الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Questions and Answers on the Quality of Herbal and Health Products

Version 1.0

Date of issue	03 August 2026

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1.0	Executive Directorate of Products Evaluation	03 August 2026	Final

Table of Content:

1. INTRODUCTION

1.1. Objective

The Saudi Food and Drug Authority (SFDA) has developed this document to provide guidance to applicants on common questions regarding herbal and health products.

1.2. Scope

This guidance applies to all herbal and health products undergoing assessment and authorization procedures in the Drug Sector.

1.3. Related Guidelines

- Data Requirements for Herbal and Health Products Submission.
- Guidelines for Variation Requirements.
- Guidelines for Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products.
- Guidance for Presenting PIL and Labeling Information of Herbal and Health Products
- Top Deficiencies in Validation and Assessment Phases of Herbal and Health Products.
- ICH Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- ICH Q3C(R9) — Impurities: Guideline for Residual Solvents.
- ICH Q3D(R2) — Guideline for Elemental Impurities.

1.4. Definitions

- **Herbal product:**
  Any plant or herb manufactured in a pharmaceutical dosage form, and presented with a medical claim.

- **Health product:**
  Finished labeled product in a pharmaceutical dosage form, which are usually low-risk ingredients that are intended to restore, correct, or modify physiological functions by exerting pharmacological, immunological, or metabolic action.

- **Herbal substance:**

  Whole, fragmented, or cut plants, plant parts, algae, fungi, or lichens, in an unprocessed state, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered herbal substances. Herbal substances are precisely defined by the botanical scientific name according to the binomial system (genus, species, variety, and author).

- **Herbal preparation:**

  A preparation obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration, or fermentation. Herbal preparations include, for example, comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices, and processed exudates.

- **Mixed extract:**

  A herbal preparation produced as a unique extract by the simultaneous extraction of two or more herbal substances using the same extraction solvent.

- **In-use stability:**

  The period during which a multi-dose product, after first opening of its container closure system, can be expected to retain its quality (physical, chemical, microbiological, and other relevant attributes) within the approved specifications, under the recommended conditions of use and storage.

- **Multi-use product:**

  A pharmaceutical product packaged in a container intended for repeated administrations from the same container after first opening, in contrast to a single-dose (single-use) product.

1.5. Abbreviations

Abbreviation	Full Term
SFDA	Saudi Food and Drug Authority
USP–NF	United States Pharmacopeia–National Formulary
Ph. Eur.	European Pharmacopoeia
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
Aw	Water activity
CoA	Certificate of Analysis
BCC	*Burkholderia cepacia* complex
RH	Relative Humidity
AFB1	Aflatoxin B1
CFU	Colony Forming Units
GMP	Good Manufacturing Practice
PDE	Permitted Daily Exposure
TAMC	Total Aerobic Microbial Count
TYMC	Total Combined Yeasts and Molds Count
CEP	Certificate of Suitability to the European Pharmacopoeia
DER	Drug-Extract Ratio
EDQM	European Directorate for the Quality of Medicines and HealthCare
EMA	European Medicines Agency
FDA	Food and Drug Administration
GACP	Good Agricultural and Collection Practice
NPC	National Pharmacovigilance Centre
PA	Pyrrolizidine Alkaloid
PIL	Patient Information Leaflet
TGA	Therapeutic Goods Administration
TSE	Transmissible Spongiform Encephalopathy
TLC	Thin Layer Chromatography
HPTLC	High-Performance Thin Layer Chromatography
HPLC	High-Performance Liquid Chromatography
MAH	Marketing Authorization Holder
DCE	Dichloroethane / Dichloroethene
TCE	Trichloroethane / Trichloroethene
WHO	World Health Organization

2. QUESTIONS AND ANSWERS ON THE QUALITY OF HERBAL AND HEALTH PRODUCTS

2.1. Manufacturing

(1) Question

In the case of multi-process manufacturing, is it necessary to clarify the role and activities of each manufacturer?

Answer

Yes, it is necessary to clearly define the roles and responsibilities of each manufacturer involved in multi-stage manufacturing, whether for an Active Substance or a Finished Product.

(2) Question

Where does Good Agricultural and Collection Practice (GACP) end and Good Manufacturing Practice (GMP) begin for herbal starting materials?

