

Serenity Herbal Dispensary

Procedure Manual



SERENITY
HERBS & SUPPLEMENTS

P: 520-465-5501 F: 520-333-2888

Serenityherbsandsupplements@gmail.com

www.serenityherbsandsupplements.com

January 1st, 2019 Edition

Table of Contents

Dispensary Access and Production Selection.....	2
Accessibility of Dispensary Services.....	2
Selection of Products Used in the Dispensary	3
Storage and Inventory Procedures.....	4
Receipt and Storage of Granules.....	4
Procedures for Checking Physical Inventory	6
Protocols for Filling Orders.....	6
Submitting Orders	7
Equipment Used When Dispensing Formulas	7
Preparation of Dispensary Workspace	9
Locating and Collecting Granules for Each Order	9
Weighing the Herbs and Assembling a Preliminary Mixture	10
Mixing the Formulas and Secondary and Tertiary Weighing	11

DISPENSARY ACCESS AND PRODUCT SELECTION

Accessibility of Dispensary Services

Serenity Herbal Dispensary (SHD) is a Chinese herbal dietary supplement dispensary that fulfills orders from licensed health care practitioners for customized granular formulations. SHD will fill formulas for customers with an order from a licensed practitioner. The written order must include: the date of the order, the patient's name, all of the ingredients in Chinese Pinyin and English with dosages, dosage and administration instructions, the practitioner's name and acupuncture license number, the practitioner's signature, and the practitioner's contact information. The dispensary cannot fill formulas if the order is incomplete or has not been issued by a licensed provider. If the order is received electronically, the dispensary may call the issuer to verify the details and insure that all legal requirements have been met.

The term *licensed practitioner* refers to individuals with a current acupuncture license who have additional, sufficient training in the professional use of Chinese herbal dietary supplements. Currently Arizona state licensure does not distinguish between licensed acupuncturists who have completed a course of study of Chinese herbal supplements and those who have not. SHD reserves the right to refuse service to those licensed acupuncturists who do not have adequate training and/or experience to safely and effectively craft custom granular formulas. Although there is no formal application process, the dispensary may require verification of licensure and good standing with the acupuncture board prior to filling orders. Additional requirements may apply. Other health practitioners, such as medical doctors or nurse practitioners, may be eligible for dispensary services but only at the discretion of the dispensary. SHD reserves the right to use any resources at its disposal to vet a practitioner's qualifications prior to filling orders.

SHD only provides dispensary services and does not formulate orders nor will its staff members offer guidance or advice on the formulation or use of Chinese dietary supplements. While we appreciate the learning process of students of Chinese medicine, the dispensary exists only to serve practitioners with current, relevant licensure. SHD takes every precaution to insure that the formulas are filled exactly according to the orders of qualified practitioners, but the dispensary does not take responsibility for the safety or appropriateness of the formula ingredients and/or administration protocols, possible interactions with other supplements or drugs, or the general suitability for the individual case. The practitioner ordering the formula must do due diligence to insure that the supplement is suitable and safe for the patient, including following up with patients using the formulations. Questions from the consumer regarding the formulation or other queries of a medical nature will not be answered by employees of SHD; the dispensary will refer customers with questions to the licensed practitioner who placed the order for the formulation. Serenity Herbal Dispensary is a retail sales business and neither Serenity Wu nor her employees are trained or licensed to practice any form of Chinese healthcare.

Selection of Products Used in Dispensary

Serenity Herbal Dispensary has gone through a rigorous selection process in choosing granules. All Chinese herbal granules dispensed must meet the following criteria:

- GMP-certified (Good Manufacturing Practice)
- Individual lot numbers on all materials
- Produced by major, reputable manufacturers
- No expired or undated products
- Stored under proper conditions
- Bottles securely sealed upon delivery from distributor

These are the minimum criteria for granules used in the Serenity Herbal Dispensary. The dispensary uses products produced by Tianjiang Pharmaceuticals wherever possible, materials far exceeding these basic standards. Tianjiang Pharmaceuticals is internationally recognized as a leader in the Chinese herbal granule market. Tianjiang was the first mainland Chinese pharmaceutical company to produce granules, and its products are used in over 1,000 large-scale hospitals in China. The company is the most award-winning granule producer in China. It holds many patents in the fields of granule research and production giving it proprietary rights to techniques that yield products of exceptional safety and potency.

