

## Compliance Package 2025



Vantage Hemp Co. is North America's only WHO GMP, FDA 21 CFR 210/211, and ICH Q7 certified hemp processor. From raw crude to registered pharmaceutical APIs and manufactured finished goods, trust Vantage Hemp.

2337 115th Avenue, Greeley, CO 80634 General: 720-633-6082 Sales: 732-788-5353 vantagehemp.com



## Introducing Vantage Hemp Co.

Vantage Hemp's mission is to continually strive to become the leading CBD supplier while maintaining 100% dedication to premium quality, science-driven process consistency, sustainability, and transparency. Vantage is dedicated to fostering positive, trustworthy relationships with our partners and community.

We accomplish our mission through precise, GMP compliant, technologically advanced, and scientifically driven processes. We build trustworthy relationships with our employees, our suppliers, our customers and our community through honesty, integrity, transparency, and respect.

Vantage is committed to producing the highest quality products and to complying with all applicable regulations and Good Manufacturing Practice guidelines.

Vantage management is responsible for the implementation and maintenance of a comprehensive and effective Quality Management System and for assuring its ongoing effectiveness through regular audits, review, and improvement.

All Vantage employees are committed to Quality and Compliance and take responsibility for the quality of their own work. Each employee has the independence, training, and authority necessary to perform their duties and to identify quality issues and opportunities for continuous improvement.



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## Statement Of Compliance

The active ingredients in Vantage's product line, including CBD Isolate, CBD Distillate, CBD Broad Spectrum Oil, CBD CO2 crude and Hydrocarbon crude are extracted and refined from industrial hemp that is grown, harvested and dried in the United States of America from approved growers in various states that have been qualified through Vantage's Biomass Compliance Program. These hemp derived products meet or exceed the definition of industrial hemp via the 2014 and 2018 Farm Bill, (any part and all parts of the Cannabis sativa L. plant, whether growing or not, with a delta-9 THC content of less than 0.3% THC by weight).

Vantage's bulk wholesale ingredients and formulations meet or exceed international standards for pharmaceutical products. Vantage is licensed and regulated by the state of Colorado's Department of Public Health and Environment. Per those regulations Vantage is also registered with the US Food and Drug Administration as a food manufacturing facility though we exceed all the food regulations.

Vantage specializes in the production of hemp-derived CBD and a variety of Full Spectrum, Distillate, and CBD Isolate products. All product types undergo a certain amount of processing, refinement, and formulation and they all meet international specifications for quality, including but not limited to heavy metals, residual solvents, pesticides, mycotoxins, and microbiologic parameters.

We are committed to compliance, quality, and reliability regardless of the product type.

Deepank Utkhede Chief Operating Officer

### **Statement of Origin**

The active ingredients in Vantage products, including CBD Isolate, CBD Distillate, CBD Broad Spectrum Oil, CBD CO2 crude and Hydrocarbon crude are extracted, and refined from industrial hemp that is grown, harvested and dried in the United States of America from approved growers in various states that have been qualified through Vantage's Biomass Compliance Program.

Other ingredients in some of our finished products, including carrier oils and flavors, may be sourced domestically or internationally. For specifics on a certain product or batch, please inquire with our Vantage representatives.

**Deepank Utkhede**Chief Operating Officer



### **FSMA Statement**

The Food and Drug Administration signed into effect and is currently enforcing the Food Safety Modernization Act (FSMA). With this enforcement, the FDA requires all Food Manufacturing Sites to implement and utilize Food Safety Plans and employ a risk-based preventative controls approach to the hazard identification and risk classification/mitigation (www.fda.gov).

Additional requirements of FSMA are each food manufacturing site must have a Food Safety Plan that is written by and monitored by a Preventative Controls Qualified Individual or Qualified Individual, current Good Manufacturing Practices must be implemented and enforced, supply chain programs in place to ensure risks and hazards are mitigated, and a written recall plan.

FSMA compliance is verified through a 3rd party audit on an annual basis.

**Deepank Utkhede**Chief Operating Officer

## Food Grade Statement

The active ingredients in Vantage products, including CBD Isolate, CBD Distillate, CBD Full Spectrum Oil, CBD CO2, and Hydrocarbon crude, are extracted and refined from industrial hemp that is grown, harvested and dried in the United States of America. These derived products mentioned above meet or exceed food grade standards and are considered safe for human consumption.

Other ingredients in our finished products, including carrier oils, flavors, etc., are sourced from food grade suppliers and are considered safe for human consumption.

**Deepank Utkhede**Chief Operating Officer



### Third Party Laboratory Statement

Vantage performs full panel testing at each stage of our process. That means that our incoming hemp is tested as well as our CO2 and Hydrocarbon crude oil, Full Spectrum Oil, Distillate, Isolate and all finished products are full panel tested at one of our approved third party analytical testing laboratories. Through our supplier qualification program, we ensure that all our third-party labs qualify and have ISO 17025. We sign quality agreements which indicate that any testing discrepancies are thoroughly investigated and re-testing is justified.

