

**Microbial Limits for Botanical Ingredients (in colony-forming units/gram or mL (cfu/g or mL))**  
[Current as of July 2014]

REFERENCE	AHPA	NSF/ANSI	USP	WHO	AHPA	NSF/ANSI	USP
MATERIAL	DRIED UNPROCESSED HERBS FOR USE AS INGREDIENTS IN DIETARY SUPPLEMENTS	BOTANICAL INGREDIENT, NON-EXTRACT	DRIED OR POWDERED BOTANICALS	RAW HERBAL MATERIAL INTENDED FOR FURTHER PROCESSING	POWDERED BOTANICAL EXTRACTS AND SOFT EXTRACTS	BOTANICAL INGREDIENT, EXTRACT	POWDERED BOTANICAL EXTRACTS
Total aerobic microbial count	10 <sup>7</sup>	10 <sup>7</sup>	10 <sup>5</sup>	NA or 10 <sup>5</sup> per specific monograph	10 <sup>4</sup>	10 <sup>4</sup>	10 <sup>4</sup>
Total combined yeast and mold count	10 <sup>5</sup>	10 <sup>5</sup>	10 <sup>3</sup>	10 <sup>5</sup> (as mold propagules); some specific monographs: 10 <sup>3</sup> -10 <sup>4</sup>	10 <sup>3</sup>	10 <sup>3</sup>	10 <sup>3</sup>
Enterobacterial Count (Bile-tolerant Gram-negative Bacteria)	10 <sup>4</sup> (as total coliforms)	10 <sup>4</sup>	10 <sup>3</sup>	NA or 10 <sup>3</sup> per specific monograph (other than <i>E. coli</i> )	10 <sup>2</sup> (as total coliforms)	10 <sup>2</sup>	NA
<i>Escherichia coli</i>	Not detected in 10 g*	10 <sup>2</sup> **	Absence in 10 g	10 <sup>4</sup> or absent per specific monograph	Not detected in 10 g*	Not detected in 10 g	Absence in 10 g
<i>Salmonella</i> spp.	Not detected in 25 g*	Not detected in 10 g	Absence in 10 g	NA or absent per specific monograph	Not detected in 25 g*	Not detected in 10 g	Absence in 10 g
<i>Staphylococcus aureus</i>	NA	Not detected in 10 g	NA	NA	NA	Not detected in 10 g	NA
<i>Shigella</i>	NA	NA	NA	Absence in 1 g	NA	NA	NA

**AHPA** – American Herbal Products Association, Guidance on Microbiology & Mycotoxins, 2012.

**NSF/ANSI** – NSF International Standard/American National Standard for Dietary Supplements 173 – 2012.

**USP** – United States Pharmacopeial Convention, USP-NF 36-31, 2013.

**WHO** – World Health Organization, *WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues*, 2007.

**NA** – Not Assigned

\*Sample size may vary depending on the method used.

\*\*If *Escherichia coli* is present, testing shall be performed based on the US FDA *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.

**Microbial Limits for Finished Botanical Products (in colony-forming units/gram or mL (cfu/g or mL))**  
[Current as of July 2014]

REFERENCE	AHPA	EP Category B <sup>†</sup>	EP Category C <sup>†</sup>	NSF/ANSI	USP	WHO	AHPA	NSF/ANSI
PRODUCT	HERBAL SUPPLEMENTS IN SOLID FORM CONSISTING OF DRIED UNPROCESSED HERBS	PRODUCT WITH INGREDIENTS PROCESSED/PRETREATED TO LEVELS BELOW THOSE STATED HERE	PRODUCT WITH INGREDIENTS DEMONSTRATED TO FAIL Category B w/ PROCESSING/PRETREATMENT	FINISHED PRODUCT CONTAINING BOTANICAL INGREDIENT, NON-EXTRACT	CONTAINING BOTANICAL INGREDIENTS	HERBAL MATERIALS FOR INTERNAL USE	HERBAL SUPPLEMENTS IN SOLID FORM CONSISTING OF POWDERED OR SOFT EXTRACTS	FINISHED PRODUCT CONTAINING BOTANICAL EXTRACT
Total aerobic microbial count	10 <sup>7</sup>	10 <sup>4‡</sup>	10 <sup>5‡</sup>	10 <sup>7</sup>	10 <sup>4</sup>	10 <sup>5</sup>	10 <sup>4</sup>	10 <sup>4</sup>
Total combined yeast and mold count	10 <sup>5</sup>	10 <sup>2‡</sup>	10 <sup>4‡</sup>	10 <sup>5</sup>	10 <sup>3</sup>	10 <sup>3</sup>	10 <sup>3</sup>	10 <sup>3</sup>
Enterobacterial Count (Bile-tolerant Gram-negative Bacteria)	10 <sup>4</sup> (as total coliforms)	10 <sup>2</sup>	10 <sup>4</sup>	10 <sup>4</sup>	NA	10 <sup>3</sup> (other than <i>E. coli</i> )	10 <sup>2</sup> (as total coliforms)	10 <sup>2</sup>
<i>Escherichia coli</i>	Not detected in 10 g*	Absence in 1 g	Absence in 1 g	10 <sup>2**</sup>	Absence in 10 g	10 in 1 g	Not detected in 10 g*	Not detected in 10 g
<i>Salmonella</i> spp.	Not detected in 25 g*	Absence in 25 g	Absence in 25 g	Not detected in 10 g	Absence in 10 g	Absence in 1 g	Not detected in 25 g*	Not detected in 10 g
<i>Staphylococcus aureus</i>	NA	NA	NA	Not detected in 10 g	NA	NA	NA	Not detected in 10 g
<i>Clostridia</i>	NA	NA	NA	NA	NA	Absence in 1 g	NA	NA
<i>Shigella</i>	NA	NA	NA	NA	NA	Absence in 1 g	NA	NA

**AHPA** – American Herbal Products Association, Guidance on Microbiology & Mycotoxins, 2012.

**EP** – European Pharmacopoeia Ed. 8.0, 5.1.8 (Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation), 2013.

**NSF/ANSI** – NSF International Standard / American National Standard (Dietary Supplements). NSF/ANSI 173 – 2012.

**USP** – United States Pharmacopeial Convention, USP-NF 36-31, 2013.

**WHO** – World Health Organization, *WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues*, 2007

**NA** – Not Assigned

\*Sample size may vary depending on the method used.

\*\*If *Escherichia coli* is present, testing shall be performed based on the US FDA *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.

<sup>†</sup> Note in text: “Higher acceptance criteria may be applied on the basis of a risk assessment that takes account of qualitative and quantitative characterisation of the bioburden and the intended use of the medicinal product.” Same limits are applicable to products containing extracts.

<sup>‡</sup>Acceptance criterion. Maximum acceptable count is five times this value.