AIRPOST, INC

MANUFACTURING PROCESS OF SOFTGELS

A. OBTAINING THE RAW MATERIAL AND MATERIALS:

• The raw material and other materials are purchased from recognized and qualified manufacturers in the nutritional supplement industry in the United States of America.

B. RECEIPT AND STORAGE OF RAW MATERIAL AND MATERIALS:

• The raw material and the purchased materials are received in the warehouses accompanied by the corresponding Certificate of Analysis issued by the suppliers.

• Upon receipt of the raw material and materials, they are identified by means of their respective labels. Samples are taken, which, duly identified, are sent to the Quality Control Laboratory.

• Raw materials and materials are quarantined until they are released by Quality Control.

Once released raw materials are stored in the appropriate places established in the manufacturing facilities depending on their own characteristics. Placing themselves in places where the required conservation conditions exist.

C. SELECTION AND WEIGHT OF COMPONENTS:

• The raw material is identified by means of its labels and they are compared with the standard samples located in the Quality Control Laboratory, checking if their physical characteristics (color, smell, texture, flavor, etc.) coincide.

• All the materials, already identified, to be used in the process, are placed on the RELEASED label, and are kept in an area designated for this purpose before use.

• The raw material ready for use is weighed and separated according to the needs of the quantities to be produced and located in the area designated for production.

• The materials are also separated and placed in the area designated for this purpose in the production área.

D. FORMULATION:

• The formulator prepares the batch manufacturing record (BMR) with the requested formula for the desired quantity to manufacture and send to the Manufacturing Manager for checking and producing.

E. PREPARATION PROCESS.

SOFTGEL ENCAPSULATION:

Gelatin Preparation: The process of mixing and heating granulated gelatin and other ingredients in warm water in a gelatin melting tank. With appropriate heat, mix and vacuum. The ingredients form a thick syrup called "gel mass" for use in encapsulation. Color can be added during the blending process or on a separate machine if applicable.
Preparation of the filling material: a process of preparation of the oil or non-aqueous paste to be encapsulated is carried out.
Preparation equipment include processing tanks, mixers, vacuum homogenizers, sieves, and mills. Heating to non-heating transfer tanks is used for filling material and gelatin while waiting for encapsulation.
Encapsulation: the process of converting the gel mass into a thin layer of gelatin and wrapping it around the filling material to form a well-sealed, homogeneous soft capsule at a controlled temperature.
Drying - A process that removes excess moisture from the gelatin shell to shrink and firm the softgel. Drying occurs by tumbling, by a combination of tumble and tray drying.
Cleaning, Inspection and Sorting - Required prior to packaging based on the intended use of the softgel.
After the softgels are encapsulated and dried in a drying tunnel, they undergo an additional stress relief step. During the stress relief stage, the temperature and humidity conditions in the drying tunnel intensify. By using the stress relief step, the volume and number of dimples and bubbles that could form is reduced, and dimensional uniformity is maximized.

F. CONTROLS AND VERIFICATIONS DURING THE ENCAPSULATION PROCESS:

TEST	PHASE	FRECUENCY	SAMPLING
WEIGHT	At the beginning, during and at the end of production	At the beginning and at 30-minute intervals	At the beginning 10 softgels together, for one softgel during the process, at the end 10 softgels together
APPEARANCE	At the beginning, during and at the end of production	At the beginning and at 30-minute intervals	25 softgels

G. QUALITY CONTROL OF THE FINISHED PRODUCT:

• Average Weight: 20 filled softgels and then empty soft shell are weighed one at a time. The weight average, standard deviation, and relative standard deviation (%) are determined.
• Appearance of the product: The size and color of the softgel are analyzed, corresponding to the Batch Record, the Color and Odor of the powder in the mixture.
• Rupture: The rupture time of the softgel is measured in the Disintegration equipment, $\leq$ 15 minutes according to the USP pharmacopoeia.
• Chemical analysis: The potency of the active ingredients is analyzed, if applicable; and heavy metals.
• Microbiological Analysis: Total Aerobic Count, Yeast & Mold Count, Pathogens: *Salmonella spp., Escherichia coli, and Staphylococcus aureus*.

H. PACKAGING OF THE PRODUCT:

• The finished softgels, once the final inspection has passed, are placed in polystyrene drums internally lined by a new polyvinyl bag. These drums are duly identified with the name of the producto, lot number and manufacturing date, closed and taken to the packaging area.

• The softgels are packed in bottles containing the indicated quantity of the product.

• The bottles are selected as per customer request. As a safety measure, a laminated liner is placed under the lid, which adheres to the edge of the bottle's mouth permanently when the thread of the lid is pressed by induction.

• To prevent counterfeiting and as a security measure, a white security seal made of extruded, pressure-sensitive polystyrene foam is placed under the cap, which permanently adheres to the edge of the bottle's mouth. by tightening the thread of the cap by induction.

• All the data on the run to be carried out are displayed on the run control board, including: the size and type of bottle, the size and type of cap, the product and batch number to be packed, the number of bottles to be packed, filled and content of each bottle.

• The bottling line, made up of the counting / filling machines, the plates, the conveyor, the cappers, the oven, the labeller / sealer, and other equipment are cleaned, then the line is checked by the personnel of the Department of Bottling. Once the line is cleaned, it is inspected by an analyst of the Quality Control Lab, who authorizes the start of the run.

