GREENWICH™ BIOSCIENCES

www.greenwichbiosciences.com

SETTING THE STANDARD IN CANNABINOID SCIENCE

Greenwich Biosciences, along with its parent company GW Pharmaceuticals plc, is at the forefront of cannabinoid science, with the first FDA-approved cannabinoid product. The company has leveraged two decades of pioneering research and investment to unlock the potential of cannabinoids to create prescription medicines.

CANNABIDIOL MANUFACTURING PROCESS

SCIENTIST-CONTROLLED GROWING PROCESS

All of the company's plant breeding is performed in-house using traditional breeding techniques to develop plants that contain high levels of cannabidiol (CBD) and low levels of other cannabinoids, including tetrahydrocannabinol (THC). To ensure that the contents of the plants are consistent, scientists control every aspect of the growing cycle, from plant breeding to the environment in which the plants are grown. From start to finish, each crop's growing process is managed to a specified growing protocol, ensuring uniform production and composition.

- The plants used are first grown to produce mother plants. Cuttings from mother plants are used to grow new plants, ensuring genetic consistency from one generation to the next.
- The growing process takes place in glasshouses where light, heat and humidity are kept at optimal levels for plant health and growth.
- All plants are grown in a controlled, pesticide and contaminant-free environment. Growers utilize a range of natural beneficial predators to maintain control of pests.
- The finished product is lightly compressed into bales and labelled with an individual batch item code and batch number for traceability, and prepared to be sent to the processing center.
- On arrival at the processing plant, the dried plant material is pelleted, allowing the batch to be stored in a stable form for an extended period prior to further processing.

ACHIEVING ACTIVE CBD VIA DECARBOXYLATION

Since cannabinoids are naturally produced in the plant in their acid form, a chemical reaction called decarboxylation is used to convert the inactive acid into the active molecule CBD.

- Pelleted material is milled to create a uniform particle suitable for extraction.
- Naturally occurring cannabidiolic acid is heated to convert it to CBD that is biologically active.

YIELDING A CBD-RICH EXTRACT

After decarboxylation is complete, the raw material is loaded into an extraction column and CO_2 is passed through at a pre-specified temperature until the extraction process is complete.

CO_2 extraction process destroys any bacteria present in the plant material and yields a CBD-rich extract containing cannabinoids and other natural plant-based components, including waxes and terpenes (aromatic compounds).

PRODUCING HIGHLY PURIFIED CBD

The isolation stage of the process purifies the refined CBD extract and removes the unwanted naturally occurring components — the waxes, terpenes and other minor cannabinoids — thereby producing a purified yield of CBD, which is a crystalline solid at room temperature.

- Remaining waxes are filtered off and ethanol is removed by evaporation.
- The powder version of the active compound is created via multi-step crystallization.
- The isolated purified CBD is quality tested before being released for final formulation.

FINAL PACKAGING OF THE PHARMACEUTICAL MEDICINE

In the final stage of the manufacturing process, the CBD oral solution is packaged prior to distribution center delivery.

- To ensure precise dosing, oral syringes and a bottle adapter are added to the branded packaging with the filled bottle of CBD oral solution. Also included is a patient information leaflet containing prescribing and product information.
- The product is placed in tamper-evident cartons, which are each stamped with a serial number for identification and traceability.

FORMULATING CBD FOR PHARMACEUTICAL USE

Once the active pharmaceutical ingredient (CBD) has passed a series of stringent quality control checks, it is now ready for manufacture of the finished product.

- As CBD is not water soluble, it is dissolved in sesame oil and a sweetener (dissolved in ethanol) and strawberry flavoring are added to ensure it is more pleasant tasting.
- Each batch is then quality-control tested and released for final filling into sterile glass bottles. The final formulation contains 100 mg CBD per ml of oral solution. Each bottle contains 100 ml and is secured with a child-resistant cap.
- Bottle labels are added with batch number, expiration date, product branding, and specifications for the active pharmaceutical ingredient and any inactive substances, which are tightly controlled and subject to FDA oversight.

COMMITMENT TO EXACTING PHARMACEUTICAL PROCESSES

The company's pharmaceutical production and manufacturing processes meet the highest standards for safety and quality, enabling them to bring forward prescription cannabinoid medicines that are safe and effective for patients. The processes are in line with World Health Organization Good Agricultural Practices and current Good Manufacturing Processes which ensures that the final product meets strict pharmaceutical standards.

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