LIST OF UPDATES FOR
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JULY 2025
(March 2025 Updates)

There are three (3) amendments for the March 2025 DRGD Updates as follows:

Main Body of DRGD Third Edition, Ninth Revision January 2025

Section B: Product Registration Process

1. Amendment of information, 10.3 Evaluation Timeline for Product Registration, Page 50

Appendix of DRGD Third Edition, Ninth Revision January 2025

Appendix 16: Bioequivalence (BE) Requirements

2. Amendment of information, 1.4 Bioequivalence (BE) Study Centre Accreditation, Page 3

Appendix 31: Change of Product Registration Holder (COH)

3. Amendment of information, 7. Other Information, Page 6

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Amendment of Section B: Product Registration Process

1. Amendment of information in 10.3 Evaluation Timeline for Product Registration on Page 50 by –

   (a) replacing the following information:

(B)	ABRIDGED EVALUATION	* EVALUATION TIMELINE
9.	Natural Products** a) Single active ingredient b) Two (2) or more active ingredients ** *Applicable for:* *i) Traditional Claims; and* *ii) Modern Claims*	a) 116 working days b) 136 working days

with,

(B)	ABRIDGED EVALUATION	* EVALUATION TIMELINE
9.	Natural Products a) Traditional and Homeopathic Medicine i) Single active ingredient ii) Two (2) or more active ingredients b) Natural Products with Modern Claim i) Single active ingredient ii) Two (2) or more active ingredients	i) 100 working days ii) 120 working days i) 116 working days ii) 136 working days

(b) replacing "a) 116 working days; b) 136 working days" for item 10. Health Supplements with "a) 100 working days; b) 120 working days".

Amendment of Appendix 16: Bioequivalence (BE) Requirements

2. Amendment of information in 1.4 Bioequivalence (BE) Study Centre Accreditation on Page 3 by –

(a) replacing the following information,

For BE studies that were conducted outside the period of facility listing on the NPRA BE Centre Compliance Programme; or were conducted at facilities not listed on the Programme, the applicant may apply for the "*Evaluation on the Need for BE Study Inspection*" to the Centre of Compliance & Quality Control (PKKK). Successful applications would allow the BE studies to be accepted for product registration review. If the applications were not successful, a study specific inspection would be required. The application form, additional details and procedure on how to apply for the *"Evaluation on the Need for BE Study Inspection"* and study specific inspections can be obtained from the *NPRA website*.

Applicable directives and circulars regarding the requirements above are as below:

Direktif Penguatkuasaan Keperluan Kajian Bioekuivalens Bagi Semua Produk Generik 'Immediate Release, Oral, Solid Dosage Form' *yang Mengandungi Bahan Aktif Racun Berjadual Serta Akreditasi Pusat Kajian Bioekuivalens Bil. (10) dlm. BPFK/PPP/01/03 Jld.1 (2 March 2011)*
Makluman susulan berkaitan BE Bil. (6)dlm. BPFK/PPP/01/03 Jld. 3 (12 September 2013)

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Direktif Penguatkuasaan Keperluan Kajian Bioekuivalens (BE) Bagi Produk Generik Dalam Bentuk Dos Oral Tablet/ Kapsul Yang Bersifat Effervescent, Dispersible, Orodispersible, Sublingual, Buccal *dan* Chewable *Yang Mengandungi Bahan Aktif Racun Berjadual* *Bil. (27)dlm. BPFK/PPP/07/25 (23 February 2015)*
Malaysian Guideline for Bioequivalence Inspection
Direktif Pelaksanaan Penilaian Keperluan Pemeriksaan Kajian Bioekuivalens (BE) *NPRA.600-1/9/13 (3) (21 July 2020)*

with the following information,

"On 21 July 2020, a new Directive was issued that necessitates a risk assessment to be performed on BE studies conducted at facilities not listed on the NPRA BE Centre Compliance Programme or conducted outside the valid listing period. This risk assessment leverages on reliance mechanisms with other regulatory agencies via the *Evaluation on the Need for BE Study Inspection (BEDE)* pathway.

Effective 18 February 2025, the scope of facility accreditation requirements has been expanded to include BE study centres listed in the *ASEAN BE Centre List* (The link to the *ASEAN BE Centre List* will be made available once it has been established). Bioequivalence (BE) studies conducted at these facilities during their valid listing period are exempt from the BEDE application, provided they involve generic products that meet the eligibility criteria. This includes *immediate-release, oral, solid dosage forms, with systemic action* containing scheduled poisons. Additionally, products eligible for evaluation under the *Facilitated Registration Pathway (FRP)* are also exempt from the BEDE requirement.

