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Botswana Medicines Regulatory Authority



Approved By: Mr. Bathusi Kgosietsile
– Director Product Evaluation and Registration

Date of Approval
(DD/MM/YY)




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Revision status sheet

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5	4.1 the background has been updated.	2	Manager CMC	Kesolofetse Keakile		30/01/2020
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14-20	Addition of annex 1 and 2	2	Manager CMC	Kesolofetse Keakile		30/01/2020
1-45	Revised title to Guideline on Application for Registration of Complementary Medicines removing Guidelines and in Botswana	5	Manager CMC	Theo Mosala		06/08/2025
6-7	Added definitions for cosmetic, stem cells and essential oils	3	Manager CMC	Theo Mosala		06/08/2025
8	Added abbreviation for BRIMS	3	Manager CMC	Theo Mosala		06/08/2025
9	Replaced outlining registrability process with reference to the registrability guideline	3	Manager CMC	Theo Mosala		06/08/2025
9-10	Replaced outlining of registration process with reference to Guideline on submission of applications	3	Manager CMC	Theo Mosala		06/08/2025

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22-24	Introduced risk-based registration pathways	3	Manager CMC	Theo Mosala		06/08/2025
25-46	Added a section on technical guidance for various section of the dossier	3	Manager CMC	Theo Mosala		06/08/2025

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1. Purpose

Provide guidance to applicants for applications for registration of complementary medicines.

2. Scope

Applicable to all complementary medicines applications to be assessed in Botswana by BoMRA

3. Definitions and Abbreviations

3.1. Definitions

3.1.1. Act – The Medicines and Related Substances Act, 2013 and as subsequently amended

3.1.2. Complementary Medicine


Means a labelled substance or mixture of substances manufactured, sold or represented for use as adjuvants to conventional therapy in:

- i. the mitigation or prevention of or abnormal physical states;
- ii. restoring, correcting or modifying physical, mental or organic functions in human and animals as determined by the Authority; and originate from plant, mineral, animal (including microorganisms), homeopathic preparations, nutritional substances in accepted pharmaceutical dosage forms, a combination of the above or any other such preparations as may be approved by the Authority.

3.1.3. Cosmetic - Means (a) any substance or mixture of substances, manufactured, sold or represented for use by rubbing, pouring, spraying, or applying by any other means to the human body, for the purpose of cleansing, beautifying or altering the appearance; or (b) any article intended for use as a component of a cosmetic;

3.1.4. Essential oils – Oils extracted from different parts of a single plant source and contribute to its flavour or fragrance.

3.1.5. Product – A complementary medicine

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3.1.6. Shelf-Life – The period that a product is expected to remain safe, efficacious and of good quality.

3.1.7. Stability – The capacity of an active ingredient or product or dosage form to remain safe, and of good quality and maintain its identity, purity and strength.

3.1.8. Stem cell products -

3.1.9. Storage Condition – Storage conditions that shall guarantee the maintenance of the quality of the product in relation to its safety, efficacy and quality throughout its shelf life.

3.2. Abbreviations

3.2.1. BoMRA – Botswana Medicines Regulatory Authority

3.2.2. BRIMS – BoMRA Regulatory Information Management System

3.2.3. BSE – Bovine Spongiform Encephalopathy

3.2.4. CoA – Certificate of Analyses

3.2.5. GMP – Good Manufacturing Practice

3.2.6. ISO – International Organization for Standardization

3.2.7. TSE – Transmissible Spongiform Encephalopathy


4. Background

BoMRA is mandated to ensure that all medicines manufactured, imported, or exported, distributed or sold in Botswana are of acceptable quality, safety and efficacy. Therefore all medicines require authorization from the Authority before being availed in the Botswana market.

4.1. Exclusions

4.1.1. Cosmetic products

4.1.2. Fortified foods such as meal replacements

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4.1.3. Any person who compounds, dispenses, or administers a complementary medicine to their patient in the practice of their profession at their premises

4.1.4. Claims

Complementary medicines may not directly address the following diseases. They may however help with symptomatic relief for symptoms associated with the diseases provided there are no drug-drug interactions and contraindications that are applicable.

- HIV
- Cancer
- Diabetes
- TB
- Malaria
- Hypertension
- Any other life-threatening conditions.

4.1.5. Dosage forms


Sterile products

Injectable and sterile products.

4.2. Determination of classification/registrability of a product

Where applicants are unsure whether a product falls within the definition of a complementary medicines in terms of the Act, there exists a process for determination of registrability as outlined in the Guideline on submission of documentation for Registrability/classification of a product **BOMRA/ER/CM/P06/G01** and Guideline for Food-Medicine borderline products **BOMRA/ER/CM/P06/G02**.

4.3. Registration Process

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All applications for screening, registration, variations, retentions and renewal shall be lodged via BRIMS.

The submission process and timelines are provided for in the Guideline on Submission of Applications and BOMRA timelines **BOMRA/ER/MD/P04/G01**.

5. Dossier Requirements

5.1. Administrative Information

5.1.1. Filled Application Form

Requires general information about the applicant, product, and the manufacturer. The applicant may or may not be the product manufacturer.

5.1.1.1. Applicant Details


- Name
- Postal Address
- Physical Address
- Contacts

5.1.1.2. Manufacturer Details

- Name
- Physical address of the manufacturing site(s)
- Valid GMP certificate details
- Valid manufacturing license details

5.1.1.3. Product Details

- Proprietary name of product
- INN or common names of ingredients
- Strength of each active ingredient
- Dosage form
- Pack sizes
- Presentation
- Sources of ingredients

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- Uses of the final product
- Countries where product is marketed (Product must be marketed in the country of origin)

5.1.2. Declaration by the Applicant

Signed, dated and notarized.