### Full panel testing includes the following:

- Microbial analysis (salmonella spp., shiga-toxin producing Escherichia coli (STEC), total aerobic plate count, total coliforms, total yeast, and mold).
- Heavy Metals (lead, cadmium, arsenic, and mercury).
- Residual Solvents (n-butane, pentane, methanol, propane).
- Mycotoxin (aflatoxins: B1, B2, G1 and G2, and ochratoxin).
- Pesticides (approximately 150).
- · Cannabinoid Profile

If your company wishes to conduct additional analyses of the products received from Vantage, or you require testing against different standards, these specifics can be agreed upon prior to purchase. Additional testing will increase the processing time and cost.

Deepank Utkhede Chief Operating Officer

### **Allergen Statement**

Vantage is committed to the compliance, quality, and reliability of our products. All ingredients used in our facilities are high quality that **do not contain celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, molluscs, mustard, peanuts, sesame, soybeans, sulphur dioxide and sulphites and tree nuts.** These are some of the top common food allergens classified by the Food Allergen Labeling and Consumer Protection Act (FALCPA) in the USA and in Annex II of Regulation (EU) No 1169/2011 for Europe.

The Food Allergen Labeling and Consumer Protection Act of 2004, Sec. 20, subsection 7, Part C. cl.qq.2.1 under Conforming Amendments, states that highly refined oils are exempt as major food allergens.

Deepank Utkhede Chief Operating Officer



## **Elemential Impurities Statement**

Vantage complies with USP/Ph Eur./ICH Q3D Guidelines for Elemental Impurities. Vantage has set all specifications well below the limits for all elemental impurities and performs testing at each step of the process to ensure compliance. No elemental impurities are present or intentionally added.

**Deepank Utkhede**Chief Operating Officer

## Residual Solvent Statement

Vantage complies with USP/Ph Eur./ICH Q3C Guidelines for Residual Solvents. Vantage has set all specifications well below the limits for all residual solvents and tests at each step of the process to ensure compliance.

**Deepank Utkhede**Chief Operating Officer



### **GMO Statement**

Vantage products: Cannabidiol (CBD) Isolate, CBD Distillate, CBD FSO, CO2 crude oil, Hydrocarbon crude oil and CBD Tinctures, do not contain any GMOs (Genetically Modified Organisms) and during manufacturing does not come into contact with any GMOs.

**Deepank Utkhede**Chief Operating Officer

## Process Validation & Stability Statement

Vantage has followed pharmaceutical cGMPs which includes full qualification and validation. Installation qualifications and operational qualifications have been completed for all process equipment. Process validations have been completed for all stages of our extraction and purification processes. As part of the process validations, three consecutive batches were produced for each stage and placed on stability. Vantage has placed batches on stability for accelerated and real time stability in Zone II and some in Zone IVB. Vantage has also placed our finished product formulations on stability on accelerated and real time stability in Zone II and some in Zone IVB.

**Deepank Utkhede**Chief Operating Officer



### **BSE-TSE Statement**

This is to certify that the CBD extracts, isolate, and CBD-based tinctures manufactured by Vantage Hemp are free from human or any other animal derived materials including bovine products. In addition, there are no animal derived components used in the manufacturing or handling processes of these products. As such, these materials can be declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

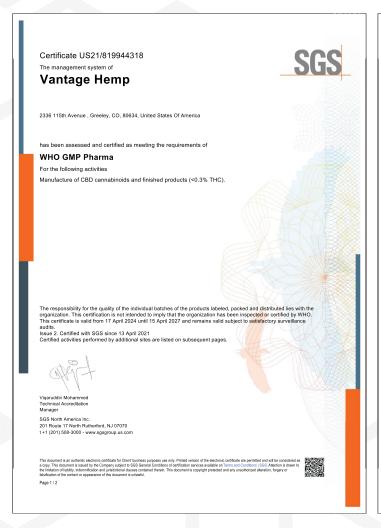
**Deepank Utkhede**Chief Operating Officer

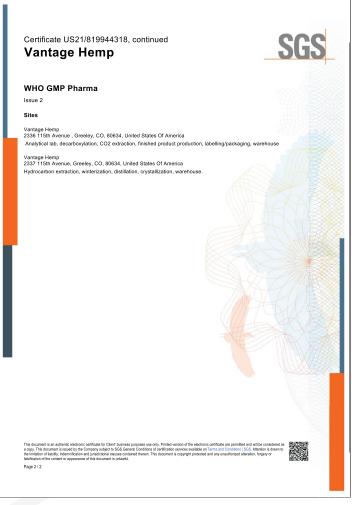
## cGMP Certification - ICH Q7





## cGMP CertificationAnnex 2 WHO





### **FDA Registration**





## Colorado Departmentof Public Health & Environment Licenses



2025 Registration to Operate: Hemp Establishment

Registration must be posted at the following location in a conspicuous place:

Registration #HMP24503

Vantage Hemp Co 2336 115th Ave Greeley CO 80634-7781

Registration valid until: 06/30/2025

This certifies that registrant shown hereon is authorized and registered to engage in business in accordance with the provisions of the laws and regulations of the Colorado Department of Public Health and Environment. Any alterations to this registration will automatically make it null and void.

