ Product



*"Your health is your greatest wealth and our #1 priority!"*

– Ray Faltinsky  
Sorvana CEO  
& Founder

Sorvana prides itself on bringing our customers the very best natural wellness products that science can offer. After all, your health is our #1 priority!! As a result, we have spent millions of dollars on formulation, development and scientific research to create a wellness product line that delivers unparalleled results.

Below is a partial outline of the most important steps we take in creating products that have already changed so many lives for the better and will change many more lives in the years to come.

### STEPS 1-11: Research and Development Phase

- 1 Concept** – Sorvana's ongoing research constantly reveals new and impactful approaches to meet specific and important healthy weight loss, aging, energy and performance needs, as well as addressing overall health and wellness.
- 2 Scientific Review** – Our global Science Team reviews the published scientific literature to assess the efficacy and safety of each ingredient, and to determine the ideal combination that will deliver the biggest benefits. This extensive and exhaustive scientific review process can be painstakingly slow, but it explains why Sorvana products have performed so outstandingly well in numerous randomized, controlled human clinical trials.
- 3 Compatibility Study** – Each new product is designed so that it can be used safely with every other Sorvana product.
- 4 Search for Ingredients** – Sorvana imports ingredients from a worldwide network of approved vendors who have demonstrated that they can meet or exceed our rigid quality specifications.
- 5 Vendor Audit** – Prospective raw material suppliers are investigated to ensure conformance with Good Manufacturing Practices (GMP), fair labor practices, and respect for the environment.
- 6 Raw Material Specifications** – Vendors are supplied with raw material specification documents that detail our exacting requirements. This ensures that our expectations will be met with every incoming raw material shipment.
- 7 Ingredient Testing Methods** – We work with analytical laboratories to ensure that appropriate and validated methods are used to verify the authenticity, purity, potency and efficacy of the ingredients in every Sorvana product.
- 8 Master Formula** – Each Sorvana product is produced from a precise Master Formula, which specifies ingredients, process equipment, detailed manufacturing instructions, and requirements for temperature and humidity conditions.
- 9 Pilot-Scale Blend Study** – A small-scale batch of ingredients is blended to determine the ideal mixing time and conditions that will ensure a uniform product when ramped up to full-scale commercial production.
- 10 Pilot-Scale Dosage-Form Study** – The pilot blend of ingredients is then converted into the appropriate dosage form (tablet, capsule, liquid, powder, cream, lotion, etc.), so that strict tolerances can be set in the Master Formula for the finished product.
- 11 Approval for Full-Scale Production** – Upon passing a thorough review to verify the formula and process, the Master Formula is approved and a requisition is issued for full-scale production.

### STEPS 12-23: Full-Scale Production Phase

- 12 Receipt of Incoming Raw Materials** – No ingredient is received at our manufacturing facilities unless it is

in properly labeled packaging with tamper-evident seals. All incoming shipments must be accompanied by full documentation, including a Certificate of Analysis (COA) and Material Safety Data Sheet (MSDS). Ingredients are placed in quarantine until they are tested for identity, purity and potency to verify the vendor COA.

- 13 Identity Testing** – Many ingredients can appear very similar to others, in ways that can fool even an expert. We confirm the identity of our ingredients by tests that include one or more of the following:
- *Microscopy* – under a high-powered microscope, one can see the distinctive tissues and cells that differentiate one plant from another, as well as one plant part from another part of the same plant. One can also see if there is any foreign matter or filth. Some adulterants can be clearly seen under the microscope.
  - *Fourier Transform Near Infrared Spectroscopy (FT-NIR)* – Quality Control inspectors employ advanced scanning probes, which send a high-intensity beam of near-infrared energy through a sample of the ingredient. As no two ingredients will absorb near infrared energy in the same way, a unique fingerprint can be determined for each ingredient (Spectral Signature™).
  - *High Performance Thin Layer Chromatography (HPTLC)* – HPTLC is another fingerprinting technique that separates the constituents of a plant and represents them graphically as a chromatogram. By comparing the chromatogram of the test sample to an authenticated reference standard, one can see if the product is pure or possibly adulterated.
  - *DNA Barcoding* – DNA analysis can be used to confirm the identity of teas and herbal ingredients
  - *Genetic Sequencing (Accu-GENX-ID®)* – this state-of-the-art genetic analysis positively identifies probiotic ingredients to the strain level
- 14 Microbiological Testing** – All incoming ingredients are tested by USP monograph procedures for harmful microbes, including yeast, mold, and pathogens such as Salmonella and E. coli.
- 15 Purity Testing** – ingredients may be tested for heavy metals, pesticides, and other chemical contaminants using sophisticated equipment and techniques, which include:
- *ICP-MS (inductively coupled plasma mass spectrometry)* – highly sensitive instrument can detect heavy metals (lead, cadmium, mercury, arsenic) at less than one part per billion.
  - *LC-MS (liquid chromatography - mass spectrometry)* – screens for trace amounts of pesticides and other