5.1.3. Declaration by the Manufacturer

Signed, dated and notarized for each finished product manufacturer.

5.2. Composition

The composition of the product should be summarized in the form of a table.

The table should contain at the least the columns shown in the table below.


Table 1: Sample composition table

Generic name of ingredient	Quantity per dosage unit, mass or volume	Purpose of inclusion	Uses of the ingredient
Copper (II) Hydroxide monohydrate 1.27 mg of Copper	2 mg	Active	Helps to produce and repair connective tissue
<i>Boswellia serrata</i> (Indian frankincense)	200 mg	Active	Helps to relieve joint pain and swelling associated with osteoarthritis of the knee
Vitamin C (Ascorbic acid)	500 mg	Active	Helps to maintain/support immune function
Microcrystalline cellulose	100 mg	Inactive	Bulking agent

Capsules, solvents, dyes should be included as well

Additional information requires and other considerations

- Generic name for organisms should include the Genus, species, and subspecies if applicable. Additionally for probiotics the strain should be indicated.


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- If another name is used in the specifications and/or CoA for an ingredient that name should be included in parenthesis alongside the generic name.
- For vitamins the source of the vitamin should be stated in parenthesis e.g. Vitamin C (Ascorbic acid) in this case ascorbic acid is the source.
- Active ingredients support the final indication of the product. Their specific uses should be stated in the composition table.
- The purpose of inclusion and use must be aligned, i.e., that is an inactive ingredient cannot have a therapeutic use in the final product.
- Where there are overages, they must be declared and relevant information for each ingredient with an overage.
- Ingredients uses in manufacturing but are not expected to be in the final product must be declared in the composition table.
- The quality standard may be omitted in the composition table if they are declared in the specifications of all the ingredients in the formulation.

5.3. Safety of Active Ingredients

5.3.1. Botanical Identification

- 5.3.1.1. The Latin (genus species and authority) of the plant species and family e.g. *Tribulus terrestris* and Zygophyllaceae must be provided and used across the dossier, in the composition table, specifications, manufacturing information, stability data, application form and wherever possible.
- 5.3.1.2. Published safety and toxicological information. In the absence of such information, evidence of long-term use should be provided.

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5.3.2. Nutraceutical Products (Vitamins and Mineral Products)

Maximum amounts of the vitamins and mineral should be in line with the daily maximum recommended levels in tables 6 - 8. Where the amounts exceed the recommendation, evidence of safety should be provided for each target age group. This is subject to MRSR and therefore products above these limits will be regarded as allopathic medicines.

5.4. Quality Assurance of Active Ingredients

Refer to tables in section 5 for further information.


5.4.1. Plant Based Products

- 5.4.1.1. Definition (i.e., Latin name of the plant including Genus, species, varieties family)
- 5.4.1.2. Synonyms (i.e., legitimate Latin binomial synonyms for the plant)
- 5.4.1.3. Part of the plant used and condition of the plant material used
- 5.4.1.4. General qualitative and quantitative tests of the plant materials such as chemical, biological or physical assays
- 5.4.1.5. Purity tests

5.4.2. For Nutraceuticals

- 5.4.2.1. Definition (form of vitamin e.g. Retinol, salt)
- 5.4.2.2. Synonyms
- 5.4.2.3. Structure
- 5.4.2.4. General properties
- 5.4.2.5. Assay
- 5.4.2.6. Specific tests including but not limited solubility, acid value, absorbance ratio, impurities
- 5.4.2.7. Microbiological tests

5.5. Specifications of Excipients

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5.5.1. Specifications for excipients from the FPP manufacturer should be provided, including those that may not be added to every batch, those that do not appear in the final FPP and any others used in the manufacturing process.

5.5.2. The claimed standard must be provided in the specifications, including tests and limits. The standard may be from an officially recognized compendial standard or in-house standard.

5.5.3. For excipient obtained from sources that are at risk of transmitting BSE/TSE agents (e.g. of ruminant origin), a letter of attestation with supporting documentation should be provided confirming that the material is not from a BSE/TSE affected country/area.

5.5.4. Other considerations should be made in line with section 5.

5.6. Manufacturing


The name, physical address, telephone number, fax number, and e-mail address of the site of manufacture shall be provided. Where different activities of manufacture/ contract manufacturers of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated as shown in the table below.

Table 2: Sample table for manufacturing details in case of multiple sites

Name of manufacturer	Full physical address of the manufacturing site	Activity of the site

5.6.1. Licensing

A valid GMP certificate from the competent authority in the country of manufacture for each manufacturing site.

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A valid manufacturing license from the competent authority in the country of manufacture for each manufacturing site.

5.6.2. Narrative and Flowchart

5.6.2.1. A flow diagram should be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted should be identified.

5.6.2.2. A narrative description of the manufacturing process, including packaging that presents the sequence of steps undertaken and the scale of production should also be provided. Novel processes or technologies and packaging operations that directly affect product quality should be described with a greater level of detail. Equipment should, at least, be identified by type (e.g. tumble blender, in-line homogeniser) and working capacity, where relevant.

5.6.3. In-process Controls

In-process controls should be shown in the flow-chart and further information should be provided along with the narrative. IPCs should test for critical parameters that affect the quality of the product. The frequency of testing, number of dosage units used for testing should be product.

5.7. Specifications of finished product

The minimum range of specifications for the finished product should be as given in the recognized pharmacopoeias.