Answer

GACP applies to cultivation, wild collection, harvesting, primary processing (drying, sorting, cutting), and packaging up to the point the herbal substance enters the medicinal-product supply chain; GMP applies thereafter, including extraction, comminution, distillation, pressing, fermentation, stabilization, and downstream operations. Reference: **WHO GACP (2003)**; **EMA/HMPC/246816/2005**; **SFDA's Guideline on Good Manufacturing Practice (GMP); SFDA's Guide to Good Manufacturing Practice for Natural Health Products**

2.2. Elemental Impurities

(1) Question

Is elemental impurities testing required for the active substance of herbal and health products?

Answer

Yes. Elemental impurities testing is required for the active substance in herbal and health products, where relevant. Testing should be conducted in accordance with the ICH Q3D Guideline for

Elemental Impurities. Alternatively, an appropriate recognized pharmacopeial reference (e.g., United States Pharmacopeia–National Formulary [USP–NF]), may be used, provided that the method used is suitable and scientifically justified. Permitted Daily Exposure (PDE) values for individual elements are summarized in **Annex 1**.

2.3. Residual Solvents

(1) Question

If solvents are used in the manufacturing of the active substance, is the applicant required to submit a list of all residual solvents used in the manufacturing process?

Answer

Yes. The applicant should submit a list of all solvents used in the manufacture of the active substance. Solvents shall be documented in section 3.2.S.2.2 and controlled in the specification (section 3.2.S.4.1) and batch analysis (section 3.2.S.4.4) of the active substance per ICH Q3C(R9). Solvent classifications, examples, and PDE-derived concentration limits are summarized in **Annex2**.

(2) Question

If a solvent that may lead to benzene formation (e.g., ethanol) is used in the manufacturing of an active substance and is controlled in accordance with ICH Q3C limits, is benzene testing still required?

Answer

Yes. Benzene testing is still required even if the solvent (e.g., ethanol) is controlled in accordance with ICH Q3C limits.

Benzene is classified as a Class 1 residual solvent by the ICH due to its carcinogenic properties, and its presence must be strictly controlled to ensure patient safety.

To justify the absence of routine benzene testing, the applicant must provide at least one of the following:

- Specifications and a certificate of analysis (CoA) for the solvent (e.g., ethanol), clearly listing benzene as a controlled impurity in accordance with the ICH Q3C limits; or

- Supporting batch data, including the analytical method and validation, from six consecutive pilot-scale batches or three consecutive commercial-scale batches, demonstrating that the benzene content is less than 30% of the ICH Q3C limit; or
- Inclusion of a benzene limit test in the active substance's specification and certificate of analysis.

2.4. Contaminants

(1) Question

What contaminants should be tested for in herbal substances, and which pharmacopeial references apply?

Answer

A risk-based contaminant testing program is required for each plant-derived active substance, taking into account the geographical origin, plant part, cultivation or wild-collection conditions, and known susceptibility to contamination or adulteration. The applicable contaminants, test methods, and numerical acceptance criteria are summarized in **Annex 3**.

Testing on the finished product in lieu of the active substance requires scientific justification demonstrating that contaminant levels are not concentrated or altered by the manufacturing process.

2.5. Microbiological Quality

(1) Question

What are the key considerations for microbiological testing of non-sterile aqueous oral herbal and health products?

Answer

Microbiological quality testing of non-sterile aqueous oral herbal and health products must be conducted in accordance with appropriate recognized pharmacopeial reference (e.g., USP–NF, Ph. Eur.). For non-sterile aqueous oral products, testing for *Burkholderia cepacia* complex (BCC) should also be considered, where applicable, in accordance with the relevant pharmacopoeial

reference (e.g., USP–NF).

Microbiological acceptance criteria for herbal medicinal products for oral use follow the three categories defined in **Ph. Eur. 5.1.8**; the numerical limits are summarized in **Annex 3**. For non-oral dosage forms (e.g., cutaneous, oromucosal, nasal), microbiological acceptance criteria follow **Ph. Eur. 5.1.4** according to the route of administration (or USP <61>/<62> with acceptance criteria per USP <1111>); these limits are summarized in **Annex 3**.

