

# W I S E W O M A N H E R B A L S

## COMMITMENT TO QUALITY

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### QUALITY ASSURANCE

For more than 25 years Wise Woman Herbals® has been considered a leader in providing quality botanical supplements. Our entire product line is handmade on-site at our botanical manufacturing facility in Creswell, Oregon. Using a time-honored traditional maceration process, we make frequent small batches to attain high concentrations, achieve superior quality, and to assure product efficacy and shelf-life. We know precisely what goes into our products, and just as importantly, what does not: all of our products are GMO-free, peanut-free, lactose-free, and wheat-free.

Quality assurance and quality control are essential components to consistently achieving WWH's established high standards. We employ a full-time regulatory team that examines and inspects the product along each step of the manufacturing process, from the intake of raw botanical to the distribution of the packaged finished product. Every step is checked, double checked, and documented for complete quality control.

Our products undergo testing and quality verification in every step of processing from sourcing, intake, maceration, extraction, packaging, and distribution. Every batch of raw material is inspected, analyzed, and quarantined upon arrival until approved for use by the Quality Control department. In-process material is compared to established specifications to ensure product conformity and consistency. Stringent testing and final evaluation is performed on finished product. Once the product has been accepted, our Quality Team performs organoleptic comparison to compare the new batch to prior retention samples to assure quality and consistency between batches. All products must pass this process before being given the Wise Woman Herbals' stamp of approval and released into inventory.

### HIGH QUALITY INGREDIENTS SOURCED FROM LOCAL FARMS

Our meticulous quality standards start with the finest organic, biodynamic, wild crafted, and best quality plants harvested by experienced wild crafters and sourced from local farms. Our trusted ethical vendors undergo a rigorous

supplier qualification process prior to acceptance as an approved source for raw materials. We take no shortcuts when it comes to the quality, purity, and safety of our products. We extract and preserve the plant's therapeutic qualities using certified organic cane alcohol, mountain spring water from a local aquifer, certified kosher vegetable glycerine, and other all-natural ingredients. Greater than 70% of all the raw materials used to manufacture our products are sourced from the Pacific Northwest.

### BOTANICAL ANALYSIS, TESTING AND VERIFICATION



We assure proper plant Genus, species, and purity as a foundation for establishing quality. Our products are examined by the following methods:

- 1. Raw Materials Custom Reference Database:** Identity confirmation is performed upon receipt of raw materials through analysis and cross-comparison with our digital Raw Materials Reference Database. This custom-developed database, comprising over 25 years of compiled knowledge and data, lists identifying characteristics specific to each material received with photos of the plant in its various forms (fresh, cut-sift, powder, in the wild), desired plant part, growth stage, and organoleptic attributes.

2. **Organoleptic Testing:** Wise Woman Herbals' highly trained and experienced staff of herbalists evaluate physical appearance, taste, color, odor, and tactile qualities to further assess raw material and product identity before the plant is released for microbiological testing and Near-Infrared Spectroscopy analysis identity testing.
3. **Near-Infrared Spectroscopy (NIR) Analysis:** Spectroscopy analysis is used for raw botanical identification and finished product consistency verification. Results are compared against Wise Woman Herbals' Botanical Reference Standards Library. Our Quality Control Laboratory verifies the various Genus and species and can confirm identity with 98-99% accuracy with the aid of NIR.
4. **Scientific Botanical Authentication:** Our Botanical Reference Standards Library is used for raw material identification and internal quality control specifications. To certify plant identity, Wise Woman Herbals works in conjunction with the botanical and scientific staff at a major West Coast University. This third party certification is used to authenticate and characterize raw materials. WWH's Botanical Reference Standards Library Database enables quality control personnel to confirm the authenticity of botanical samples through laboratory methods of analysis.
5. **Microbiology Profile and Heavy Metals Testing:** In-house microbial tests are performed to identify Total Aerobic Plate Count (TPC), Total Coliforms, Yeast, Molds, E. coli, and Salmonella using USP testing methodology. Heavy metals screenings are performed using the FDA preferred Inductively Coupled Plasma on a Mass Spectrometer (ICP-MS).
6. **Microbiology and Heavy Metals Specification Comparisons:** The specifications to which the raw material or finished product will comply is generated with consideration from United States Pharmacopeia (USP) standards, American Herbal Products Association (AHPA) standards, and other industry recommendations, including California's Prop 65 limits for lead.
7. **Chromatography Analysis:** High performance Liquid Chromatography (HPLC) testing is used for chemical profile breakdown to compare/contrast a material against a known standard.
8. **Third Party Testing:** We employ independent U.S. certified laboratories for outside testing for further verification. These laboratories utilize FDA and/or AOAC validated test methods.
9. **Shelf Life Studies:** On-going, real-time Shelf Life Studies ensure that the "Best used by" dates established for products can be substantiated. Continuous monitoring of "Best used by" dating for all products assure that our products are meeting the stated quality goal of remaining optimally viable throughout their stated shelf life.
10. **Quality Management:** All raw materials are kept under our sole control after receipt. Every raw material is assigned a unique identifier, which is electronically recorded. This identifier will forever be associated with the raw material to which it is assigned and all products that the material goes into. This assures total traceability of all of our raw materials and products. All products are handmade from these raw materials on-site, using our own botanical manufacturing equipment and facilities. We know precisely what goes into our products, and just as importantly, what does not. All of our products are GMO free.

At every stage in the production process, our Quality Unit applies state-of-the-art testing methods to assure quality. If any batch of raw material fails to meet our standards, it is immediately returned to the supplier, removed from the production process, rejected, destroyed, or discarded. At WWH, we reject raw materials that other manufacturers would consider to be acceptable and place into production. This may at times create an "out of stock" situation on some of our products that may occasionally be inconvenient, but we adhere to our dictate to not compromise on quality.

## STAYING TRUE TO OUR VALUES

All of these steps are vital in maintaining the purity and quality of the products we produce. Wise Woman Herbals maintains the highest level of quality in order to protect our core values of purity, integrity, and the production of superior botanical supplements.

## BOTANICAL MEDICINE REGULATION

The manufacture and sale of botanical medicines is regulated by the US Food and Drug Administration (FDA). The comprehensive regulations established by the FDA govern the handling and processing of botanicals, the testing requirements, record keeping procedures, labeling requirements, and advertising, among other stipulations. All WWH manufacturing facilities are regularly inspected by FDA officials. This ensures compliance with all FDA mandates.