5.7.1. Microbiological contamination and tests for other toxins

5.7.2. Uniformity of weight (e.g., tablets, single-dose powders, suppositories, herbal tea in sachets, capsules etc

5.7.3. Disintegration time (tablets, capsules, suppositories and pills)

5.7.4. Hardness and friability (e.g., uncoated tablets

5.7.5. Viscosity (for internal and external fluids)

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5.7.6. Consistency (semisolid preparations)

5.7.7. Dissolution (tablets or capsules)

5.7.8. Physical appearance such as colour, odour, form, shape, size, texture

5.7.9. Loss on drying or water content

5.7.10. Identity tests, qualitative determination of relevant substances of the plants (e.g. fingerprint chromatograms)

5.7.11. Quantification of relevant active ingredients if they are identified and the adequate analytical methods are available

5.7.12. Limit tests for residual solvents

5.7.13. Performance tests e.g. disintegration and dissolution, weight.

5.7.14. Assay

All actives in the FPP. In the case of herbal ingredients specific bioactive components must be assayed for each ingredient.

A certificate of analysis that confirms the signed, dated and version controlled specifications should be provided.

FPP specifications should be aligned with provisions in section 5.

5.8. Stability studies and expected shelf life


5.8.1. Accelerated and long-term testing

Stability data must demonstrate stability of the medicinal product throughout its intended shelf life under the climatic conditions for Climatic Zones III & IV

Table 3: Stability data requirements

	Storage Temperature (°C)	Relative Humidity (%)	Minimum time period (months)
Accelerated	40 ± 2	75 ± 5	6
Long-term	30 ± 2	65 ± 5 OR 35 ± 5	12

5.8.2. Shelf-Life

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To establish the shelf-life, data should be provided on not less than one batch of at least commercial scale and a second batch which may be smaller of each proposed strength of the FPP. These batches should be manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch.

5.8.3. Stability Data

Data for each testing interval should be provided. The testing intervals shall be at 0, 3, 6, 12, 18, 24, 36 months and every 12 months thereafter.

The information on the stability studies should include details such as;


- Storage conditions
- Strength
- Batch number, including the API batch number(s) and manufacturer(s)
- Batch size
- Container closure system including orientation (e.g., erect, inverted, on-side) where applicable

The stability testing programme should be summarised and the results of stability testing should be reported in the dossier and summarised using the table below.

Table 4: Sample on how to summarize stability data

Storage conditions (°C, % RH)	Strength and batch number	Batch size	Container closure system	Completed intervals

The actual results measured should be provided, **not** an interpretation of the results. Therefore complies or similar wording should be not be used. The discussion of results should focus on observations noted for the

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various tests, rather than reporting comments such as “all tests meet specifications”. This should include ranges of analytical results and any trends that were observed. For quantitative tests (e.g. individual and total degradation product tests and assay tests), it should be ensured that actual numerical results are provided rather than vague statements such as “within limits” or “conforms”. Dissolution results should be expressed at minimum as both the average and range of individual results.

Applicants should consult ICH’s Q1E guideline for details on the evaluation and extrapolation of results from stability data (e.g. if significant change was not observed within 6 months at accelerated condition and the data show little or no variability, the proposed shelf-life could be up to two times the period covered by the long-term data, but should not exceed the long-term data by 12 months).

5.9. Container Closure System

5.9.1. Primary

Describe the materials of the immediate container in contact with the product. E.g., amber glass bottle, polypropylene tube.

5.9.2. Secondary


Describe the materials not in contact with the finished product e.g., stopper, secondary container box.

5.10. Package Insert and Labelling


All information should be in English or have an English translation.

5.10.1. Package Insert

- I. The name and address of the manufacturer
- II. Quantity and strength of the active ingredients
- III. The house-mark, if any, of the principal or manufacturer of the medicine

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- IV. The strength of the medicine where applicable
- V. The requirements for the method storage or other necessary precautions for the preservation of the medicine
- VI. the dosage of the medicine and the directions for use;
- VII. the description of the pharmacological action of the medicine
- VIII. indications of the medicine
- IX. contra – indications of the medicine
- X. warnings relating to the use of the medicine and such warning shall be printed in a colour as approved by the Authority
- XI. the side-effects and special precautions of the medicine
- XII. known symptoms of over dosage and particulars of its treatment
- XIII. the identification of the medicine
- XIV. the form in which the medicine is presented, whether tablet, capsule, liquid, etc., and the colour thereof
- XV. the date of publication of the package insert
- XVI. Any necessary warning concerning the administration or use of the medicine by children, old people, pregnant women or patients suffering from certain diseases, or the use of the medicine in conjunction with the consumption of alcohol or any particular food or any other medicine
- XVII. a summary of relevant information concerning the purpose and the beneficial, detrimental, injurious or other effects of the medicine, and the possible dangers that may arise from the prolonged use of the medicine
- XVIII. relevant information, including particulars in regard to a specific medicine as an antidote (if known), concerning the treatment of a patient in cases where an overdose of the medicine has been administered or where a patient reacts adversely to the medicine

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XIX. Any other particulars or warning notices as may be directed by the Authority.

5.10.2. Label

- I. Name of the Product
- II. Package size
- III. Quantity of the active ingredient per dosage unit
- IV. Batch number
- V. Expiry date
- VI. Storage conditions
- VII. Warnings and precautions;
- VIII. Directions for use
- IX. Manufacturer's name and address
- X. Any other particulars or warning notices as may be directed by the Authority.