Tianjiang Pharmaceuticals

- Rigorously selects superior raw herbs based on laboratory analysis of active ingredients, cultivation conditions, and traditional quality discernment.
- Sources raw herbs through established relationships with over 320 farms and production regions spanning 22 provinces in China. Many herbs come from GAP (Good Agricultural Practices) certified farms or ethically wild-crafted sources.
- Identifies correct botanical species using TLC, HPLC, microscopy, and organoleptic assessment by trained experts. Considerable attention is given to selecting material that exemplifies ideal growing regions and most favorable species.
- Only uses raw herbs materials that are free of sulfur. Many products are prepared fresh from a single crop in a one annual batch shortly after harvest.
- Employs individualized techniques to optimize the extraction process by calculating the ideal decoction time, temperature, water-to-herb ratio, appropriate preparation method, and maximum concentration ratio for each agent decocted for use in granule production.
- Tests for authenticity and potency with microscopic examination, HPLC, GC, and TLC. Identity and potency testing are used at both the raw material and finished product stages.
- Performs advanced heavy metal testing with ICP-AES verified in Germany and the U.S.

- Applies microbiology testing which confirms the absence of microorganisms and pesticide residues. Additional third-party testing for pesticide residues is conducted in Germany.
- Extracts raw herbs in purified water to replicate traditional water-based decoction.
- Uses low temperature extraction for maximum concentration without damage to delicate chemical constituents that might compromise effectiveness.
- Employs complete capture and re-introduction of volatile oils for best efficacy and flavor.
- Distinguishes itself through the use of patented extraction methods using cutting-edge technology to produce granules with superior solubility that come out like a decoction.

Moreover, the Tianjiang brand granules used by Serenity Herbal Dispensary are distributed by Legendary Herbs, a company founded and operated by Eric Brand. Mr. Brand is known both in the United States and China as an expert on herb identification and quality assessment. He is author of several books on Chinese herbal medicine and is particularly renowned for his expertise in the field of granules. As a pioneer in the assessment and safe and effective usage of granular Chinese herbal dietary supplements, Eric Brand provides the highest quality product available. Legendary Herb granules far exceed industry standards for safety, potency, and consistency.

Due to supply issues, some granules required by our clients may not be available from Legendary Herbs in the quantities or form needed by our dispensary. In these cases, a suitable substitute will be employed. All granules must meet our in-house criteria (see above) and be of sufficiently high quality to be combined with our Tianjiang brand materials. These substitute products are produced by other well-known granular manufacturers such as KPC or MinTong, companies with lengthy histories of manufacturing safe and effective granular extracts.

STORAGE AND INVENTORY PROCEDURES

Receipt and Storage of Granules

Dispensary granules are unpacked by dispensary staff and the contents are checked against the packing slips and order forms. The shipment is inspected for gross damage to the box, and the individual bottles are assessed for any damage which may have occurred during shipping. If the seals or containers are broken or otherwise compromised, the items will not be accepted into inventory. This process protects against contamination as a result of exposure during shipping.

All granules are stored at SHD in the factory or distribution packaging with any shrink wrap or pressure sensitive internal seals intact. Bottle lots may be separated prior to storage; otherwise, protective sealing will be removed immediately prior to use using a cutting implement dedicated to this task and stored with other equipment used during formula preparation. Retaining seals on stored bottles of granules helps to maintain freshness and prevent compromising the contents.

Serenity Herbal Dispensary stores all granules in the factory bottles on mobile wire rack shelving units in air-conditioned storage. There are several features of this storage method which facilitate hygiene and safety. Unlike many dispensaries which utilize recycled shelving units

either made of porous materials that are difficult to disinfect or which feature deep spaces that cannot be cleaned easily, SHD uses steel wire shelving which is easily cleaned and lack surfaces that are readily contaminated. Every 90 days, all of the containers are removed from the racks, placed in a safe area away from potential contaminants, and the shelving units are thoroughly cleaned with natural disinfectant and allowed to air dry before replacing the containers of granules and dispensary supplies.

