AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Recommended Microbial Limits for Botanical Ingredients

[Current as of June 2022]

Organization	AHPA	NSF/ ANSI	USP[c]	WHO[d]	THIE	AHPA	USP
Plant material	Dried, unprocessed herbs for use as ingredients in dietary supplements	Botanical ingredients, non-extract	Dried or powdered botanicals	Crude material intended for further processing	Dry raw materials	Powdered botanical extracts and soft extracts	Powdered botanical extracts
	Amounts listed in colony-forming units (cfu)/g or mL where not otherwise specified.						
Total aerobic microbial count	10^7	10^7	10^5	NA	10^8	10^4	10^4
Total combined yeast & mold count	10^5	10^5	10^3	10^5 (mold propagules)	10^6 for each[d]	10^3	10^3
Enterobacteria count (bile-tolerant gram-negative bacteria)	10^4 (total coliforms)	10^4	10^3	NA	NA	10^2 (total coliforms)	NA
Escherichia coli	ND in 10 g[a]	10^{2b}	Absent in 10 g	10^4	10^4	ND in 10 g[a]	Absent in 10 g
Salmonella spp.	ND in 25 g[a]	ND in 10 g	Absent in 10 g	NA	Absent in 125 g	ND in 25 g[a]	Absent in 10 g
Staphylococcus aureus	NA	ND in 10 g	NA	NA	NA	NA	NA

These values are for comparison only. Source material may include other commodity-specific or form-based limits. Consult the cited source before using any of the above limits.

NA – Not Assigned.
ND – Not Detected.

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References:

AHPA – American Herbal Products Association, Microbiology & Mycotoxins Guidance (July 2012).
a. Sample size may vary depending on the method used.

NSF/ANSI – NSF International Standard/American National Standard for Dietary Supplements 173 – 2021 (January 2021), Tables 5.1, 5.2
b. If the presence of *Escherichia coli* is confirmed, then testing shall be performed to determine whether the colonies are pathogenic enterovirulent *Escherichia coli* (EEC), not limited to 0157:H7. There is a zero tolerance for the presence of EEC.

USP – United States Pharmacopeial Convention USP 35–NF 30 (2023) Microbiological attributes of nonsterile nutritional and dietary supplements, (August 2013), Table 2.
c. This guidance includes a separate set of limits for botanicals to be treated with boiling water before use.

THIE – Tea & Herbal Infusions Europe microbiological specification for trade in herbal infusion raw materials (dry) (June 2018).
d. Separate 10^6 limits apply for molds and for yeasts. No yeasts limit is applicable for mint due to its high natural yeast load.
WHO – World Health Organization, *Quality control methods for medicinal plant materials*, (1998).

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Recommended Microbial Limits for 'Finished' Botanical Products

Organization	AHPA	EP Cat B	EP Cat C[c]	NSF/ANSI	USP	WHO	AHPA	NSF/ANSI
Product	Supplements in solid form consisting of dried, unprocessed herbs	Herbal medicinal products	Herbal medicinal products	Containing botanical ingredients, non-extract	Supplements with botanicals	Plant materials for internal use	Herbal supplements in solid form consisting of powdered or soft extracts	Containing botanical ingredients, extract
	Amounts listed in colony-forming units (cfu)/g or mL where not otherwise specified.							
Total aerobic microbial count	10^7	10^{4b}	10^{5b}	10^7	10^4	10^5	10^4	10^4
Total combined yeast & mold count	10^5	10^{2b}	10^{4b}	10^5	10^3	10^3	10^3	10^3
Enterobacteria count (bile-tolerant gram-negative bacteria)	10^4 (total coliforms)	10^2	10^4	10^4	NA	10^3	10^2 (total coliforms)	10^2
Escherichia coli	ND in 10 g[a]	Absent in 1 g	Absent in 1 g	10^{2d}	Absent in 10 g	10	ND in 10 g[a]	ND in 10 g[e]
Salmonella spp.	ND in 25 g[a]	Absent in 25 g	Absent in 25 g	ND in 10 g	Absent in 10 g	None	ND in 25 g[a]	ND in 10 g
Staphylococcus aureus	NA	NA	NA	ND in 10 g	NA	NA	NA	ND in 10 g

These values are for comparison only. Source material may include other commodity-specific or form-based limits. Consult the cited source before using any of the above limits.

NA – Not Assigned.
ND – Not Detected.

References:

AHPA – American Herbal Products Association, Microbiology & Mycotoxins Guidance (July 2012).
a. Sample size may vary depending on the method used.

EP Cat B & C – European Pharmacopoeia 10th ed. (July 2019), Chapter 5.8.1 – Categories B and C.
b. Acceptance criterion. Maximum acceptable count is five times this value.
c. Category C limits are applicable "where it can be demonstrated that the method of processing or pre-treatment would not reduce the level of organisms sufficiently to reach the criteria required under B".

NSF/ANSI – NSF International Standard/American National Standard for Dietary Supplements 173 – 2021 (January 2021), Tables 5.3, 5.4.
d. If the presence of *Escherichia coli* is confirmed, then testing shall be performed to determine whether the colonies are pathogenic enterovirulent *Escherichia coli* (EEC), not limited to 0157:H7. There is a zero tolerance for the presence of EEC.
e. Detection level for this test is specified as 10 cfu/g.

USP – United States Pharmacopeial Convention USP 35–NF 30 (2023) Microbiological attributes of nonsterile nutritional and dietary supplements (August 2013), Table 2.

WHO – World Health Organization, *Quality control methods for medicinal plant materials*, (1998).