5.11. Evidence of Claim

Provide proof of claim supported by:

5.11.1. Clinical Data


Clinical data (i.e. including medical indications which are well-established in some countries and which have been validated by clinical trials, the results of which are recorded in the scientific literature)

5.11.2. Non-Clinical Data

5.11.2.1. Monographs

For uses described in pharmacopoeias and other well-recognized documents (i.e. medicinal uses that have been well-established in many countries and are included in official pharmacopoeias or official government monographs.

5.11.2.2. Scientific Articles

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For uses described in traditional medicine (i.e. indications described in non-official pharmacopoeias and other forms of literature or purely traditional uses).

5.12. Post Marketing Surveillance Plan

5.12.1. Post-Marketing surveillance (PMS)

Ensures the continued safety, quality, and efficacy of complementary medicines once they are available on the market. Applicants and market authorization holders (MAHs) must establish and maintain a PMS plan proportionate to the product's risk profile.

5.12.2. Objectives of PMS

- 5.12.2.1. Detect, assess, and prevent adverse events or product-related risks.
- 5.12.2.2. Monitor product quality in the market (e.g., substandard, falsified, or adulterated products).
- 5.12.2.3. Ensure continued compliance with labeling, advertising, and regulatory requirements.
- 5.12.2.4. Strengthen public confidence in complementary medicines.

5.12.3. Key Components


5.12.3.1. a) Adverse Event Reporting System

- 5.12.3.1.1. MAHs must establish mechanisms for collecting, recording, and reporting suspected adverse reactions.
- 5.12.3.1.2. A standardized form and reporting channel should be used.

5.12.3.2. b) Periodic Safety Update Reports (PSURs)

- 5.12.3.2.1. MAHs should submit periodic safety summaries
- 5.12.3.2.2. Reports should include cumulative safety data, emerging risks, and benefit–risk assessment.

5.12.3.3. c) Quality Surveillance

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5.12.3.3.1.1. Routine market sampling and laboratory testing of complementary medicines to detect adulteration, contamination, or substandard batches.

5.12.3.4. **d) Risk-Based Inspections**

5.12.3.4.1. The Authority may conduct post-marketing inspections at manufacturing sites, distribution channels, and retail outlets.

5.12.3.5. **e) Signal Detection and Risk Management**

5.12.3.5.1. Data from national and international sources must be reviewed for safety signals.

5.12.3.5.2. Where risks are identified, MAHs must implement corrective actions (label updates, recalls, or withdrawal).

5.12.4. Corrective Actions

5.12.4.1. Depending on the risk level, actions may include label revisions, additional warnings, batch recall, product suspension, or deregistration.

5.12.5. Communication

5.12.5.1. Timely and transparent communication of safety information to stakeholders and the public.

5.12.5.2. Use of safety alerts, press releases, or updated guidelines when significant risks are identified.


6. Registration Pathways for Complementary Medicines

There are three (3) registration pathways that are possible for complementary medicines. These shall be risk-based and are outlined below.

6.1. Listed

Products with low risk indications and ingredients are identified at screening, further classified at evaluation and finalized at peer review.

6.2. Listed Assessed

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Products with low-level to intermediate indications are assessed for minimal requirements such as efficacy proof, confirmation of composition, cGMP etc.

6.3. Full assessment


Products undergo full assessment before they are availed to the market.

7. Determination of Risk Class


The risk shall be determined on a per product basis using indications, target groups, dosage form, and ingredients. Ingredients are further considered under three categories, the ingredient itself, the number of active ingredients in the FPP and the strength of each of the ingredients.

Table 5: Factors used in the determination of Risk Class

Category	Low-Risk	Medium-Risk	High-Risk
Timeline	60 days	120 days	8 months/12months
Fees	Per BoMRA schedule of fees		
Target Groups			<ul style="list-style-type: none"> Persons aged 6 years and younger Pregnant and breastfeeding women
Dosage Forms	Herbal teas, topical creams, simple tablets, lozenges, aromatherapy	Well controlled DEG/EG containing formulations like solutions and syrups	<ul style="list-style-type: none"> All dosage forms
Number of ingredients	Single ingredient herbal formulation from table	Less than 7 well established herbal ingredients with monographs	<ul style="list-style-type: none"> 4 or more less established ingredients 7 or more herbal ingredients in exclusive herbal formulation (well established ingredients)

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			<ul style="list-style-type: none"> • 21 or more ingredients in multivitamin/mineral formulation • 10 or more ingredients in other products
Ingredients and their strengths	Tables 2, 3, 4		
Indications	Tables 5 & 6 for specified ingredients	Modified but still fits a profile of lower risk compared to evaluated products	Mentions illnesses, indications may delay seeking health care
FPP Manufacturer compliance			Proven lack of compliance related to GMP and refusal for GMP inspections.
Applicant/manufacture history			Prior failure to prove safety and quality of a product

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8. Technical guidance on various sections of the dossier

