



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 2 Botanical Identity and Quality**. Supporting information for specific elements can be attached to this form.

Botanical identity and quality must be assured throughout the growing, harvesting, post-harvest handling, and further processing of botanical materials. Improper or careless practices at any stage may result in material that is misidentified, adulterated, or that fails to meet the necessary specifications.

All steps in the production of a botanical material must be performed properly to ensure the quality of the resulting finished material. This includes everything from site location and cultivation, to harvest, to post-harvest steps such as washing, cutting, dehydrating, packaging, storing, and transporting.

Any material offered as a particular genus, species, subspecies, variety, cultivar, hybrid, or other lesser division of a species must in fact be that exact taxon.

Limits should be established for impurities and contaminants that may adulterate the material or adversely affect its quality.

Section 2 Botanical Identity and Quality

BQ2 Botanical Identity and Quality		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
BQ2.1 General considerations					
BQ2.1 ii.1-2)	Appropriate written specifications have been established for botanical materials.				
Comments:					
BQ2.1 iii)	Specifications and test methods are referenced to pharmacopoeial monographs and other compendia.				
Comments:					
BQ2.1 iv)	Tests and examinations for botanical materials are performed on properly representative samples.				
Comments:					
BQ2.1 v)	All representations made about botanical materials in labels and labeling, specification documents, certificates of analysis, guarantees, written agreements, and other documentation are accurate.				
Comments:					
BQ2.2 Identity					
BQ2.2 ii.1-5)	The botanical identity of each botanical material has been documented with as much specificity as appropriate, including scientific name.				
Comments:					
BQ2.2 iii)	The botanical species has been examined and identified by a botanical specialist with knowledge of the plant's morphologic characteristics.				
Comments:					
BQ2.2 iv.1-4)	Other evidence of identity has been documented using chemical fingerprinting, DNA analysis, quantitative testing, or infrared testing.				
Comments:					
BQ2.2 v.1-3)	Voucher specimens of the plant or other archival samples (e.g., of viable seeds or of the crude botanical prior to processing) have been taken.				
Comments:					
BQ2.2 vi)	The identity of <u>processed botanicals</u> , such as those that have been powdered, extracted, and/or blended with other botanicals has been established using microscopy, chemical testing, and/or DNA testing where adequate and scientifically valid methods exist.				
Comments:					

Section 2 Botanical Identity and Quality

BQ2 Botanical Identity and Quality		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
BQ2.3 Physical characteristics					
BQ2.3 i.1)	A specification has been set for the moisture content or loss on drying.				
Comments:					
BQ2.3 i.2)	For <u>cut, chopped, or milled materials</u> , a specification for the size of the pieces or particles has been set.				
Comments:					
BQ2.3 i.3)	For <u>powdered materials</u> specifications for tapped density and bulk density have been set.				
Comments:					
BQ2.3 i.4)	For <u>liquid materials</u> specifications for pH, density or specific gravity, viscosity, and total dissolved solids have been set.				
Comments:					
BQ2.3 ii.1-3)	For <u>crude botanical materials</u> , especially in whole form, specifications have been set for soil content, foreign matter, and substandard botanical material.				
Comments:					
BQ2.4 Chemical characteristics					
BQ2.4 i.1)	Specifications have been set for the content of extractable material (extractives).				
Comments:					
BQ2.4 i.2)	Specifications have been set for the levels of one or more botanical constituents (markers) in the material.				
Comments:					
BQ2.4 i.3)	Specifications have been set for the content of essential oils or fixed oils, total ash, acid-insoluble ash, water-soluble ash, crude fiber, etc. as applicable.				
Comments:					
BQ2.5 Contaminants					
BQ2.5 ii)	Specifications have been set to exclude the presence of known adulterants and substitutes.				
Comments:					
BQ2.5 iii)	Specifications for the microbiological characteristics of the botanical material (including indicator organisms, spoilage organisms, and/or potential pathogens) have been set.				
Comments:					

Section 2 Botanical Identity and Quality

BQ2 Botanical Identity and Quality		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
BQ2.5 iv)	Specifications have been set for heavy metals such as arsenic, lead, cadmium, and mercury.				
Comments:					
BQ2.5 v)	Specifications have been set for pesticide residues on botanical materials that are applicable for the intended use of the material.				
Comments:					
BQ2.5 vi)	A specification for content of radioactivity has been set (for material sourced from an area known to be contaminated).				
Comments:					
BQ2.5 vii)	Specifications have been set for other relevant parameters such as sulfur dioxide, ethylene oxide residue, polycyclic aromatic hydrocarbons (PAHs), aflatoxins and other mycotoxins, presence of genetically modified DNA, solvent residues, etc.				
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: _____