(2) Question

Is it acceptable to replace microbiological quality testing with water activity (Aw) testing?

Answer

No. Water activity (Aw) testing should not be used as a standalone replacement for microbiological quality testing.

Aw testing may be used as a supportive tool to assess the potential for microbial growth and to justify, where appropriate, a reduced frequency of microbiological testing. However, this should be supported by an appropriate risk assessment and sufficient product-specific data.

Microbiological quality testing remains necessary for products with high water activity or products that are susceptible to microbial contamination. Therefore, Aw testing should be considered as part of an overall microbial control strategy, rather than an alternative to microbiological quality testing.

2.6. Testing

(1) Question

If a mixed extract is produced by simultaneous extraction of several herbal substances using the same solvent, is it acceptable to perform testing using only one representative analytical marker?

Answer

No. Testing using only one representative analytical marker is generally not acceptable for mixed extracts produced by the simultaneous extraction of several herbal substances.

A mixed extract should be adequately characterized and controlled with respect to the relevant constituents of each herbal substance included in the preparation. Although the extraction is performed using the same solvent, the resulting extract contains components derived from different herbal substances. Therefore, appropriate analytical methods should be applied to identify and, where applicable, quantify relevant analytical markers or constituents from each herbal substance.

Where quantitative testing for each component is not feasible, the applicant should provide an appropriate scientific justification, supported by relevant analytical data.

(2) Question

How should a herbal preparation or extract used as the active substance be characterized in the dossier?

Answer

The herbal preparation shall be declared in Module 3.2.S with: Latin botanical name (genus, species, variety, author); plant part; type of preparation; native drug-extract ratio (**DER**), expressed as a range and referenced to the genuine herbal preparation (i.e., the extract prior to any subsequent excipient addition or marker-content standardization); extraction solvent(s) and concentration; and quantitative content of active markers, where applicable. Extracts shall be classified per Ph. Eur. 0765 as **standardized**, **quantified**, or **other**, consistent with Ph. Eur. 1433/1434. Reference: SFDA Data Requirements for Herbal and Health Products Submission, Module 3.

(3) Question

What identification and authentication testing is required for the herbal substance used as the active substance?

Answer

The herbal substance shall be authenticated by: (i) macroscopic and microscopic examination per the relevant Ph. Eur. or USP monograph; (ii) appropriate identification tests (TLC, HPTLC, or HPLC fingerprinting) per the monograph or a validated alternative; and (iii) DNA barcoding where validated species-discrimination protocols are available, particularly for morphologically similar

or commonly adulterated taxa. References: Ph. Eur. 2.8.20 (Herbal drugs: sampling and sample preparation), WHO Guidelines on Good Herbal Processing Practices, and SFDA Data Requirements for Herbal and Health Products Submission, Module 3.

(4) Question

What reference standards are required for analytical testing of herbal substances and preparations?

Answer

Reference standards shall be obtained from a recognized pharmacopeial source (Ph. Eur., USP–NF) where available. Where no pharmacopeial standard exists, a characterized in-house secondary standard may be used, qualified against a primary standard or by orthogonal analytical methods, with full qualification documentation provided in the dossier. Reference: **Ph. Eur. 5.12 (Reference Standards)**; SFDA Data Requirements for Herbal and Health Products Submission, Module 3.

2.7. Excipients

(1) Question

If gelatin or other animal-derived materials such as lactose or magnesium stearate are used, is the applicant required to provide information on their origin?

Answer

Yes. The applicant should provide information on the origin of any animal-derived materials used in the product, including gelatin, lactose, magnesium stearate, or any other relevant excipient of animal origin.

Where applicable, the information should include the animal species, country of origin, source material, supplier details, and relevant declarations or certificates confirming compliance with applicable requirements.

(2) Question

For products containing materials of ruminant origin, what evidence of TSE risk minimization is required?

Answer

Materials of ruminant origin shall be supported by a current **EDQM Certificate of Suitability for TSE compliance (CEP)**, or equivalent documentation per EMA/410/01 Rev. 3 and Ph. Eur. 5.2.8. Equivalent documentation from a stringent regulatory authority (e.g., US FDA, TGA) may be accepted, subject to SFDA review.