8.1. Vitamins, Minerals and Amino Acids

8.1.1. Limits

Table 6: Limits for vitamins and minerals for different age groups

Group	Age	Min	Max	Min	Max	Min	Max
		Biotin (µg/day)		Folate I (µg/day)		Vitamin B3 Niacin/niacinamide2 (mg/day)	
Infants	0-12 months	-	-	-	-	-	-
Children	1-3 years	1	500	15	300	0.6	10
	4-8 years	1	500	15	400	0.6	15
Adolescents	9-13 years	1	500	15	600	0.6	20
	14-18 years	1.8	500	30	800	1	30
Adults	19 years and older	1.8	500	30	1,000	1	500
		Vitamin B5 Pantothenic acid (mg/day)		Vitamin B2 Riboflavin (mg/day)		Vitamin B1 Thiamine (mg/day)	
Infants	0-12 months	-	-	-	-	-	-
Children	1-3 years	0.2	500	0.04	100	0.04	100
	4-8 years	0.2	500	0.04	100	0.04	100
Adolescents	9-13 years	0.2	500	0.04	100	0.04	100
	14-18 years	0.4	500	0.08	100	0.07	100
Adults	19 years and older	0.4	500	0.08	100	0.07	100
		Vitamin B6 (mg/day)		Vitamin B12 (µg/day)		Vitamin C (mg/day)	
Infants	0-12 months	-	-	-	-	-	-
Children	1-3 years	0.05	30	0.09	1,000	2.2	400
	4-8 years	0.05	40	0.09	1,000	2.2	650
Adolescents	9-13 years	0.05	60	0.09	1,000	2.2	1,200
	14-18 years	0.1	80	0.14	1,000	6	1,800
Adults	19 years and older	0.1	100	0.14	1,000	6	2,000

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		Vitamin D (µg/day)		Vitamin K1, vitamin K2 and total vitamin K1 + K2 (µg/day)	
Infants	0-12 months	0.5	25	-	-
			10		
Children	1-3 years	0.8	25	3	30
			10		
	4-8 years	0.8	25	3	55
			10		
Adolescents	9-13 years	0.8	25	3	60
			10		
	14-18 years	1	25	6	75
			10		
Adults	19 years and older	1	25	6	120
			10		

Table 7: Limits for Vitamin A for different age groups

Vitamin A3 (µg RAE/day)					
		Min	all-trans-Retinol - Max	all-trans-RetinyI acetate - Max	all-trans-RetinyI palmitate - Max
Infants	0-12 months	30	600	600	600
Children	1-3 years	30	600	600	600
	4-8 years	30	900	900	900
Adolescents	9-13 years	30	1,700	1,700	1,700
	14-18 years	65	2,250	2,250	2,250
Adults	19 years and older	65	3,003	3,000	3,022
			2,250	2,250	2,250

Table 8: Limits for minerals for different age groups

Life Stage Group	Calcium I (mg/day)		Chromium (µg/day)		Cobalt2 (µg/day)	
	Min	Max	Min	Max	Min	Max



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Infants	0-12 months	-	-	-	-	-	-
Children	1-3 years	65	1,500	-	-	0.004	44
	4-8 years	65	1,500	-	-	0.004	44
Adolescents	9-13 years	65	1,500	-	-	0.004	44
	14-18 years	65	1,500	-	-	0.006	44
Adults	19 years and older	65	1,500	2.2	500	0.006	44
Life Stage Group		Copper (µg/day)		Iodine (µg/day)		Iron (mg/day)	
		Min	Max	Min	Max	Min	Max
Infants	0-12 months	-	-	-	-	0.6	40
Children	1-3 years	35	700	6	133	0.6	40
	4-8 years	35	2,500	6	200	0.6	40
Adolescents	9-13 years	35	4,000	6	400	0.6	40
	14-18 years	65	6,500	14	800	1.4	45
Adults	19 years and older	65	8,000	14	800	1.4	45
Life Stage Group		Magnesium I,4 (mg/day)		Manganese (mg/day)		Molybdenum (µg/day)	
		Min	Max	Min	Max	Min	Max
Infants	0-12 months	-	-	-	-	-	-
Children	1-3 years	12	65	-	-	-	-
	4-8 years	12	110	-	-	-	-
Adolescents	9-13 years	12	350	-	-	-	-
	14-18 years	20	350	-	-	-	-
Adults	19 years and older	20	500	0.13	9	2.5	2,000
Life Stage Group		Phosphorus (mg/day)		Selenium (µg/day)		Silicon (mg/day)	
		Min	Max	Min	Max	Min	Max



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Infants	0-12 months	-	-	-	-	-	-
Children	1-3 years	62	2,000	-	-	-	-
	4-8 years	62	2,000	-	-	-	-
Adolescents	9-13 years	62	2,000	-	-	-	-
	14-18 years	62	2,000	-	-	-	-
Adults	19 years and older	62	2,000	3.5	200	>0	84
Life Stage Group		Zinc (from non-picolinate sources) 1,5,6 (mg/day)		Zinc (from zinc picolinate) 1,5,6 (mg/day)			
		Min	Max	Min	Max		
Infants	0-12 months	0.2	4	-	-		
Children	1-3 years	0.4	7	-	-		
	4-8 years	0.4	12	-	-		
Adolescents	9-13 years	0.4	23	-	-		
	14-18 years	0.7	34	-	-		
Adults	19 years and older	0.7	50	0.7	25		


8.1.2. Acceptable Claims

Table 9: List of acceptable claims for minerals and vitamins.


Vitamins/ minerals/amino acids	Acceptable Claims
Biotin	<ul style="list-style-type: none"> Helps to maintain/support healthy hair/nail/mucous membranes/(and) skin. Helps to prevent biotin deficiency.² Helps to maintain/support the body's ability to metabolize nutrients.
Folate	<ul style="list-style-type: none"> Helps to form red blood cells.