Registration Type: Hemp

Issued by: Colorado Department of Public Health and Environment



2025 Registration to Operate: Hemp Establishment

Registration must be posted at the following location in a conspicuous place:

Registration #HMP24546

Vantage Hemp Co 2337 115th Ave Greeley CO 80634-7781

Registration valid until: 06/30/2025

This certifies that registrant shown hereon is authorized and registered to engage in business in accordance with the provisions of the laws and regulations of the Colorado Department of Public Health and Environment. Any alterations to this registration will automatically make it null and void.

Registration Type: Hemp

Issued by: Colorado Department of Public Health and Environment



2025 Registration to Operate: Safe Harbor Hemp Establishment

Registration must be posted at the following location in a conspicuous place:

Registration #SHH24504

Vantage Hemp Co 2337 115th Ave Greeley CO 80634-7781

Registration valid until: 06/30/2025

This certifies that registrant shown hereon is authorized and registered to engage in business in accordance with the provisions of the laws and regulations of the Colorado Department of Public Health and Environment. Any alterations to this registration will automatically make it null and void.

Registration Type: Safe Harbor Hemp

Issued by: Colorado Department of Public Health and Environment

### Ethical Code Statement

Through the utilization of Vantage's quality management systems, Vantage can and will provide your company with a product adhering to legal, quality, and safety requirements. The successful business operations and reputation of Vantage is built upon principles of fair dealings and ethical conduct of our employees. Our reputation for dependability and excellence requires careful observance of the spirit of this letter and all applicable laws and regulations, as well as a scrupulous regard for the highest standards of conduct and personal integrity.

The continued success of Vantage is dependent upon our customers' trust, and we are dedicated to preserving that trust. Personnel owe a duty to Vantage, it's customers and its growers, to act in a way that will merit the continued trust and confidence of the public.

Vantage will comply with all applicable laws and regulations and expects its directors, officers, employees, and contractors to conduct business in accordance with the letter, spirit, and intent of all relevant laws and to refrain from any illegal, dishonest, or unethical conduct.

In general, the use of good judgement, based on the Vantage shared beliefs, values, morals, and ethical principles, will guide you with respect to lines of acceptable conduct. Compliance with this policy of business ethics and conduct is the responsibility of every Vantage employee.

Deepank Utkhede Chief Operating Officer



### Phthalates Statement

Vantage does not use phthalates in any of our current or future formulations and have no plans to do so.

If there are any questions regarding your products, please contact a quality representative of Vantage.

**Deepank Utkhede**Chief Operating Officer

### Nitrosamines Statement

Vantage Hemp acknowledges the concerns regarding nitrosamine impurities in pharmaceutical manufacturing.

Fortunately, cannabinoids inherently lack primary aromatic amines, precursors for nitrosamine formation. Moreover, Vantage Hemp's manufacturing processes do not involve any chemical conversions that could lead to nitrosamine generation.

While nitrosamine risk is not applicable to Vantage Hemp products, we remain vigilant about industry updates. Our commitment to patient well-being and product integrity remains paramount.

Deepank Utkhede Chief Operating Officer



# GMP Certificate - Therapeutic Goods Administration of Australia



### **Australian Government**

**Department of Health and Aged Care** Therapeutic Goods Administration

### Certificate of GMP Compliance for the purposes of Therapeutic Goods Order 93

**Certificate Number:** 

MI-2022-CE-09906-1

### Issued to:

Vantage Hemp Co

### Primary Manufacturing Site Address:

2337 115th Avenue Greeley CO 80634 United States Of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected for the purposes of Section 13 of the Therapeutic Goods Order 93 (Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022) for supply of medicinal cannabis products to Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 22 to 25 August 2023, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 May 2021.

This certificate reflects the status of the manufacturing sites at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

Issue Date: 27 February 2024

Expiry Date:

25 February 2026

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 ABN 40 939 406 804 Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au TGA Health Safety Regulation

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### Australian Government

### Department of Health and Aged Care Therapeutic Goods Administration

### Certificate of GMP Compliance for the purposes of **Therapeutic Goods Order 93**

**Certificate Number:** 

MI-2022-CE-09906-1

### MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site addresses as specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Not Applicable	Active Material Manufacture
Medicine manufacture	Non Sterile	Oil	Not Applicable	Finished Product Manufacture
Medicine manufacture	Non Sterile	Liquids - Tinctures Group	Not Applicable	Finished Product Manufacture

### CONDITIONS

The following limitations are applicable to these manufacturing operations:

The manufacture of active pharmaceutical ingredient (API) and medicinal dosage forms is limited to medicinal cannabis products.

The manufacture of API is limited to cannabidiol (CBD) isolates.

Testing is limited to physical testing and FTIR identification tests.

 $Chemical\ and\ microbiological\ testing, other\ than\ FTIR\ identification\ tests, are\ restricted\ to$ testing performed at Eurofins, 6304 Ronald Reagan Avenue, Madison, WI 53704 USA, under the control of Vantage Hemp Co.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804 Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.go



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