2.8. Stability

(1) Question

Is the applicant required to provide an official letter indicating the expected production size range and confirming that it will not be changed before obtaining SFDA approval?

Answer

Yes. The applicant is required to provide an official letter indicating the expected production batch size range and confirming that it will not be changed without prior SFDA approval.
This information should be included in the Batch Formula part of the finished product (section 3.2.P.3.2) and should be consistent with the proposed manufacturing process and submitted stability data.

(2) Question

If a long-term stability study for a herbal or health product is conducted under storage conditions of 25 °C ± 2 °C / 60% RH ± 5% RH, is it acceptable for regulatory submission?

Answer

Yes, a long-term stability study conducted at 25 °C ± 2 °C / 60% RH ± 5% RH is generally acceptable for regulatory submission. However, for products containing chemically synthesized material(s) (e.g., antiseptics or anti-lice agents), the long-term stability study should be conducted at 30 °C ± 2 °C / 65% RH ± 5% RH to ensure appropriate evaluation under conditions relevant to

the product's composition.

(3) Question

For multi-use herbal and health products, is it required to conduct an in-use stability study?

Answer

Yes. An in-use stability study is required for multi-use herbal and health products, where applicable.

The study should demonstrate the period during which the product remains within the approved specifications after first opening, under the recommended conditions of use and storage. The proposed in-use period should be justified based on the product formulation, container closure system, dosage form, route of administration, and potential risk of physical, chemical, or microbiological changes after opening.

(4) Question

Is a stability study for the active substance of herbal and health products required?

Answer

A stability study for the active substance of herbal and health products is generally optional according to the Data Requirements for Herbal and Health Products Submission guideline.

However, the SFDA may request stability data for the active substance during the evaluation process, where considered necessary based on the nature of the active substance, manufacturing process, or potential impact on the quality of the finished product.

(5) Question

Are reduced-design stability protocols (bracketing and matrixing) acceptable for stability studies of herbal and health products?

Answer

Yes. Reduced-design stability protocols (bracketing and matrixing) in accordance with **ICH Q1D** may be used for herbal and health products marketed in multiple strengths, container sizes, or fill

volumes, provided the design is scientifically justified and the assumptions underlying the reduced design (e.g., comparability of degradation profiles across the bracketed strengths or container sizes) are demonstrated.

2.9. Labelling and Patient Information Leaflet

(1) Question

What labelling and PIL requirements apply to herbal and health products registered with the SFDA?

Answer

Labelling and the Patient Information Leaflet shall be provided in both **Arabic and English** per the **SFDA Guidance for Presenting PIL and Labeling Information of Herbal and Health Products**.

3. References

1. Saudi Food and Drug Authority. Data Requirements for Herbal & Health Products Submission.
2. Saudi Food and Drug Authority. Guidelines for Variation Requirements.
3. Saudi Food and Drug Authority. Guidelines for Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products
4. Saudi Food and Drug Authority. Top Deficiencies in Validation and Assessment Phases of Herbal and Health Products.
5. Saudi Food and Drug Authority. Saudi FDA products classification guidance.
6. International Council for Harmonisation. ICH Q3C(R9): Impurities: Guideline for Residual Solvents.
7. International Council for Harmonisation. ICH Q3D(R2): Guideline for Elemental Impurities.
8. United States Pharmacopeia–National Formulary. General Chapters and Relevant Monographs.
9. Saudi Food and Drug Authority. Guidance for Presenting PIL and Labeling Information of Herbal and Health Products, current version.
10. European Pharmacopoeia. General Chapters and Relevant Monographs.
11. European Medicines Agency, CPMP. Note For Guidance on In-Use Stability Testing Of Human Medicinal Products, CPMP/QWP/2934/99. 1 march 2001.
12. European Medicines Agency, HMPC. Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products, EMA/HMPC/CHMP/CVMP/201116/2005 Rev. 3.
13. European Medicines Agency, HMPC. Guideline on Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products, EMA/HMPC/CHMP/CVMP/162241/2005 Rev. 3.
14. European Medicines Agency, HMPC. Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products, EMA/HMPC/CHMP/CVMP/287539/2005 Rev. 1.
15. European Medicines Agency, HMPC. Questions & Answers on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products, EMA/HMPC/41500/2010 Rev. 7, 22 November 2023.