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	<ul style="list-style-type: none"> • Helps to prevent folate deficiency.² • Helps to maintain/support the body's ability to metabolize nutrients.³ <p><i>Products providing 400 µg or more of folate per day:</i></p> <ul style="list-style-type: none"> • Helps to reduce the risk of neural tube defects when taken daily at least three months prior to becoming pregnant and during early pregnancy. • Helps to support normal early fetal development (brain and spinal cord).
Niacin/ Niacinamide	<ul style="list-style-type: none"> • Helps normal growth and development. • Helps in energy metabolism/(and) tissue formation. • Helps to prevent niacin/niacinamide/vitamin B₃ deficiency. • Helps to maintain/support the body's ability to metabolize nutrients.
Pantothenic acid	<ul style="list-style-type: none"> • Helps in energy metabolism/(and) in tissue formation. • Helps to prevent pantothenic acid deficiency. • Helps to maintain/support the body's ability to metabolize nutrients
Riboflavin	<ul style="list-style-type: none"> • Helps in energy metabolism/(and) in tissue formation. • Helps to maintain/support healthy mucous membranes. • Helps to maintain/support normal red blood cells. • Helps to maintain/support normal metabolism of iron. • Helps to prevent riboflavin deficiency.² • Helps to maintain/support the body's ability to metabolize nutrients.
Thiamine	<ul style="list-style-type: none"> • Helps in energy production. • Supports energy production. • Helps normal growth. • Helps to prevent thiamine deficiency.² • Helps to prevent thiamine deficiency² which helps supports normal growth. • Helps to maintain/support the body's ability to metabolize nutrients.
Vitamin A	<ul style="list-style-type: none"> • Helps to maintain/support normal vision/eyesight/eye health/(and) night vision. • Maintains/supports normal vision/eyesight/eye health/(and) night vision. • Helps to maintain/support skin health/(and) mucous membranes health.

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	<ul style="list-style-type: none"> • Maintains/supports skin health/(and) mucous membranes health. • Healthy skin/(and) mucous membranes support. • Helps to maintain/support immune function/the immune system. • Helps with immune function/the immune system. • Helps to provide eyesight/skin/mucous membranes/(and) immune function support. • Helps in the development and maintenance of night vision. • Helps in the development and maintenance of bones/(and) teeth. • Helps to build strong bones/(and) teeth. • Helps to maintain/support normal metabolism of iron. • Helps to prevent vitamin A deficiency.
Vitamin B₆	<ul style="list-style-type: none"> • Helps in energy metabolism/(and) in tissue formation. • Helps to form red blood cells. • Helps to prevent vitamin B₆ deficiency.² • Helps to maintain/support the body's ability to metabolize nutrients.
Vitamin B₁₂	<ul style="list-style-type: none"> • Helps in energy metabolism. • Helps to form red blood cells. • Helps to maintain/support immune function/the immune system. • Helps with immune function/the immune system. • Helps to maintain/support healthy metabolism. • Helps to prevent vitamin B₁₂ deficiency.² • Helps to maintain/support the body's ability to metabolize nutrients
Vitamin C	<ul style="list-style-type: none"> • Helps in the development and maintenance of bones/cartilage/teeth/(and) gums. • Helps in wound healing/(and) connective tissue formation. • Source of/Provides (an) antioxidant(s) for the maintenance of good health.

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	<ul style="list-style-type: none"> • Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. • Helps in collagen formation (to maintain/support healthy bones/cartilage/teeth/(and) gums). • Helps to maintain/support immune function/the immune system. • Helps with immune function/the immune system. • Helps to prevent vitamin C deficiency.² • Helps to maintain/support the body's ability to metabolize nutrients.
Vitamin D	<ul style="list-style-type: none"> • Helps in the development and maintenance of bones/(and) teeth. • Helps to build strong bones/(and) teeth. • Helps in the absorption (and use) of calcium and phosphorus. • Vitamin D intake, when combined with sufficient calcium, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis. • Helps to maintain/support immune function/the immune system. • Helps with immune function/the immune system. • Helps to prevent vitamin D deficiency.
Vitamin E	<ul style="list-style-type: none"> • Source of/Provides (an) antioxidant(s) for the maintenance of good health. • Source of/Provides an antioxidant that protects the fat in body tissues from oxidation. • Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. • Helps to prevent vitamin E deficiency. •
Vitamin K₁ and K₂	<ul style="list-style-type: none"> • Helps in the maintenance of bones. • Helps to prevent vitamin K deficiency.
Calcium	<ul style="list-style-type: none"> • Helps in the development and maintenance of bones/(and) teeth.

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	<ul style="list-style-type: none"> • Helps in the development and maintenance of bones/(and) teeth especially in children and young adults. • Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may reduce the risk of developing osteoporosis (in peri- and postmenopausal women) (in later life). • Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may help prevent bone loss/osteoporosis (in peri- and postmenopausal women) (in later life). • As part of a healthy diet (when taken with Vitamin D) may help prevent bone loss/osteoporosis. • Source of/Provides (an) electrolyte(s). • Source of/Provides (an) electrolyte(s) for the maintenance of good health. • Helps to maintain/support normal muscle function. • Helps maintain/support bone health. • Helps to prevent calcium deficiency.
Chromium	<ul style="list-style-type: none"> • Provides support for healthy glucose metabolism. • Helps to maintain/support normal blood glucose levels. • Helps to prevent chromium deficiency.² • Helps to maintain/support the body's ability to metabolize nutrients.
Cobalt	<ul style="list-style-type: none"> • Cobalt is a structural component of vitamin B₁₂ that helps form red blood cells. • Cobalt is a structural component of vitamin B₁₂ that helps prevent vitamin B₁₂ deficiency.² • Cobalt is a structural component of vitamin B₁₂ that helps to maintain/support the body's ability to metabolize nutrients.
Copper	<ul style="list-style-type: none"> • Helps to produce and repair connective tissue. • Helps to form red blood cells. • Helps to maintain/support normal iron transport in the body.