BE studies conducted outside the valid listing period of facilities in the *NPRA BE Centre Compliance Programme* or *ASEAN BE Centre List* or at facilities not listed in either programme must undergo the BEDE evaluation pathway. The outcome of the BEDE application will determine if the BE study may be accepted to support product registration review or require a study-specific inspection with a satisfactory outcome for acceptance.

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Regardless of the mechanism that accepts the BE study for product registration review, the NPRA reserves the right to inspect study sites if concerns arise regarding BE study data during the review. Refusals for the inspection or inspection with unsatisfactory outcomes will result in the product's rejection.

Applications for BE centre inspections and BEDE should be submitted to the Bioequivalence Centre and Ethics Committee Section, Centre of Compliance and Quality Control. Details on BE centre inspections, BEDE, and relevant guidance, including application forms and procedures for BEDE and study-specific inspections, are available on the NPRA website.

Applicable directives and circulars regarding the requirements above are as follows:

- *Direktif Penguatkuasaan Keperluan Kajian Bioekuivalens Bagi Semua Produk Generik 'Immediate Release, Oral, Solid Dosage Form' yang Mengandungi Bahan Aktif Racun Berjadual Serta Akreditasi Pusat Kajian Bioekuivalens Bil. (10) dlm. BPFK/PPP/01/03 Jld.1* (2 March 2011)

- *Direktif Penguatkuasaan Keperluan Kajian Bioekuivalens (BE) Bagi Produk Generik Dalam Bentuk Dos Oral Tablet/ Kapsul Yang Bersifat Effervescent, Dispersible, Orodispersible, Sublingual, Buccal dan Chewable Yang Mengandungi Bahan Aktif Racun Berjadual Bil. (27) dlm. BPFK/PPP/07/25* (23 February 2015)

- *Direktif Pelaksanaan Penilaian Keperluan Pemeriksaan Kajian Bioekuivalens (BE) NPRA.600-1/9/13 (3)* (21 July 2020)

- Malaysian Guideline For Bioequivalence Inspection 2nd Edition

- *Direktif Perluasan Skop Keperluan Akreditasi Pusat Kajian Bioekuivalens (BE) dan Pengecualian Penilaian Keperluan Pemeriksaan Kajian BE Bagi Tujuan Pendaftaran Produk NPRA.600-1/9/13 (50) Jld. 1* (18 February 2025)"

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Amendment of Appendix 31: Change of Product Registration Holder (COH)

3. Amendment of information in 7. Other Information on Page 6 by –

   (a) replacing the following statement, "7.1 Refer also to Directive No. 4, 2013, *Bil. (3) dlm.BPFK/PPP/07/25*: *Direktif Untuk Meminda Prosedur Permohonan Pertukaran Pemegang Pendaftaran Produk* (3 June 2013)" with, "7.1 Refer also to Directive No. 2, 2025, *NPRA.600-1/9/13(49)Jld.1: Direktif Berkenaan Pengemaskinian Prosedur Permohonan Pertukaran Pemegang Pendaftaran Produk* (COH) (18 February 2025)".

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There are three (3) amendments for the April 2025 DRGD Updates as follows:

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Section B: Product Registration Process

1. Amendment of information, 6.3.3 Registration of For Export Only (FEO) Product, Page 28
2. Amendment of information, 10.3 Evaluation Timeline for Product Registration, Page 50

Appendix of DRGD Third Edition, Ninth Revision January 2025

Appendix 28: Licensing

3. Amendment of information, 2. License Application Form, Page 1

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(April 2025 Updates)

Amendment of Section B: Product Registration Process

1. Amendment of information in 6.3.3 Registration of For Export Only (FEO) Product on Page 28 by –

   (a) adding the following statement, "The PRH shall be responsible in ensuring compliance with the regulatory requirement of the importing country." to "b) For Export Only (FEO) product refers to locally manufactured products for exporting purpose only and not marketed locally."