The wire storage racks are mobile for convenience and are moved as necessary to facilitate dispensary procedures. Owing to the mobility of the storage units, there are several restrictions on placement, regardless of how long the racks are left in place. These guidelines minimize the possibility of exposure to conditions that might compromise the stability of the granules or result in contamination. The placement of the racks must adhere to the following guidelines:

1. The racks must be stored an adequate distance from active heat sources, including heating vents, furnaces, direct sunlight exposure, and ovens and stovetops. If material become warmer than ambient room temperature, the racks must be relocated.
2. Storage racks are to be stored at least 3 meters away from any areas where foodstuffs are stored or prepared to avoid cross-contamination.
3. Wire racks must be stored at least 3 meters away from any solid or liquid chemical substances, including but not limited to household cleaners, paint, and automotive supplies. If there is a possibility of airborne contamination from a distance of 3 meters or more, the racks must be placed a sufficiently safe distance from the potential contaminant.
4. Owing to the mobile nature of the racks, wheels should be in locked position except when being repositioned. Also, the floor under the racks should be level, and the location of the racks should minimize the risk of physical impacts which might jeopardize the stability of the racks or dislodge stored containers.
5. Accessibility to the stored contents must be controlled. If persons other than the SHD staff are allowed into the space where the racks are stored, the racks should be monitored or secured in order to prevent unauthorized access to the stored herbal granules. The dispensary is not a public space and access is carefully regulated.
6. All other reasonable precautions should be taken to insure that the herbal material is:
1) stored under optimal conditions, including humidity and temperature; 2) secure from accidental and/or deliberate human contamination; 3) placed in a location where contamination from biological, heavy metal, or chemical substances is minimized.

In the event that the stability or purity of the granular material is compromised, the contaminated product will be immediately discarded. The material eliminated from stock may be a single container, multiple containers, or the entire supply, depending on the circumstances of contamination.

Only qualified staff are permitted to handle the granule containers. The granules are placed on the racks after receipt into inventory and are only handled by SHD workers for the purposes of inventory or during the process of filling orders. When containers are examined as part of the inventory review, containers of granules must remain sealed. Granule containers are only opened in the context of preparation of orders following the guidelines under Filling Orders which follows below.

Procedures for Checking Physical Inventory

Serenity Herbal Dispensary performs regular physical inventories of granular Chinese herbal dietary supplement materials. A physical inventory is employed to:

1. Review quantities for accounting purposes
2. Assess stock to maintain sufficient amounts of each material
3. Inspect containers for signs of physical damage or deterioration
4. Check dates of manufacture to insure product viability
5. Evaluate organization and relocate misplaced items when necessary

Serenity Herbal Dispensary is a small-scale dispensary with a limited staff. Orders are filled frequently and stock is replenished regularly from the distributor. The proprietor oversees all operations and has a good awareness of the stock available. Invoices from the distributor and packing slips are organized and filed for easy review of inventory received. Moreover, Chinese granulated herbal dietary supplements have been found to be stable and have a long shelf-life. Experts in the field have estimated that granules remain viable and chemically unaltered for at least seven years or more. For these reasons, physical inventory is only performed once a year. The containers are inspected regularly at other times during the year for physical damage or deterioration, especially during the quarterly cleaning of the wire storage racks.

The annual physical inventory is done by removing all containers from the wire shelving, checking the condition of each bottle, and recording how many bottles exist in stock for each type of Chinese dietary herbal supplement. This procedure is the work of SHD workers who observe basic protocols to maintain the security and safety of the materials. Product that is determined to be too old to be viable is discarded. Generally speaking, any product manufactured more than 7 years prior to the date of inventory is removed from inventory and orders are placed to procure new material. During the physical inventory any material shelved in the wrong order—e.g. not conforming to the alphabetization of the Pinyin names—will be identified and reorganized.

The date of the physical inventory varies and is at the discretion of the proprietor. It is usually performed at the end of the year so that an inventory may be recorded for fiscal purposes. Physical inventories may be done more frequently if there is need to assess the current stock.