16. European Medicines Agency, HMPC. Guideline on Good Agricultural and Collection Practice (GACP) for Starting Materials of Herbal Origin, EMA/HMPC/246816/2005.
17. European Medicines Agency, HMPC. Public Statement on Contamination of Herbal Medicinal Products/Traditional Herbal Medicinal Products with Pyrrolizidine Alkaloids, EMA/HMPC/893108/2011 Rev. 1.
18. European Medicines Agency. Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products, EMA/410/01 Rev. 3.
19. World Health Organization. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, Geneva, 2003.
20. International Council for Harmonisation. ICH Q1A(R2): Stability Testing of New Drug Substances and Products.
21. International Council for Harmonisation. ICH Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products.
22. European Pharmacopoeia, general chapter 5.12: Reference Standards.
23. European Pharmacopoeia, general chapter 5.1.8: Microbiological Quality of Herbal Medicinal Products for Oral Use and Extracts Used in their Preparation.
24. European Pharmacopoeia, general chapter 5.2.8: Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.
25. GSO 2055 series (Halal Products).
26. European Commission. EU GMP Guide, Annex 7 — Manufacture of Herbal Medicinal Products.

4. Annexes

Annex 1: ICH Q3D(R2) Permitted Daily Exposure (PDE) for Elemental Impurities, Oral Route

Class	Element	Symbol	Oral PDE (µg/day)
Class 1 (human toxicants)	Cadmium	Cd	5
	Lead	Pb	5
	Arsenic	As	15
	Mercury	Hg	30
Class 2A (route-dependent)	Cobalt	Co	50
	Nickel	Ni	220
	Vanadium	V	120
Class 2B (lower abundance)	Silver	Ag	167
	Gold	Au	322
	Iridium	Ir	100
	Osmium	Os	100
	Palladium	Pd	100
	Platinum	Pt	108
	Rhodium	Rh	100
	Ruthenium	Ru	100
	Selenium	Se	170
	Thallium	Tl	8
Class 3 (low toxicity; PDE > 500)	Antimony	Sb	1200
	Barium	Ba	1460
	Chromium	Cr	10700
	Copper	Cu	3400
	Lithium	Li	560
	Molybdenum	Mo	3400
	Tin	Sn	6400

Source: ICH Q3D(R2) Guideline for Elemental Impurities. Parenteral and inhalation PDE values differ; consult ICH Q3D(R2) for non-oral routes. Concentration limit (µg/g) for an element = PDE / Maximum Daily Dose (g/day).

Annex 2: ICH Q3C(R9) Residual Solvents Classification

Class	Description	Examples	Limit
Class 1	Solvents to be avoided (carcinogens / environmental hazards)	Benzene; carbon tetrachloride; 1,2-dichloroethane; 1,1-dichloroethene; 1,1,1-trichloroethane	Benzene: 2 ppm; CCl_4: 4 ppm; 1,2-DCE: 5 ppm; 1,1-DCE: 8 ppm; 1,1,1-TCE: 1500 ppm
Class 2	Solvents to be limited (inherent toxicity)	Methanol; acetonitrile; methylene chloride; hexane; 1,4-dioxane; toluene	Methanol: 3000 ppm; acetonitrile: 410 ppm; DCM: 600 ppm; hexane: 290 ppm; 1,4-dioxane: 380 ppm; toluene: 890 ppm
Class 3	Low toxic potential (no health hazard at typical levels)	Ethanol; acetone; ethyl acetate; isopropanol; butanol; heptane	≤ 5000 ppm (0.5%) or 50 mg/day; otherwise per ICH Q3A/Q3B

Source: ICH Q3C(R9) Impurities: Guideline for Residual Solvents. PDE = Permitted Daily Exposure. Concentration limits (ppm, w/w) are calculated assuming a maximum daily dose of 10 g; for higher daily doses, refer to the PDE-based calculation in ICH Q3C(R9).

