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الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

مملكة البحرين
Kingdom of Bahrain

Pharmacy & Pharmaceutical Product Regulation

Medicine Licensing Guideline

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Dr. / Ahmed Mohamed Al Ansari

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Summary of Changes:

No.	Section	Description of Change
1	4.7. Submission & Validation	Addition of - 4.7.1 Fast Track Pathway - 4.7.2 Normal Registration Pathway
2	4.8. Assessment & Queries	Update Assessment duration
3	Annex III New Medicine Checklist	Deleted
4	Annex V Hospital Pack Size Registration FAQ	Deleted

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Definitions

Batch Releaser	The final manufacturing site from which the medicine is dispatched/released to Bahrain.
Bulk Manufacturer	Manufacturer of the bulk product is defined as any product which has completed all processing steps, up to but not including, final packaging. A manufacturing process generally involves a series of unit operations, where intermediate product is processed to become bulk product.
Certificate of Pharmaceutical Product (CPP)	A certificate issued in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product and the applicant for the certificate in the exporting country.
Country of Origin (COO)	It is the country where the pharmaceutical product has been released with certificate of analysis signed by the responsible qualified person.
ICH	The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).
Local Agent	Licensed pharmacy in Bahrain; designated by the MAH to act on its behalf in communication with NHRA.
Marketing Authorization Holder (MAH)	The pharmaceutical company that legally holds the right and responsibility of marketing the medicine in Bahrain.
NHRA	National Health Regulatory Authority.
Package Leaflet (PL)	The package leaflet is the medicine information provided in the pack. It should be drawn up in accordance with the summary of the product characteristics.
PPR	Pharmacy & Pharmaceutical Product Regulation is the responsible department for medicine licensing at NHRA.
Primary Packager	The manufacture responsible for a primary packaging i.e. a packaging component that is or may be in direct contact with the dosage form.
Secondary Packager	The manufacturer responsible for secondary packaging i.e. a packaging component that is not and will not be in direct contact with the dosage form.
Summary of Product Characteristics (SmPC)	The definitive description of the product. The SmPC is an integral part of the marketing authorization.

Introduction

Guideline documents are meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. Guideline documents also provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

This guideline has been developed to assist license holders in the preparation and submission of applications for licensing medicines in the Kingdom of Bahrain.

Medicine licensing is done through Pharmacy & Pharmaceutical Product regulation section in NHRA.

It should be noted that the NHRA has the right to request any further information and data.

This document should be read in conjunction with other applicable guideline documents.

1. Scope

This guidance document describes the procedures and requirements for submission of an application to obtain a new medicine license in the Kingdom of Bahrain.

Applicants are expected to comply with the procedures and requirements laid out in this guidance.

2. Medicine Licensing

Any medicine must be licensed before marketing in Bahrain as per decree-law # (18) of 1997 amended by decree-law # (20) of 2015, and in accordance with the resolution (63) of 2019 (on NHRA website). Medicine importation and distribution must be done through authorized pharmacy only (Local agent), this agent can be the applicant on behalf of the pharmaceutical company if the agreement is prone to NHRA and acknowledged.

3. Agency Registration Procedure

The local agent must inform NHRA of any agreement made with new pharmaceutical companies for review and approval before starting licensing process.

Pharmaceutical companies (MAH) should note that they are responsible for the medicine's quality, efficacy, and safety throughout its life cycle. Responsibility starts with the licensing of the medicine and ends when the medicine license is cancelled. Since the medicine quality, efficacy and safety can change at any time during the course of its life cycle, it is the MAH responsibility to inform NHRA when these changes occur as per the current guidelines.

These responsibilities include:

1. To ensure that all the information given in the application form and product dossier are true and valid.
2. To notify NHRA if the application submitted to NHRA has been rejected, withdrawn, or deferred by any drug regulatory agency, with reasons in each case if applicable, throughout the medicine life cycle.
3. To notify NHRA of any change in the information submitted in the application and of any new significant safety information during the course of evaluation and throughout the product's life cycle.
4. To respond to NHRA queries or requests for more data for review, within the timelines.
5. To ensure that the medicine will be sold, supplied, and recommended for use in accordance with the approved product information and in compliance with all license conditions, applicable legislation, and guidelines.
6. To mandatorily market the product within 2 years of registration in Bahrain, however different conditions may apply for products locally manufactured in Bahrain.

Failure to comply with the above shall render the product registration license being cancelled. NHRA, thus reserves the right to suspend or cancel the registration license of the product anytime during the life cycle of the product, if found non-compliant.

4. Licensing Procedure

4.1. Before Submission

Prior to submission of medicine licensing application, below are vital instructions:

1. Batch releaser for all formulations must have a valid site license issued by NHRA.
2. Bulk manufacturer and batch releaser of the sterile formulation must have a valid site license issued from NHRA.
3. Generic formulation (first generic only) and first biosimilar product application must have relevant documents from Bahrain patent office (MOIC).
4. The applicant must prepare the file according to requirements laid out in this guideline and ensure all the requested documents are available.