   (b) replacing the following information,

   "e) Applications for registration of FEO products are only accepted under the following condition(s) and must be supported with evidence issued by the competent Authority of the importing countries (self-declaration is not accepted):
   (i) Countries that do not impose the same specific regulatory requirements as Malaysia (e.g. formulation with banned/ prohibited ingredients, Zone IVb stability study, bioavailability/ bioequivalence study, API evaluation, etc.); OR
   (ii) Countries that have different requirements such as different formulation (e.g. colour or strength of ingredients), shape or manufacturing process, etc. as compared to a registered product; OR
   (iii) Difference in classification category of the products (e.g. as food in the importing country) for health supplements and natural products (Traditional and Homeopathic Medicines).

   f) Applications for registration of FEO products are processed based on abridged evaluation. However, the following additional requirements must be fulfilled for pharmaceutical products. It is not applicable to health supplements and natural products (Traditional and Homeopathic Medicines):
   (i) Certificate of Analysis (CoA) of finished product for at least 1 pilot batch; AND
   (ii) Minimum 6 months stability data (real time and accelerated stability study) for at least 1 pilot batch."

   with the following information,

"e) In cases where a pharmaceutical product is needed for local use, submission of an FEO application alone will not be accepted. As such, concurrent submission of the FEO application alongside the product registration application for the local market is required. In these circumstances, priority will be given to the FEO application process to facilitate the commencement of export activities without the need to await approval for product registration intended for the local market.

f) Applications for registration of FEO products should be supplemented with the following:
(i) Justification letter from PRH
(ii) Valid GMP evidence/manufacturing license
(iii) Product Formulation (Batch Manufacturing Formula)
(iv) Product Specification"

(c) adding the following information to, "h) Applicant may apply for a Certificate of Pharmaceutical Product (CPP) for registered FEO products.":

"Evaluation remarks of the product applied for Certificate of Pharmaceutical Products (CPP) shall be reflected on the certificate as:

(i) FEO without concurrent submission for local market approval

This product has not been evaluated by the National Pharmaceutical Regulatory Agency. The information as reflected in this certificate is provided by the applicant and shall not be construed as an endorsement and/or approval by National Pharmaceutical Regulatory Agency of the product or any claims made for it.

(ii) FEO with concurrent submission for local market approval

This product is currently under evaluation by the National Pharmaceutical Regulatory Agency. The information as reflected in this certificate is provided by the applicant and shall not be construed as an endorsement and/or approval by National Pharmaceutical Regulatory Agency of the product or any claims made for it."

(d) replacing the reference, "Bil. (11)dlm.BPFK/07/25 Jld.2, Arahan Pengarah Kanan Perkhidmatan Farmasi Bil. 11 Tahun 2018: Direktif Kaji Semula Pendaftaran Produk Untuk Tujuan Eksport Sahaja (FEO) (6 March 2018), with, "NPRA.600-1/9/13(52)Jld.1, Arahan Pengarah Perkhidmatan Farmasi Bil.5 Tahun 2025: Direktif Berkenaan Penambahbaikan Proses Permohonan Pendaftaran Produk Untuk Tujuan Eksport Sahaja/ For Export Only (FEO) Bagi Produk Farmaseutikal, Suplemen Kesihatan dan Produk Semulajadi (7 April 2025)".

2. Amendment of information in 10.3 Evaluation Timeline for Product Registration on Page 50 by –

(a) adding the following information:

(B)	ABRIDGED EVALUATION	* EVALUATION TIMELINE
11.	Product for Export Only (for all product categories)	40 working days

Amendment of Appendix 28: Licensing

3. Amendment of information in 2. License Application Form on Page 1 by –

(a) replacing the following information,

"Applications must be submitted with the following supporting documents:

a) A copy of Company/ Business Registration Certificate
b) A copy of the License Holder's Identity Card/Passport (if foreigner). Copy of Identity Card/Passport and Type A License (wholesale) must belong to the same License Holder if the application involves Scheduled Poison A products
c) A copy of Business License (Local Authority) for business premises
d) A copy of Business License (Local Authority) for store (if any). All the stores must be in the same state as the business/ manufacturing premise. Exception is only for Selangor and Wilayah Persekutuan Kuala Lumpur
e) A copy of the License Holder's Type A License (wholesale). This document is necessary if products manufactured/ imported/ wholesaled are Scheduled Poison A products or any other products that require a Pharmacist
f) For renewal application, documents (c) to (e) together with a copy of previous Manufacturer's, Import and Wholesaler's License shall be submitted"

with the following information,

"Applications must be submitted with the following supporting documents:

