

INFORMATION SHEET

Heavy Metals in Herbal Drugs and Herbal Preparations

Parameter	07/2024: 20427 "Heavy metals in herbal drugs and herbal drug preparation"	07/2017: 1433 "Herbal Drugs"	07/2010: 1434 "Herbal drug preparations"	07/2023: 1435 "Herbal teas"	04/2019: 0765 "Herbal drug extracts"	07/2024: 3028 "Cannabis flower"
Matrices	<p>Herbal drugs and herbal drugs pr</p> <p>All matrices not clearly attributed to a specific monograph but classified under "herbal drugs" or "herbal drug preparations".</p>	<p>Herbal Drugs</p> <ul style="list-style-type: none"> • Whole, fragmented, cut, broken, dried or fresh plant materials. • Algae • Fungi • Lichens 	<p>Herbal Drug Preparations</p> <p>Homogeneous products obtained from herbal drugs through:</p> <ul style="list-style-type: none"> • Extraction • Distillation • Expression • Fractionation • Purification • Concentration • Fermentation <p>Exemples of resulting products:</p> <ul style="list-style-type: none"> • Extracts • Essential oils • Pressed juices • Processed exudates • Crushed or encapsulated powdered herbal drugs. 	<p>Herbal Teas</p> <p>Composed exclusively of one or more herbal drugs.</p> <p>Must comply with the requirements of Ph. Eur. monographie 07/2017: 1433 apply.</p>	<p>Extracts</p> <p>Liquid (fluid extracts), semi-solid (soft extracts, oleoresins) or solid (dry extracts) preparations derived from herbal drugs using appropriate solvents.</p> <p>Heavy metal testing must follow Ph. Eur. 07/2024: 20427.</p> <p>If no individual monograph is available, limits from 07/2017: 1433 apply.</p>	<p>Cannabis Flower (<i>Cannabis sativa</i> L.)</p> <p>Whole or fragmented, dried, fully developed female inflorescences.</p>
Lead [mg/kg]	≤5.0	≤5.0*	≤5.0*	≤5.0 / ≤0.5**
Cadmium [mg/kg]	≤1.0	≤1.0*	≤1.0*	≤1.0 / ≤0.3**
Mercury [mg/kg]	≤0.1	≤0.1	≤0.1	≤0.1 / ≤0.1**
Arsenic [mg/kg]	n/a	n/a	n/a	n/a / ≤0.2**
Quality	GMP compliant***	GMP compliant***	GMP compliant***	GMP compliant***	GMP compliant***	GMP compliant***

* For teas and extracts, the same limits apply as for herbal drugs (1433), unless otherwise specified in a specific monograph or justifiably approved.

** Limit values for medical use.

*** GMP requires an established Acceptable Validation Limit (LAV)

Date and signature

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