AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Recommended Microbial Limits for Botanical Ingredients (in colony-forming units (cfu)/g)

[Current as of July 2012]

Organization	AHPA	NSF/ANSI	USP	WHO	EHIA	EP	AHPA	USP
Plant material	Dried, unprocessed herbs for use as ingredients in dietary supplements	Botanical ingredient, non-extract	Dried or powdered botanicals	Untreated crude intended for further processing	NA	NA	Powdered botanical extracts and soft extracts	Powdered botanical extracts
Total aerobic microbial count	10^7	10^7	10^5	NA or 10^5-10^7 as per specific monographs	NA	NA	10^4	10^4
Total combined yeast & mold count	10^5	10^5	10^3	10^5 (mold propagules); Occasionally 10^4 for specific monographs	NA	NA	10^3	10^3
Enterobacteria count (bile-tolerant Gram-negative bacteria)	10^4 (Total coliforms)	10^4	10^3	10^3	NA	NA	10^2 (Total coliforms)	NA
Escherichia coli	Not detected in 10 g*	10^{2}**	Absence in 10 g	10^4	NA	NA	Not detected in 10 g*	Absence in 10 g
Salmonella spp.	Not detected in 25 g*	Not detected in 10 g	Absence in 10 g	NA or absent	NA	NA	Not detected in 25 g*	Absence in 10 g
Staphylococcus aureus	NA	Not detected in 10 g	NA	NA or absent	NA	NA	NA	NA

AHPA – American Herbal Products Association, Guidance, 8630 Fenton St. #918, Silver Spring, MD 20910; 301-588-1171.
EHIA – European Herbal Infusions Association
EP – European Pharmacopoeia
NSF/ANSI – NSF International Standard/American National Standard for Dietary Supplements 173 – 2006
USP – United States Pharmacopeial Convention, USP-NF 35-30, 2012
WHO – World Health Organization, *Quality control methods for medicinal plant materials*, Geneva, 1998
NA – Not Assigned
*Sample size may vary depending on the method used.
**If the presence of *Escherichia coli* is confirmed, then testing shall be performed based on the USFDA *Bacteriological Analytical Manual* in Chapter 4A 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.

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Recommended Microbial Limits for 'Finished' Botanical Products (in colony-forming units (cfu)/g)

[Current as of July 2012]

Organization	AHPA	EP	EP	NSF/ANSI	USP	WHO	AHPA	NSF/ANSI
Product	Herbal supplements in solid form consisting of dried, unprocessed herbs	Antimicrobial pre-treatment and/or microbial reduction in production process	If pretreatment or process fail to achieve compliance	Containing botanical ingredients, non-extract	Containing botanical ingredients	Plant materials for internal use	Herbal supplements in solid form consisting of powdered extracts or soft extracts	Containing botanical extract
Total aerobic microbial count	10^7	10^4**	10^5**	10^7	10^4	10^5	10^4	10^4
Total combined yeast & mold count	10^5	10^2**	10^4**	10^5	10^3	10^3	10^3	10^3
Enterobacteria count (bile-tolerant Gram-negative bacteria)	10^4 (total coliforms)	10^2	10^3 (inc. certain others)***	10^4	NA	10^3	10^2 (coliforms)	10^2
Escherichia coli	Not detected in 10 g*	Absent in 1 g	Absent in 1 g	10^2****	Absence in 10 g	10	Not detected in 10 g*	Not detected in 10 g
Salmonella spp.	Not detected in 25 g*	Absent in 25 g	Absent in 10 g	Not detected in 10 g	absence in 10 g	none	Not detected in 25 g*	Not detected in 10 g
Staphylococcus aureus	NA	NA	NA	Not detected in 10 g	NA	NA	NA	Not detected in 10 g

AHPA – American Herbal Products Association, Guidance, 8630 Fenton St. #918, Silver Spring, MD 20910; 301-588-1171.
EHIA – European Herbal Infusions Association
EP – European Pharmacopoeia Edition 6.8, Chapter 5.8.1 – Category B and C
NSF/ANSI – NSF International Standard/American National Standard for Dietary Supplements 173 – 2006
USP – United States Pharmacopeial Convention, USP-NF 35-30, 2012
WHO – World Health Organization, *Quality control methods for medicinal plant materials*, Geneva, 1998
NA – Not Assigned
*Sample size may vary depending on the method used.
** Acceptance criterion. Maximum acceptable count is five times this value.
***Other types of organisms (*e.g. Aeromonas, Pseudomonas*) may be recovered.
****If the presence of *Escherichia coli* is confirmed, then testing shall be performed based on the USFDA *Bacteriological Analytical Manual* in Chapter 4A 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.