

# Guidance on Limits of Foreign Matter in Herbal Ingredients

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Prepared by the American Herbal Products Association



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## AHPA Guidance Policy

The American Herbal Products Association (AHPA) provides the following guidance on maximum quantitative limits of foreign matter in herbal raw materials: Plant parts of the same herbal raw material species, other than those named in specifications, should not exceed 5% (by weight), and all other foreign matter should not exceed 2% (by weight).

### Notes:

- For purposes of this guidance, herbal raw materials are parts of plants that may be dehydrated and subject to minimal cutting but have not been subject to any additional processing, such as powdering, extraction, etc., at a stage in commerce in which the material is for use as a component in a consumer product or processed into an ingredient for use as a component in a consumer product.
- An article (e.g., herb powder, extract, essential oil, traditionally processed herb, etc.) derived or manufactured from herbal raw materials that is in compliance with this guidance is also assumed to be in compliance with this guidance.
- For quantitative determination of foreign matter content in an herbal raw material, suitable physical test procedures, as described in the 2011 WHO publication, *Quality control methods for herbal materials: Updated edition of quality control methods for medicinal plant materials 1998*, may be utilized. Note that determination of foreign matter content in processed herbal ingredients and articles derived or manufactured from herbal raw materials may not be possible by such procedures.
- This guidance is relevant only to foreign matter consisting of those identified in the “Context and background” section of this document.
- This guidance does not allow or imply allowance of any portion of an herbal raw material to consist of economically motivated adulterants, deliberately substituted ingredients, or diluents
- This guidance does not allow or imply allowance of presence of allergens, potential choking hazard objects, or poisonous, dangerous or otherwise harmful foreign matter or residue.
- This AHPA guidance does not apply to an herbal ingredient labeled or otherwise identified as meeting a different standard, whether more or less stringent than the limits established in this guidance.



## Context and background

It is natural for herbal raw materials to contain some foreign matter which may consist of any or all of the following:

- Plant parts of the herbal raw material other than those named in its specification and description, for example the European Pharmacopeia Hawthorn Leaf with Flower monograph limits lignified branches with a diameter > 2.5mm to not more than 8%;
- Any organism, part or product of an organism, other than those named in the specification and description of the herbal raw material, for example grass clippings in mint leaves;
- Mineral admixtures present in the herbal raw material, for example soil, stones, metal, sand and dust.

Official pharmacopeias worldwide recognize quantitative limits of foreign matter as part of monograph specifications for herbal raw materials. Limits of foreign matter for the same herbal material may differ in various pharmacopeias. Examples are provided in Table 1. Although not specific to foreign matter as defined here, the U.S. Food and Drug Administration (FDA) establishes maximum levels of natural or unavoidable defects in foods that present no health hazards for humans<sup>1</sup>. Based on review of various pharmacopeial standards, the tolerance range for foreign matter can be up to 10% (by weight) of plant parts of the herbal material other than those named in its specification<sup>2</sup>. A range of 2% to 5% (by weight) of other plant parts of the same herbal material accommodates most pharmacopeial standards. In the case of other foreign matter not consisting of plant parts of the same herbal material, a limit of not more than 2% is commonly listed in pharmacopeial standards.

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<sup>1</sup> See U.S. FDA Defect Levels Handbook.

<sup>2</sup> AHP, British Herbal Pharmacopeia (1986, 1992, 1996), ChP, EP, MHP, USP-NF, WHO. Description of these abbreviations are provided with Table 1.



## Handling of foreign matter in herbal raw material

Standard industry practices for the detection and mitigation of foreign matter include:

- Visual and physical examination for all batches of herbal raw materials for the presence of extraneous foreign matter;
- Removal of soil, stones, sand, dust, glass, plastic, metal and foreign inorganic matter as much as practical;
- Examination for the absence of visible signs of contamination by molds or insects, and other animal contamination, including animal excreta; and
- Examination for the absence of abnormal odor, discoloration, slime or signs of deterioration.

Following good agriculture and collection practices, such as those outlined in the *AHPA Guidance for Good Agricultural and Collection Practices and Good Manufacturing Practices for Botanical Materials*, should help ensure foreign matter content is kept to a minimum. In addition, other tests or examinations may be needed to ensure compliance with other specifications for the herbal ingredient, such as those for identity or for contaminants that may adulterate a finished product that will contain the ingredient.



**Table 1: Examples of monograph limits for foreign matter (% by weight)**

Article	AHP	ChP	EP	MHP	USP-NF	WHO
<b>Chamomile Flower Head</b>	NA	NA	NA	NA	NMT 2.0% foreign organic matter	NMT 10% stems and NMT 2% foreign organic matter. No flowering heads of <i>Anthemis cotula</i> or <i>A. nobilis</i>
<b>Ginkgo Leaf</b>	NMT 5% stems and 2% other foreign matter	NMT 2% foreign matter	NMT 5% stems and 2% other foreign matter	NMT 5% stems and 2% other foreign matter	NMT 3.0% stems and NMT 2.0% other foreign organic matter	NMT 5% of twigs and NMT 2% of other foreign matter
<b>Hawthorn Leaf with Flower</b>	NMT 8% lignified branches with a diameter > 2.5mm and NMT 2% other foreign matter	NA	NMT 8% lignified branches with a diameter > 2.5mm and NMT 2% other foreign matter	NMT 8.0% of lignified matter	NMT 8.0% of lignified matter	NMT 8% lignified branches with a diameter > 2.5mm and NMT 2% other foreign matter
<b>St. John's Wort Flowering Tops</b>	NA	NA	NMT 3% stems with a diameter > 5mm and NMT 2% other foreign matter	NMT 3% stems with a diameter > 5mm and NMT 2% other foreign matter	NMT 2.0% foreign organic matter	NMT 3% stems with a diameter > 5mm and NMT 2% other foreign matter
<b>Valerian Root</b>	NMT 5% stem bases and NMT 2% other foreign organic matter	NA	NMT 5% stem bases and NMT 2% other foreign matter	NMT 5% stem bases and NMT 2% other foreign organic matter	NMT 2.0% foreign organic matter	NMT 5%

- AHP: American Herbal Pharmacopoeia
- ChP: Pharmacopoeia of the People's Republic of China (2015)
- EP: European Pharmacopoeia 9.0
- MHP: Farmacopea Herbolaria de los Estados Unidos Mexicanos (2013)
- NA: Not available
- NMT: Not more than
- USP-NF: United States Pharmacopeial Convention USP39-NF34
- WHO: World Health Organization