Annex 3: Contaminant Specifications for Herbal Substances and Preparations

Contaminant	Test Method	Limit / Acceptance Criteria	Reference
Heavy metals (Cd, Pb, Hg)	Ph. Eur. 2.4.27	Cd: ≤ 1.0 ppm; Pb: ≤ 5.0 ppm; Hg: ≤ 0.1 ppm	Ph. Eur. 2.4.27; Ph. Eur. 1433
Pesticide residues	Ph. Eur. 2.8.13 / USP <561>	Specific limits per Ph. Eur. Table 2.8.13.-1 (69 substances; e.g., aldrin + dieldrin ≤ 0.05; chlordane (sum) ≤ 0.05; DDT (sum) ≤ 1.0; endrin ≤ 0.05; HCH isomers (sum) ≤ 0.3; lindane ≤ 0.6; malathion ≤ 1.0; sum endosulfans ≤ 3.0 mg/kg). Unlisted pesticides: per Regulation (EC) No 396/2005	Ph. Eur. 2.8.13; USP <561>; EC 396/2005
Aflatoxin B1	Ph. Eur. 2.8.18	AFB_1: ≤ 2 µg/kg; Sum (B_1+B_2+G_1+G_2): ≤ 4 µg/kg (where required)	Ph. Eur. 2.8.18; EC 1881/2006
Ochratoxin A (OTA)	Ph. Eur. 2.8.22	≤ 20 µg/kg (Ph. Eur. Liquorice root monograph value, used as default reference for other herbal substances per EMA HMPC)	Ph. Eur. 2.8.22; EMA/HMPC/CHMP/CVMP/162241/2005 Rev. 3
Microbial contamination	Ph. Eur. 5.1.8; methods 2.6.12 / USP <61>, 2.6.13 / USP <62>, and 2.6.31	**Category A** (herbal teas / preparations to which boiling water is added before use): TAMC ≤ 10^7 CFU/g; TYMC ≤ 10^5 CFU/g; *E. coli* ≤ 10^3 CFU/g; absence of *Salmonella* (25 g). **Category B** (extracts and/or herbal drugs where processing or pre-treatment reduces organisms below these levels): TAMC ≤ 10^4 CFU/g; TYMC ≤ 10^2 CFU/g; bile-tolerant Gram-negative bacteria ≤ 10^2 CFU/g; absence of *E. coli* (1 g) and *Salmonella* (25 g). **Category C** (extracts and/or herbal drugs where processing or pre-treatment does not reduce organisms sufficiently to meet Category B): TAMC ≤ 10^5 CFU/g; TYMC ≤ 10^4 CFU/g; bile-tolerant Gram-negative bacteria ≤ 10^4 CFU/g; absence of *E. coli* (1 g) and *Salmonella* (25 g).	Ph. Eur. 5.1.8; Ph. Eur. 2.6.12 / USP <61>; Ph. Eur. 2.6.13 / USP <62>; Ph. Eur. 2.6.31
Microbial contamination (non-oral forms)	Ph. Eur. 5.1.4; methods 2.6.12 / USP <61>, 2.6.13 / USP <62>	Cutaneous, oromucosal, and nasal use: TAMC ≤ 10^2 CFU/g; TYMC ≤ 10^1 CFU/g; absence of *S. aureus* and *P. aeruginosa* (1 g). See Ph. Eur. 5.1.4, Table 5.1.4.-1 for other routes (e.g., transdermal, vaginal).	Ph. Eur. 5.1.4; USP <1111>
Pyrrolizidine alkaloids (PAs)	Ph. Eur. 2.8.26	≤ 1.0 µg PA/day for adults (permanent limit, sum of identified PAs)	Ph. Eur. 2.8.26; EMA/HMPC/893108/2011 Rev. 1
Aristolochic acids (AAs)	Ph. Eur. 2.8.21	Zero tolerance; species of the genus *Aristolochia* and known confusable taxa shall not be used.	Ph. Eur. 2.8.21

Notes: For finished products, ICH Q3D(R2) Permitted Daily Exposure (PDE) values apply additionally to heavy metals, including arsenic (As, Class 1; see Annex 3). For ochratoxin A, the analytical method (Ph. Eur. 2.8.22) applies generally; the 20 µg/kg figure derives from the Ph. Eur. Liquorice root monograph and is endorsed by EMA HMPC as a reference value for other susceptible herbal substances