a) A copy of Company Registration Certificate
b) A copy of the License Holder's Identity Card or Passport (for non-Malaysian). A copy of Identity Card or Passport and the Type A Poison License (Wholesale) should be from the same person if the application involves the Scheduled Poison products
c) A copy of valid Business License from the Local Authority for business premises
d) A copy of valid Business License from the Local Authority for the store (if any). Stores and business premises must be in the same state except for the state of Selangor and the Federal Territory of Kuala Lumpur & Putrajaya
e) A copy of valid Type A Poison License (Wholesale) for activity involves the Scheduled Poison products
f) Completed Lampiran B for new Import and Wholesaler's License application (https://www.npra.gov.my/easyarticles/images/users/1110/Makluman-Penambahbaikan-Proses-Pengeluaran-Lesen-Mengimport--Pemborong-2025.pdf)
g) For renewal application, documents (c) to (e) together with a copy of previous Manufacturer's, Import or Wholesaler's License shall be submitted

License renewal applications shall be submitted according to the date announced by NPRA or before the license expires."

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(May 2025 Updates)

There are three (3) amendments for the May 2025 DRGD Updates as follows:

Appendix of DRGD Third Edition, Ninth Revision January 2025

Appendix 20: Specific Labelling Requirements

1. Addition of new ingredient and safety information, No. 116, Isotretinoin, Page 113
2. Addition of new ingredient and safety information, No. 195, Rituximab, Page 190
3. Amendment of existing safety information, No. 213, Statins, Page 211

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Amendment of Appendix 20: Specific Labelling Requirements

1. **Addition of new ingredient 116. Isotretinoin and safety information on page 113** as follows in accordance with Directive No. 7, 2025: *Direktif untuk semua produk yang mengandungi isotretinoin: Pengemaskinian sisip bungkusan dan Risalah Maklumat Ubat untuk Pengguna (RiMUP) dengan maklumat keselamatan berkaitan risiko sacroiliitis dan urethritis* as decided in DCA Meeting No. 408, which takes effect on 1 May 2025 –

"**ISOTRETINOIN**

The following statements shall be included in the package insert and Consumer Medication Information Leaflet (RiMUP) for products containing isotretinoin;

Package Insert

a) Warnings & Precautions:

Musculo-skeletal and connective tissue disorders
Sacroiliitis has been reported in patients exposed to [product name]. To differentiate sacroiliitis from other causes of back pain, in patients with clinical signs of sacroiliitis, further evaluation may be needed including imaging modalities such as MRI. In cases reported post-marketing, sacroiliitis improved after discontinuation of [product name] and appropriate treatment.

b) Adverse Effects/ Undesirable Effects:

Musculo-skeletal system disorders
Cases of sacroiliitis have been observed in patients treated with isotretinoin (see section Warnings and Precautions)

Renal and urinary disorders
Cases of urethritis have been reported.

Consumer Medication Information Leaflet (RiMUP)

a) While you are using it:

Things you must do:

Talk to your doctor if you experience persistent pain in your lower back or buttocks during treatment with [product name]. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with [product name] and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be needed including imaging modalities such as MRI.

b) Side effects:

- persistent pain in the lower back or buttocks
- inflammation of the urethra

Reference: Directive No. 7, 2025. *NPRA.600-1/9/13 (54)Jld.1* *Direktif untuk semua produk yang mengandungi isotretinoin: Pengemaskinian sisip bungkusan dan Risalah Maklumat Ubat untuk Pengguna (RiMUP) dengan maklumat keselamatan berkaitan risiko sacroiliitis dan urethritis"*

2. **Addition of new ingredient 195. Rituximab and safety information on page 190** as follows in accordance with Directive No. 8, 2025: *Direktif untuk semua produk yang mengandungi rituximab (sediaan injeksi sahaja): Pengemaskinian sisip bungkusan dengan maklumat keselamatan berkaitan risiko enteroviral meningoencephalitis dan false negative serologic testing of infections* as decided in DCA Meeting No. 408, which takes effect on 1 May 2025 –

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"RITUXIMAB (INJECTION ONLY)

The following statements shall be included in the package insert for products containing rituximab (injection only);

Package Insert

a) Warnings & Precautions:

Infections
Cases of enteroviral meningoencephalitis including fatalities have been reported following use of rituximab.