• The Analyst of the Quality Control Lab verifies the correspondence between the product, lot number, bottle, cap, and label that is established in the Batch Packaging Process, and the materials that will be used for the run and once confirmed this authorizes the beginning of operations.

• During the process of counting and filling the bottles, samples are taken at random, but never less than 5% of the run to verify the number of capsules per bottle, the correctness of the closure of the bottle, the presence of products defective or presence of foreign matter, the security closures, the identity and adhesion of the labels, the correspondence of the batch number and the printed expiration date. If the product meets all the standards, it will be approved for use.

• The bottles with the producto are packed in corrugated cardboard boxes.

• The boxes are identified with the label of the product and the number of bottles is marked under the label.

I. STORAGE CONDITIONS:

• The finished product is kept covered, and stored in a cool, dry place, within the temperature range between 15°C - 30°C (59°F - 86°F).

J. PRODUCT STABILITY TESTS

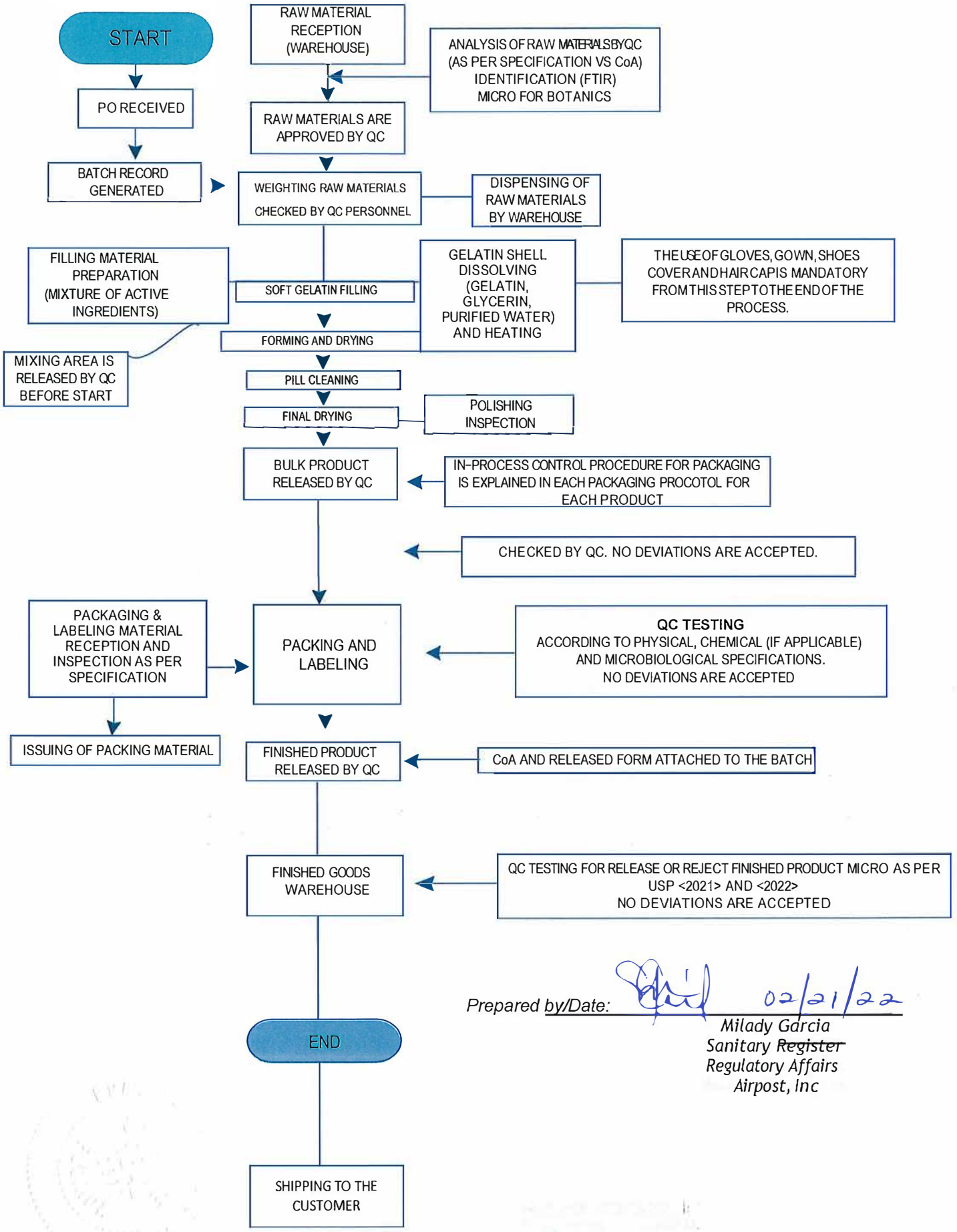
• The Quality Control Department performs product stability tests. These consisted of tests in accelerated conditions (temperature 40°C and relative humidity of 75%) and long-term condicitons (temperature 30°C and relative humidity of 65%) as environmental conditions like climatic zone IV. As a result of these tests, it was demonstrated that the product does not lose its qualities for a period of three years; therefore, it is proper to grant it a period of effectiveness for its active ingredients of three (3) years from the date of manufacturing.

2/21/2022

Milady Garcia
Sanitary Register

Date

MANUFACTURING PROCESS FLOW CHART - SOFTGELS



Prepared by/Date: 02/21/22

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Sanitary ~~Register~~
Regulatory Affairs
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