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	<ul style="list-style-type: none"> Helps to prevent copper deficiency.
Iodine	<ul style="list-style-type: none"> Helps in the function of the thyroid gland. Helps to prevent iodine deficiency.
Iron	<ul style="list-style-type: none"> Helps to form red blood cells (and helps in their proper function). Helps to prevent iron deficiency.² Helps to prevent iron deficiency anaemia.² Helps to prevent iron deficiency anemia and associated tiredness and fatigue.² <p><i>Products providing 16 mg or more of iron, per day:</i></p> <ul style="list-style-type: none"> Helps pregnant women meet (the) (Health Canada's) recommended intake for iron, when taken in conjunction with a healthy diet.
Magnesium	<ul style="list-style-type: none"> Helps in the development and maintenance of bones/(and) teeth. Helps in bone development. Helps in energy metabolism/(and) tissue formation. Helps to maintain/support normal muscle function. Helps to maintain/support normal muscle function, including the heart muscle. Helps to maintain/support heart muscle function. Source of/Provides (an) electrolyte(s). Source of/Provides (an) electrolyte(s) for the maintenance of good health. Helps to maintain/support normal electrolyte balance. Helps to prevent magnesium deficiency.^{2,6} Helps to maintain/support the body's ability to metabolize nutrients.
Manganese	<ul style="list-style-type: none"> Helps in the development and maintenance of bones. Helps to prevent manganese deficiency.²

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	<ul style="list-style-type: none"> Helps to maintain/support the body's ability to metabolize nutrients.
Molybdenum	<ul style="list-style-type: none"> Helps to prevent molybdenum deficiency.² Helps to maintain/support the body's ability to metabolize nutrients.
Phosphorus	<ul style="list-style-type: none"> Helps in the development and maintenance of bones/(and) teeth. Source of/Provides (an) electrolyte(s) Source of/Provides (an) electrolyte(s) for the maintenance of good health. Helps to prevent phosphorus deficiency.² Helps to maintain/support the body's ability to metabolize nutrients.
Selenium	<ul style="list-style-type: none"> Helps normal growth and development. Source of/Provides (an) antioxidant(s) for the maintenance of good health. Source of/Provides an antioxidant that helps protect against oxidative stress. Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. Helps to maintain/support normal function of the thyroid gland Helps to prevent selenium deficiency.
Zinc⁷	<ul style="list-style-type: none"> Helps in connective tissue formation. Helps in energy metabolism/(and) tissue formation. Helps to maintain/support healthy skin. Helps to maintain/support immune function/the immune system. Helps with immune function/the immune system. Helps to maintain/support healthy bones/hair/nail/(and) skin. Maintains/supports healthy bones/hair/nail/(and) skin. Helps to prevent zinc deficiency.² Helps to maintain/support the body's ability to metabolize nutrients.

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8.2. Herbal ingredients

Table 10: Guidance on PIL inclusions and age groups for specified herbal ingredients

Any herbal active with a monograph from EMA, Health Canada or any other source as may be determined qualified for low-risk (in line with other provisions) provided all conditions of the monograph are met.

Ingredient	Age groups and limits	Therapeutic Indications	Contraindications	Warnings and Precautions	Interactions	Undesirable effects
Ivy leaf	2 – 6 years old 52.5 mg 6 – 12 years old 105 mg 12 years and older 175 mg	Alleviate the symptoms of chronic-inflammatory bronchial disorders; acute inflammations affecting the airways associated with cough	Hypersensitivity to the active substance or to plants of the Araliaceae family. Children under 2 years of age because of the general risk of aggravation of respiratory symptoms through secretolytic drugs.	Persistent or recurrent cough in children between 2-4 years of age requires medical diagnosis before treatment. When dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted. Caution is recommended in patients with gastritis or gastric ulcer. For extracts containing ethanol, the appropriate labelling for ethanol, taken	None reported	Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known. Allergic reactions (urticaria, skin rash, dyspnoea, anaphylactic reaction) have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.



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from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included. Preparation d) should not be administered to children under 6 years of age because of the alcohol content.

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8.3. Essential Oils

Essential oils may be administered topically, ingested or via inhalation. Oils that are exclusively administered topically and do not carry any therapeutic claims may be considered cosmetic per the Guideline for regulation of cosmetic products **BOMRA/ER/CM/P07/G02**.

If the essential oil is used for inhalation or ingested, it is **not** a cosmetic.

8.3.1. Uses

Topical

- Symptomatic relief of acne/boils
- Helps relieve minor skin irritation/cuts/bruises/burns
- Symptomatic relief of eczema/dermatitis
- Help relieve joint/muscle pain associated with sprain/strain/rheumatoid arthritis

Topical and/or Inhalation

- As a nervine/calming
- Helps relieve headache
- Carminative/antispasmodic for symptomatic relief of digestive discomfort
- Helps relieve colds/cough

8.3.2. Populations

Adults 18 years and older

8.3.3. List of Essential Oils

Table 11: Allowed limits for essential oils

Ingredient	Concentration (%)
<i>Abies balsamea</i>	1 – 10
<i>Abies sibirica</i>	1 – 2.5
<i>Angelica archangelica</i>	0.78
<i>Aniba rosaeodora</i>	1 – 10
<i>Apium graveolens</i>	1 – 4
<i>Boswellia frereana</i>	1 – 8