False negative serologic testing of infections
Due to the risk of false negative serologic testing of infections, alternative diagnostic tools should be considered in case of patients presenting with symptoms indicative of rare infectious disease e.g. West Nile virus and neuroborreliosis.

b) Adverse Effects/ Undesirable Effects:

Infections and infestations
Frequency 'not known': Enteroviral meningoencephalitis*
*observed during post-marketing surveillance

Reference: Directive No. 8, 2025. ***NPRA.600-1/9/13 (55)Jld.1*** *Direktif untuk semua produk yang mengandungi rituximab (sediaan injeksi sahaja): Pengemaskinian sisip bungkusan dengan maklumat keselamatan berkaitan risiko enteroviral meningoencephalitis dan false negative serologic testing of infections"*

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3. **The specific labelling requirements for existing ingredient, No. 213, Statins on page 211** is amended as follows in accordance with Directive No. 6, 2025: *Direktif untuk semua produk yang mengandungi statin (termasuk produk kombinasi): Pengemaskinian sisip bungkusan dan Risalah Maklumat Ubat untuk Pengguna (RiMUP) dengan maklumat keselamatan berkaitan risiko myasthenia gravis* as decided in DCA Meeting No. 408, which takes effect on 1 May 2025 –

"STATINS

The following statements shall be <u>included in the package insert and Consumer Medication Information Leaflet (RiMUP)</u> for products containing statins;

<u>Package Insert</u>

a) Warnings & Precautions:

<u>Myasthenia Gravis/ Ocular Myasthenia</u>
In few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. [Product name] should be discontinued in case of aggravation of symptoms. Recurrences when the same or a different statin was (re-) administered have been reported.

b) Adverse Effects/ Undesirable Effects:

<u>Nervous system disorders</u>
Frequency 'not known': myasthenia gravis

<u>Eye disorders</u>
Frequency 'not known': ocular myasthenia

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Consumer Medication Information Leaflet (RiMUP)

a) Before you start to use it:

Talk to your doctor or pharmacist before taking [product name]:

- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

b) Side effects:

Unknown frequency:

- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Reference: Directive No. 6, 2025. ***NPRA.600-1/9/13 (53)Jld.1*** *Direktif untuk semua produk yang mengandungi statin (termasuk produk kombinasi): Pengemaskinian sisip bungkusan dan Risalah Maklumat Ubat untuk Pengguna (RiMUP) dengan maklumat keselamatan berkaitan risiko myasthenia gravis"*

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There are five (5) amendments for the July 2025 DRGD Updates as follows:

Main Body of DRGD Third Edition, Ninth Revision January 2025

Section B: Product Registration Process

1. Amendment of information, 7.10 Proposed Package Insert, Page 42
2. Amendment of information, 7.11 Consumer Medication Information Leaflet (RiMUP), Page 43

Appendix of DRGD Third Edition, Ninth Revision January 2025

Appendix 6: Guideline on Registration of Health Supplements

3. Amendment of information, Table 17: Allowable claims for specific active ingredients in HS products, Page 56

Appendix 7: Guideline on Registration of Natural Products

4. Amendment of information, 2.7.6 Certificate of Analysis (Active Ingredient), Page 57

Appendix 19: General Labelling Requirements

5. Amendment of information, Additional Requirements, Page 6

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(July 2025 Updates)

Amendment of Section B: Product Registration Process

1. Amendment of information in 7.10 Proposed Package Insert on Page 42 by –

   (a) replacing "(ii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia" with,

   "(ii) Directive No. 11, 2025. *NPRA.600-1/9/13 (58) Jld.1 Direktif Berkenaan Peluasan Skop Produk Yang Melaksanakan Electronic Labelling (E-Labelling) Kepada Kategori Produk Generik Bukan Racun Berjadual (Over-The-Counter, OTC)*

   (iii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia, Revision 2 August 2025"

2. Amendment of information in 7.11 Consumer Medication Information Leaflet (RiMUP) on Page 43 by –

   (a) replacing "g (ii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia" with,

   "g (ii) Directive No. 11, 2025. *NPRA.600-1/9/13 (58) Jld.1 Direktif Berkenaan Peluasan Skop Produk Yang Melaksanakan Electronic Labelling (E-Labelling) Kepada Kategori Produk Generik Bukan Racun Berjadual (Over-The-Counter, OTC)*

   (iii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia, Revision 2 August 2025"

Amendment of Appendix 6: Guideline on Registration of Health Supplements

3. Amendment of information in Table 17: Allowable claims for specific active ingredients in HS products on Page 56 by –

   (a) adding new functional claim, "Helps maintain muscle function" to Calcium.