PROTOCOLS FOR FILLING ORDERS

The procedure for filling orders is designed to meet legal and industry standards while remaining practical and economical. SHD is committed to the safety and health of its customers and utilizes some of the most stringent protocols being used by small-scale dispensaries today. In order to

maintain a contamination-free environment, the dispensary is not open to the public, but you are welcome to ask us any questions you may have regarding our dispensary space and professional protocols.

Submitting orders

Orders for the dispensary may be submitted directly by the licensed practitioner placing the order, or the patient may place an order herself or himself with a prescription signed by the licensed healthcare provider. SHD accepts orders for custom formulations sent by mail, e-mail, Fax, or presented in person at the dispensary. The dispensary reserves the right to contact practitioners by phone for verbal confirmation of prescriptions received.

For recordkeeping purposes, Serenity Herbal Dispensary recommends at least three physical copies be made for each prescription. One copy should be included in the patient's record on file at the office of the prescribing health care provider, and additional copy should be given to the patient. If the practitioner chooses to send the order by mail, the third copy is sent directly to the dispensary. When orders are placed electronically, Serenity Herbal Dispensary will print two copies of the prescription and keep a hard copy on file in a secure file cabinet, while the second copy will accompany the completed order and will be provided to the patient. If the dispensary receives a physical copy of the prescription it will be filed and one additional copy will be made for the patient. Each patient will have his or her own file at the dispensary containing all of the prescriptions filled for that individual organized by date. In the case that the dispensary ceases its operation, the documents will be archived or destroyed according to the legal requirements. Long-term maintenance of patient records is the responsibility of the office of the licensed health care provider, but SHD will keep prescriptions on file for the duration of its active service as an herbal dispensary. Confidential patient documents can only be released according to HIPPA statutes and regulations and will necessitate a signed document authorizing the release of PHI.

Each prescription is carefully checked by the dispensary for accuracy. All prescriptions must include the date of the order, the patient's name, all of the ingredients in Pinyin and English with dosages, dosage and administration instructions, the practitioner's name and acupuncture license number, the practitioner's signature, and the practitioner's contact information. If the SHD worker discovers a discrepancy, such as a granule total that is not the correct sum of the individual dosages, or if the information is incomplete, then the practitioner will be contacted as soon as possible to rectify the error(s). The prescription cannot be filled until the order is complete and accurate. Although the content of the prescription is the responsibility of the licensed healthcare provider who has submitted the order, SHD may contact the provider if the prescription includes any dosages that exceed the amounts recommended by the standard of care. SHD foremost obligation is always the safety of the recipients of its products.

Equipment Used When Dispensing Formulas

1. **Scale** – Many small dispensary employ kitchen scales or traditional manual scales for weighing Chinese herbal dietary supplement materials. SHD has chosen an extremely

accurate, electronic, legal-for-trade scale with multiple features to check the precision and reliability of the device. The scale is accurate 1/10 of a gram, providing enough precision to fill dispensary orders accurately. The scale has a stainless steel platform that is easily removed and cleaned. It is cleaned after each use with soap and hot water and stored in a dedicated space with other supplies. The scale is prepared and plugged into a wall socket prior to use.

2. **Weighing scoops** – Granules are weighed into scoops which sit atop the stainless steel scale platform. After use for filling formulas, the scoops are washed with hot water and soap and allowed to dry before being stored in an air-tight box used exclusively for dispensary supplies. Each scoop is visually inspected prior to use to insure it is clean and ready for use.
3. **Empty containers** – SHD does not reuse containers. Each formula is filled in a new bottle designed to hold pharmaceutical or supplements. The back stock of bottles and lids are stored in storage boxes with lids closed and in a dedicated storage area. Prior to filling formulas, an adequate number of containers for each formula are taken from the sealed containers and placed on the clean field with lids removed. Each container is visually assessed for cleanliness prior to use.
4. **Mixing vessel** – The dispensary incorporates a stainless steel mixing container to mix granules manually. Stainless steel is easily cleaned and non-porous, making it ideal for this purpose. This dedicated container is cleaned with hot water and soap and allowed to air dry after each usage. Furthermore, the vessel is stored in an air-tight box with other supplies when not in use. Prior to mixing formulas, the container is visually inspected and cleaned again if necessary.
5. **Spoons** – Stainless steel spoons are used in the dispensary process for transferring granules from bottles into the measuring scoops and, in some cases, from the scoops back into the storage bottles. Stainless steel is inert and nonporous, making them safe to use and easy to clean. The spoons used for this purpose are dedicated to dispensary usage and cleaned with soap and hot water after use.
6. **Straight-Edge** – A dedicated straight-edge is used to hold written orders in place when orders are being filled and to highlight the medicinal agent being added to the prescription. This allows the individual dispensing the formula to check to see those agents which have been added and those that have not.
7. **Baskets**—Plastic baskets are utilized to collect and organize bottles of granules when filling orders. For dispensary purposes, plastic baskets offer several advantages: smaller surface area, non-porous material, and the ability to be stacked away from potential contaminants. All of these characteristics reduce the risk of cross-contamination.

