



Good agricultural and collection practices and good manufacturing practices for botanical materials

Company Information

Company name			
Street Address			
City/State		Country	
Contact name		Contact phone	
Contact email		Company website	
Botanical material operation	<Describe the scope of the botanical material operation addressed by this form>		

This form is for use in conjunction with Section 8 Further Processing and Handling. Supporting information for specific elements can be attached to this form.

After being cleaned and often dried, the botanical material may be packed and held for distribution, or it may first be subject to additional processing such as size reduction or extraction. As with other activities, these steps should be optimized appropriately in order to prevent degradation or contamination.

Plant material can be traded in a number of forms, including whole, chopped, cut and sifted, teabag cut, shredded, and powder. Cutting or chopping of plant materials can occur either before or after dehydration, while milling to powder is normally performed after drying. Size reduction operations should be conducted with practices that ensure that the material's quality and purity are maintained.

Plant material may be extracted using various solvents and extraction technologies.

Extracting a botanical material for food use (as opposed to a non-food use such as for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.) is considered a food processing operation by FDA. Facilities that perform food extraction are generally (subject to certain exemptions) required to register with FDA as a food processing facility and to comply with 21 CFR Part 117 and/or Part 111 as well as other relevant FDA regulations, if the extracted material will be distributed in the US. This applies even if the facility is located outside the US.

Section 8 Further Processing and Handling

FP8 Further Processing and Handling		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
FP8.1 Special preparation					
FP8.1 ii)	Special preparation (roasting, frying, steaming, etc.) is performed in a manner that ensures the prepared material meets established specifications.				
Comments:					
FP8.1 ii)	Special preparation is performed by appropriately trained personnel using appropriate procedures and equipment.				
Comments:					
FP8.1 ii)	Records of special preparations are kept for an appropriate length of time.				
Comments:					
FP8.2 Size reduction					
FP8.2 ii)	The operation is registered with FDA as a food processing facility and complies with 21 CFR Part 117 and/or Part 111 as well as other relevant FDA regulations.				
Comments:					
FP8.2 iii)	Size reduction operations are performed as close to the time of manufacture of finished products as possible.				
Comments:					
FP8.2 iv)	Advance preparation such as cleaning and screening steps and inspection to remove foreign or otherwise unacceptable material is performed prior to size reduction.				
Comments:					
FP8.2 v)	Adequate ventilation and any needed protective gear is provided to personnel in the size reduction facility.				
Comments:					
FP8.2 vi)	Milling facilities are equipped with suitable dust control equipment to minimize the chance of explosion and to minimize the spread of cross-contamination and allergens.				
Comments:					
FP8.2 vii)	The temperature in milling equipment is monitored or controlled to avoid damage to the quality of the botanical material.				
Comments:					
FP8.2 viii)	After size reduction, botanical material meets all established specifications with regard to particle size, length, and/or density requirements.				
Comments:					

Section 8 Further Processing and Handling

FP8 Further Processing and Handling		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
FP8.2 ix)	The botanical material is passed through a magnet bank or metal detector to ensure that any metal fragments from the equipment or screens are removed.				
Comments:					
FP8.2 x.1-3)	Records of the size reduction operation are created and retained for an appropriate length of time.				
Comments:					
FP8.2 xi.1-3)	A retention sample of each lot of material after size reduction is maintained for an appropriate length of time.				
Comments:					
FP8.3 Extraction					
FP8.3 ii)	The operation is registered with FDA as a food processing facility and complies with 21 CFR Part 117 and/or Part 111 as well as other relevant FDA regulations.				
Comments:					
FP8.3 iii)	The extraction process and conditions are determined by the desired characteristics of the final product.				
Comments:					
FP8.3 iv)	Advance preparation such as cleaning and size reduction is performed prior to extraction.				
Comments:					
FP8.3 v)	Prepared material is extracted according to defined conditions and using a specified extraction technology.				
Comments:					
FP8.3 vi)	Post-extraction processing is performed as needed to separate the liquid from spent botanical material and to ensure compliance with extract specifications.				
Comments:					
FP8.3 vii)	Adequate ventilation and any needed protective gear is provided to personnel in the extraction facility.				
Comments:					
FP8.3 viii)	Records of the extraction operation are created and retained for an appropriate length of time.				
Comments:					

Section 8 Further Processing and Handling

FP8 Further Processing and Handling		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
FP8.3 ix)	A retention sample of each lot of extracted material is maintained for an appropriate length of time.				
Comments:					
FP8.4 Packing, packaging, and storage					
FP8.4 iii.1-4)	Packing and packaging materials are constructed of appropriate materials that pose no risk of introducing contamination to the botanical material.				
Comments:					
FP8.4 iv)	Where appropriate, packing/packaging is equipped with tamper-evident features.				
Comments:					
FP8.4 v.1-5)	Packing/packaging material is appropriate for its intended use, e.g., fresh or dried plant material, protection from light or oxidation.				
Comments:					
FP8.4 vi)	Labels are clearly printed, permanently affixed, and conform to any labeling regulations in the country of origin and in any countries to which it is intended to be shipped.				
Comments:					
FP8.4 vi)	Labels or labeling of bulk botanical materials include the relevant information about the botanical material.				
Comments:					
FP8.4 vii)	Botanical materials are stored in cool, dry areas away from direct sunlight and off the ground.				
Comments:					
FP8.4 vii)	Storage facilities are appropriately designed with adequate ventilation, temperature control, and pest control.				
Comments:					
FP8.4 viii)	Botanical materials are segregated from storage of chemicals and other non-food items.				
Comments:					
FP8.4 ix)	Botanical materials are stored in a manner that allows for control of odor absorption where necessary.				
Comments:					
FP8.4 x)	Records of the packing/packaging operation are created and retained for an appropriate length of time.				

Section 8 Further Processing and Handling

FP8 Further Processing and Handling		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
Comments:					
FP8.4 xi)	When packaged for retail sale, a retention sample of each lot of packaged material is maintained for an appropriate length of time.				
Comments:					
FP8.5 Shipping					
FP8.5 ii)	Botanical materials that conform to various certifications (e.g., organic, biodynamic, or Kosher) bear clearly stated shipping and handling instructions to maintain the integrity of the certification.				
Comments:					
FP8.5 iii)	Secondary shipping containers used for packed or packaged botanical materials are suitable for transporting food products and any special needs of the material.				
Comments:					
FP8.5 iv)	Botanical materials are shipped via carriers that are suitable for transportation of food products, as applicable.				
Comments:					
FP8.5 v)	Botanical materials intended for food use (including both conventional foods and dietary supplements) are classified appropriately on bills of lading.				
Comments:					
FP8.5 vi)	Botanical materials used for food that originate in, or will be distributed within, the U.S. are shipped in accordance with 21 CFR Part 1 Subpart O (regulations on the Sanitary Transportation of Human and Animal Food).				
Comments:					
FP8.5 vii)	Records of shipping operations are created and retained for an appropriate length of time.				
Comments:					
¹ Assessments are used to indicate the degree of compliance or adherence to the specific element. N/A = This element is not applicable to the operation Meet = Fully compliant or adherent to the element Partial = Greater than 50% compliant to the element Deficient = Less than 50% or no compliance to the element					

I attest that all the information contained in this form is correct to the best of my knowledge.

Signature: _____

Date: _____