agricultural chemicals

- *GC-MS (gas chromatography - mass spectrometry)* – can find even minute amounts of solvents and adulterants

- 16 Potency Testing** – Ingredient potency is confirmed by rigorous analysis using state-of-the-art equipment and techniques, including UPLC (ultra high performance liquid chromatography). UPLC gives rapid and accurate analysis of vitamins, amino acids, standardized botanical extracts, and other active ingredients found in Sorvana's cosmetic, personal care and home care products.
- 17 Release of Raw Materials** – Upon completion of successful testing, the ingredients are released for use in production.
- 18 Production Site Assignment** – All Sorvana products are produced under climate-controlled conditions in state-of-the-art facilities across North America that operate under strict current Federal Good Manufacturing Practices (cGMP). Each product is assigned for production at the most suitable manufacturing facility.
- 19 Master Batch Record** – From the Master Formula for each product, a Master Batch Record (MBR) is prepared, which gives in detail the complete set of instructions that must be followed to manufacture the product. The MBR is used as a template for the computer-generated individual Batch Record that is specific to each manufacturing lot.
- 20 Weighing and Blending** – Each ingredient, in the amount required by the Batch Record, is weighed into a container that is sealed and marked with an identifying tag. As each ingredient is weighed, both the operator and supervisor must sign off on the batch record. This double signoff is repeated again when each ingredient is added to the blender or mixing vessel. Bar code scanners are also used to check off each ingredient on the batch record. As a final check, the tags from each ingredient are tallied to eliminate any possibility of error.
- 21 Weight/Volume Variation Analysis** – In-process, tablets and capsules are spot-weighed every ten minutes by quality control technicians to certify that all products are of uniform weight for consistent dosage. Liquids, creams and powders are similarly checked for uniform density or specific gravity.
- 22 Size Variation Analysis (Tablets and Capsules)** – Pharmaceutical micrometer gauges verify that all tablets and capsules conform to specifications. These special gauges are accurate to 5/1000 of an inch.

- 23 **Coating (Tablets)** – Finished tablets are sprayed with a natural protective cellulose coating for ease of swallowing and to ensure freshness.

#### STEPS 24- 29: Finished Product Testing Phase

- 24 **Physical Testing** – Physical parameters - which can include appearance, color, odor, taste, density and viscosity - are compared to our laboratory standard to ensure consistency from batch to batch.
- 25 **Potency Testing** – Potencies of all Sorvana products are confirmed by rigorous analysis, using the same array of sophisticated laboratory equipment and techniques that are used in testing the ingredients.
- 26 **Microbiological Testing** – As with ingredients, finished products are tested to confirm the absence of harmful bacteria, yeast, and mold. This attests to the cleanliness and sanitation of plant, equipment, and ingredients.
- 27 **Packaging Materials Barrier Testing** – Bottles, jars and other containers are specially designed to protect the product contents from the effects of oxygen and moisture.

- 28 **Packaging** – The products are packaged on modern, high-speed, fully automated equipment. Tamper-evident closures or safety seals are used where appropriate.

- 29 **Product Stability Testing** – To ensure stability, samples of Sorvana products are subjected to rigorous challenge testing for 12 weeks under stressful conditions of heat and humidity. This extreme test is equivalent to two years at normal room temperature, and it is how we can guarantee full potency throughout the dated shelf life.

#### STEP 30: Total Quality Management

- 30 **Total Quality Management** – At Sorvana, we stand committed to constant and never-ending improvement – of our products, our processes, our procedures and our practices. Our quality commitment includes ongoing GMP training, continuing education, and cross-disciplinary communication. Our Quality Assurance program even calls for internal audits, to make certain that we continue to live up to the high standards written into our policies.