Preparation of Dispensary Work Space

The dispensary employs a folding table for the purpose of filling orders. The table, easy to disinfect due to its metal and plastic construction, is cleaned with a natural disinfectant spray before and after use, and debris, such as granular residue, is removed prior to usage.

Once the table has been cleaned and allowed to dry, the dispensary worker covers the table surface with a fresh piece of dispensary table sheeting paper. The sheeting paper is always placed with the side inside the roll facing up on the dispensary table surface. Rolls of dispensary table sheeting paper are stored with other dispensary supplies in a storage space dedicated to storing dispensary supplies. It is secured at the edges of the table with tape to prevent the paper from being dislodged and to provide stability when filling orders.

All of the equipment necessary must be collected, inspected, and organized on the preparation table. The scale is inspected to insure that it has been thoroughly cleaned. If the unit is clean and ready for use, the dispensary worker will connect it to an AC outlet, check to verify that the scale is fully operational, and position it centrally in the work space. A weighing scoop is examined and placed on top of the stainless steel platform of the scale, and a small stainless spoon—used to transfer granules from the bottles to the scoop on the scale—is also placed in a convenient location on the field. These are the primary tools utilized to construct granular formations.

To the right of the primary preparation area, the dispensary worker places the written prescriptions to be filled with a straight edge to secure the page to the table and keep track of the herb being weighed. These are stacked in order with the first prescription to be filled on the top of the stack. At the edge of the preparation table farthest from the dispensary worker, a sufficient number of new, empty bottles with lids removed will be placed to hold the finished product. Finally, the stainless mixing vessel is checked for readiness and placed immediately to the left of the scale with the two halves separated. The lower half of the mixing vessel receives all of the weighed dosages of granules to be physically blended into an evenly distributed mixture. The mixing vessel will remain on the preparation table until all of the herbs in a single prescription have been weighed and added into the mixture. Once the formula is complete, a SHD worker will remove the container and physically agitate the vessel an adequate number of times to insure that all of the granules have been combined together in an even mixture.

Locating and Collecting Individual Granules for Each Order

Serenity Herbal Dispensary maintains a large stock of herbs exceeding 350 different varieties. Each herb, with the appropriate *pao zhi* or processing as requested, needs to be located and placed into a plastic basket with all of the other herbs needed to fill the order. Bottles of granules are stored in alphabetical order following the Pinyin name of each herb, while overstock is stored on a separate shelving unit using the same organizational scheme. The herbs are identified using both the Pinyin and English names to insure that the final product matches the practitioner's order exactly. While in the storage baskets, the individual bottles of granules remain sealed to

minimize the risk of contamination. Once preparation of formulas begins, the bottles of granules will be placed on the rear portion of the preparation space where they remain until all of the orders have been completed. The bottles are sealed with lids except when herbal material is being extracted for mixing into a formulation.

Each basket contains the herbs necessary to fill a single formula accompanied by the written prescription for that order. If several prescriptions with the same herb or herbs are filled simultaneously, a bottle of granules may be taken from another basket and left on the preparation table until all of the formulas are filled. When not in use, the baskets are stacked and stored in a dedicated space. The baskets are regularly cleaned with natural cleaners, and SHD workers check the baskets prior to use to insure that they remain clean and free of debris.