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<i>Boswellia sacra</i>	1 – 3
<i>Cananga odorata</i>	0.8 – 2
<i>Carum carvi</i>	1 – 4
<i>Cedrus atlantica</i>	1 – 5
<i>Chamaemelum nobile</i>	1 – 4
<i>Chrysopogon zizanioides</i>	1 – 1.5
<i>Cinnamomum camphora</i>	1 – 20
<i>Cinnamomum verum</i>	0.6 – 5
<i>Cistus ladanifer</i>	1 – 8
<i>Citrus aurantiifolia</i>	1 – 15
<i>Citrus aurantium</i>	1 – 10
<i>Citrus bergamia</i>	1 – 20
<i>Citrus paradisi</i>	1 – 4
<i>Citrus limon</i>	1 – 10
<i>Citrus sinensis</i>	1 – 10
<i>Commiphora myrrha</i>	1 – 8
<i>Corymbia citriodora</i>	1 – 20
<i>Cuminum cyminum</i>	0.4

8.4. Stem Cell Products

In addition to other considerations outlined in this guideline, for these products, the manufacturing narrative must clearly outline the methods used to extract the stem cells. Additionally under evidence of claim the mechanism of action of the stem cells must be clearly described, including references to published literature.

8.5. Finished Product Quality Control Guide

The following limits are recommended. They can be exceeded provided a compendial standard is used.

8.5.1. Limits


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Table 12: Limits for heavy metals

Heavy Metal	Limit
Arsenic	NMT 1.5 ppm
Cadmium	NMT 0.5 ppm
Lead	NMT 0.5 ppm
Mercury	NMT 3 ppm

Table 13: Disintegration test limits

Formulation	NMT (mins)
Uncoated tablet	30
Film-coated tablet	30
Sugar-coated tablet	60
Enteric-coated tablet	NLT 120 mins in acid solution, NMT 60 mins in buffer
Capsules	30

Table 14: Microbial limits


Routes of Administration	TAMC (CFU/g or mL)	TYMC (CFU/g or mL)
Non-aqueous preparations for oral use	1000	100
Aqueous preparations for oral use	1000	100

Table 15: Absence of pathogens

Pathogen	Absent
<i>Escherichia coli</i>	1 g or mL
<i>Salmonella spp.</i>	10 g or mL
<i>Staphylococcus aureus</i>	1 g or mL

Table 16: Control of other impurities

Impurity	Excipients and/or Formulation	Limits
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Diethylene glycols	Glycerin, Propylene glycol, maltitol solution, hydrogenated starch, Hydrolysate, Sorbitol solution, polysorbates, polyethylene glycol MW < 1000. Cough syrups, Antihistamines, analgesic, antiemetics	NMT 0.10%
Ethylene glycols		
Asbestos	Talc	Absent
TSE/BSE	Excipients of animal origin, magnesium stearate, gelatin, vitamin D	Absent
Pesticides	Excipients of plant origin	Per monograph
Nitrosamine		NMT 0.5
Preservatives	Solid oral dosage forms	Absent

Table 17: Vitamins & Minerals, and Other API Limits in the FPP

Ingredient	Limits
Water soluble vitamins	90 – 150% capsules with no beta-carotene, Vitamin A, D, E, K or minerals of nutritional values
Oil soluble vitamins with minerals	Tablets 90 – 125% Vitamins 90 – 125% Ca, Cu, Fe, Mn, Mg, P, K, Zn 90 – 160% B, Cr, F, I, Mo, Ni, Se, Sn, V
Other	90 – 110%

Where overages are used, justification and supporting data must be provided. Combination of overages and widened limits is not allowed.

8.6. Minimum parameters for herbal specifications

These should be used in addition to other considerations provided for in this guideline and other guidance.

Table 18: Minimum specifications for various products

Test	Herbal Substances	Herbal Preparations	Vitamins and Mineral	Herbal Medicinal Products
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Description	√	√	√	√
Identification	√	√	√	√
Foreign Matter	√			
Total Ash	√			
Ash Insoluble in HCl	√			
Water soluble extractive	√			
Inorganic Impurities	√	√	√	√
Heavy Metals	√	√		
Microbial Limits	√	√		√
Mycotoxins	√	√		
Pesticides, Fumigation agents	√	√		
Assay	√	√	√	√
Residual Solvents		√	√	

Table 19: Minimum specifications for various products

	Tablet	Capsule	Oral Liquid	Oral Liquid Suspension	Herbal Exclusive
Description	√	√	√	√	√
Identification	√	√	√	√	√
Dissolution/Disintegration	√	√			
Hardness/Friability	√	√			
Uniformity of dosage units	√	√		√	√
Water content	√	√	√		
Microbial limits	√	√	√		
Heavy metals	√	√	√		
Loss on Drying	√	√		√	√
Purity				√	√
Uniformity of mass	√	√		√	√
Assay	√	√	√	√	√
Particle size	√	√		√	√



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Microbial quality	√	√		√	√
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9. References

- Guideline on submission of documentation for Registrability/classification of a product **BOMRA/ER/CM/P06/G01**
- Guideline for Food-Medicine borderline products **BOMRA/ER/CM/P06/G02**
- Guideline on Submission of Applications and BOMRA timelines **BOMRA/ER/MD/P04/G01**
- Health Canada Monographs [Compendium of Monographs - Canada.ca](http://www.hc-sc.gc.ca/monographs/)
- SAHPRA Complementary Medicines – Health Supplements safety and efficacy Guideline
- Malaysia Guideline on safety data requirements for complementary products
- Therapeutic Goods Administration Australian regulatory guidelines for complementary medicines