   (b) adding the following new ingredient and claims:

Ingredients	Claims		
	General	Functional	Reduced Risk Reduction Claim
Nicotinamide Mononucleotide (NMN)	- Helps in maintenance of good health	- Helps in energy metabolism	

(c) adding new functional claim, “Supports hair and nail health” to Zinc.

Amendment of Appendix 7: Guideline on Registration of Natural Products

4. Amendment of information in 2.7.6 Certificate of Analysis (Active Ingredient) on Page 57 by –

(a) replacing the following information, “Applicants shall submit a certificate of analysis for each active ingredient used, which may be purchased from the supplier.” with,

“Certificate of Analysis (COA) for one batch of active ingredient (herbal substance/preparation/quantified extract), issued by both the active ingredient supplier and the product manufacturer, shall be submitted during traditional product registration application. The COA consists of the following tests (as in **Table 1 and Table 2**), shall be submitted for **all active ingredients** in the formulation.

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Table 1: List of testing requirements for active ingredients (**herbal substances**[1])

Tests	**Specifications**	**Results**
Appearance/Organoleptic characteristics		
Identification: (should be specific for the herbal substance and are usually a combination of three or more of the following): Macroscopy/Microscopy/ Chromatographic procedures or Chemical tests		
Quantitative assay (for active ingredient compounds that are claimed on label)		
Purity Tests: Foreign Matter Total Ash Content Ash insoluble in hydrochloric acid* Water content		
Extractive Values*		

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Tests	**Specifications**	**Results**
Water Soluble extracts Ethanol Soluble extracts Extractable matter		
Microbial Contamination Tests: Total Aerobic Microbial Count (TAMC) Total Yeast and Mould Count (TYMC) Bile tolerant gram-negative bacteria *Salmonella* *Escherichia coli* *Staphylococcus aureus* *Pseudomonas aeruginosa*		
Heavy metal limit: Arsenic Mercury Lead Cadmium		
Other Tests*: Residual solvents Mycotoxins (Aflatoxin, Ochratoxin A) Pesticides Particle size		

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Notes:

[1]**Herbal substances** refers to all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

*These tests might not apply to all herbal substances and must be justified by the applicant.

Table 2: List of testing requirements for active ingredients (**herbal preparations[2]/ quantified extracts[3]**)

Tests	**Specifications**	**Results**
Appearance/Organoleptic characteristics		
Identification: Chromatographic procedure (Identification tests should be specific for the herbal preparation, and optimally should be discriminatory with regard to substitutes/adulterants that are likely to occur. Identification solely by chromatographic retention time, for example, is not regarded as being specific; however, a combination of chromatographic tests (e.g.		

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Tests	Specifications	Results
HPLC and TLC-densitometry) or a combination of tests into a single procedure, such as HPLC/UV-diode array, HPLC/MS, or GC/MS may be acceptable.)		
Quantitative assay (for active ingredient compounds that are claimed on label)		
Purity Tests: Water Content		
Microbial Contamination Tests: Total Aerobic Microbial Count (TAMC) Total Yeast and Mould Count (TYMC) Bile tolerant gram- negative bacteria *Salmonella* *Escherichia coli* *Staphylococcus aureus* *Pseudomonas aeruginosa*		
Heavy metal limit: Arsenic Mercury Lead Cadmium		

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Tests	Specifications	Results
Other Tests**: Residual solvents Mycotoxins (Aflatoxin, Ochratoxin A) Pesticides		

Notes:

[2]**Herbal preparations** are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminute or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

[3]**Quantified extracts** refer to herbal substances/herbal preparations adjusted to one or more active markers, the content of which is controlled within a limited, specified range. Adjustments are made by blending batches of the herbal substance/herbal preparation.

** These tests might not apply to all herbal preparations/quantified extracts and must be justified by the applicant."

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, TENTH REVISION

JULY 2025

(July 2025 Updates)

Amendment of Appendix 19: General Labelling Requirements

5. Amendment of information in Additional Requirements on Page 6 by –

(a) replacing the following information, "m) (ii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia" with,

"m) (ii) Directive No. 11, 2025. *NPRA.600-1/9/13 (58) Jld.1 Direktif Berkenaan Peluasan Skop Produk Yang Melaksanakan Electronic Labelling (E-Labelling) Kepada Kategori Produk Generik Bukan Racun Berjadual (Over-The-Counter, OTC)*

(ii) Guideline on Electronic Labelling (E-labelling) for Pharmaceutical Products in Malaysia, Revision 2 August 2025"