Weighting the Herbs and Assembling a Preliminary Mixture

Weighing and assembling herbal mixtures is the primary activity in the dispensary. Serenity Herbal Dispensary has developed protocols that exceed the industry standard and satisfy all legal and professional requirements. SHD workers exercise great care in weighing each dosage precisely, and a system of checks and balances has been developed to insure accuracy.

Once the work area is prepared, the dispensary worker will position himself or herself at the preparation table. The table is clean and covered with fresh sheeting paper. On the tabletop, the scale is centered in the space with a clean scoop and a clean measuring spoon. To the right of the work space, the prescription for the first formula is secured with a straight edge that will allow the dispensary worker to track each herb as it is added to the mixture. A clean mixing vessel is placed to the left of the preparation area with the lid removed and set adjacent to the body. Bottles of granules for the first formula to be filled are arranged on the far edge of the table outside of the clean work space. The baskets containing bottles for filling prescriptions are set aside, each with a copy of the written prescription along with a label with the date, the name of the client, and the name of the ordering practitioner written into the spaces provided.

The worker begins by washing his or her hands thoroughly with soap and warm water. Once the hands are dry, the worker will put on a pair of fresh, clean, disposable gloves. The SHD employee will wear a lab coat to reduce the risk of cross-contamination. A face mask is another optional accessory that the worker may choose to use to insure optimal risk management.

Standing on an ergonomic work mat, the dispensary worker will use the straight edge to highlight each herb that needs to be filled. This method helps to prevent any errors when the granules are being weighed and combined. Each bottle—already prepared with any plastic sealing removed—is opened in order and then resealed with its lid after use. The dispensary worker pours granules directly from the storage bottles into the clean scoop positioned on top of the scale. This technique minimizes the need to make contact with the granules within the bottle. Occasionally, it may be necessary to adjust the amount of granular material using the small, clean spoon, either removing excess granules or adding a bit more. Due to the excellent training and

experience of SHD workers, most granules can be transferred to the weighing scoop without the aid of a spoon, resulting in an exceptionally clean process.

Serenity Herbal Dispensary maintains high standards in terms precision in the weighing process. Each granular ingredient is weighed separately with very low tolerance for error. After weighing, the dispensary worker uses the scoop to transfer each granule to the stainless steel mixing vessel. Proceeding methodically, each granules is added to the vessel, and storage bottles are sealed and set aside after use. By highlighting each herb to be filled with the straight edge on the written order and resealing and moving aside the storage bottles as each ingredient is added, errors can be avoided.

Mixing the Formulas and Secondary and Tertiary Weighing

Once all of the herbs for given formula have been added to the mixing vessel, the vessel—still without its top portion—will weighed to verify that the combined weight is correct. This intermediary step is especially utilized for larger than normal prescriptions. At this point, the mixing vessel is assembled and a dispensary worker will manually mix the granules with vigorous agitation. Each formula is shaken a minimum of 200 times to facilitate complete mixing of every formulation.

A new, pre-inspected bottle is placed on the scale tray in preparation for filling. The dispensary uses funnels that are cleaned with soap and water prior to use. A funnel of appropriate size is placed into the mouth of the clean bottle and the formula is poured carefully from the mixing container into the bottle. Once the transfer is complete, the funnel is removed and the formula is weighed again to verify that the final weight is within SHD's strict tolerances. If the total weight of the formulation meets our rigorous in-house standards—generally plus or minus less than 1 gram, it is sealed with a lid and set aside for the final steps in the dispensary process.

Final steps in the Dispensary Process

The filled, sealed bottles are labeled using an FDA-compliant label that has the date the formula was filled, the name of the ordering practitioner, and the name of the patient written in the spaces provided. Any residual powder is cleaned from the bottle, and the dispensary worker sets the bottle aside while the other formulas are being prepared.

As a final step in maintaining the integrity and purity of each formulation, each bottle is sealed with shrink wrap. This prevents foreign material from accidentally contamination the finished formulation and demonstrates to the recipient that the supplement has been sealed since its completion in the dispensary. The sealed final product is then transported in dedicated locking bags to its point of distribution or carefully packaged in a sealed mailer for shipping. The primary work of the dispensary is now complete.