Please note that for each application the most up to date version of forms should be downloaded directly from NHRA website.

4.2. Fees

As per resolution 17 of 2016, application fees and service fees are chargeable for each new medicine application submitted to NHRA, subject to relevant revision in resolution. The applicant must refer to the latest fee structure from NHRA website.

4.3. Data Requirement

The data requirement for each application will differ, depending on the drug submission type. However, all required data should be in accordance with GHC & ICH Common Technical Document (CTD) in eCTD format.

The common technical document is organized into five modules. Module 1 is region specific. Modules 2, 3, 4, and 5 are intended to be common for all regions and must be submitted in soft copy according to ICH guideline.

In case of New Chemical Entity (NEC), Biologicals and Biosimilars all modules are required.

In case of generic products, the comparative bioavailability/bioequivalence study report should be presented under module 5. It is mandatory that the center conducting bioavailability/bioequivalence study should either be approved with Gulf Health Council (GHC) or approved from any of the competent authorities: WHO, USFDA, Health Canada, TGA, MHRA & EMA.

The applicant must refer to GHC approved bioavailability/bioequivalence center list on NHRA website.

The good clinical practice (GCP) certificate to be valid for at least 5 years at the time of submission.

A. Module 1 Requirements:

Module 1: Regional Administrative Information

1.0 Cover letter: Original company paper signed and dated.

1.2 Application Forms: Completed forms must be included in this section. Latest version of the forms must be filled, signed, and stamped with date by the MAH Company.

1.3 Product Information.

1.3.1 Summary of product characteristics (SmPC): English version of the document should be submitted.

1.3.2 Labeling: Label text (immediate and secondary packaging).

1.3.3 Patient information leaflet, electronic generated PIL “e-PIL” can be accepted.

1.3.3.1 Arabic leaflet.

1.3.3.2 English leaflet.

1.3.4 Artwork (outer pack, inner pack, and package leaflet).

1.3.5 One finished product sample.

1.4 Contact details for the marketing authorization holder responsible person for communication with the NHRA on quality issues.

1.7 Certificates & Documents

1.7.1 GMP Certificates:

i. Copy of valid good manufacturing practice (GMP) certificates for all finished product manufacturer(s) including bulk manufacturer, primary packager, secondary packager, and batch releaser.
ii. Copy of valid good manufacturing practice (GMP) certificates of active pharmaceutical ingredient (API), and complete (with all annexes) valid certificate of suitability (CEP) issued by EDQM if applicable.
iii. Electronic generated GMP “e-GMP” can be accepted without legalization as long as there’s method for verification.
iv. Manufacturer registration certificate in Bahrain (batch releaser).
v. Manufacturer registration certificate in Bahrain (bulk manufacturer in case of sterile formulation).

1.7.2 CPP:

I. Certificate of Pharmaceutical Product (CPP) according to WHO format; legalized and issued from the COO (batch releaser country)/Marketing Authorization Holder (MAH) country.
II. For centrally registered products in Gulf Health Council (GHC) copy of product license to be submitted with complete annexes.
III. Electronic generated CPP “e-CPP” can be accepted without legalization as long as there’s method for verification.

1.7.3 Certificate of analysis for the drug substance from the API supplier and finished product.

1.7.4 Certificate of analysis for the excipients from the supplier.

1.7.5 Alcohol content declaration.

1.7.6 Pork content declaration.

1.7.7 Certificate of suitability for TSE/BSE.

1.7.8 The diluents and coloring agents in the product formula.

1.7.9 Patent information:

I. Generics (first generic only) and first biosimilar product: proof that the innovator patent is expired from Bahrain patent office (MOIC).

1.7.10 Letter of access or acknowledgment to DMF/CEP

1.8 Pricing–NHRA price form must be signed and stamped by MAH.

1.9 Response to questions.

Additional data:

I. Declaration from MAH that the SmPC submitted is correct and similar to the one approved in country of origin (COO)/MAH country. If there is any difference, the company shall declare it.
II. Worldwide registration status (registered, marketing date), under registration and rejected).
III. Bioequivalence study summary template for generic application in accordance with GCC bioequivalence guideline (if applicable). Annex IV.

B. Module 2 Requirements:

Module 2: Common Technical Document Summaries

Module 2 Should reflect the information provided in modules 3, 4 and 5.

The following sections are required to be submitted under Module 2:
- 2.1 Table of Contents of Module 2-5.
- 2.2 Introduction:
This section should begin with a general introduction to pharmaceuticals, including its pharmacologic class, mode of action, and proposed clinical use. In general, the introduction should not exceed one page.
- 2.3 Quality Overall Summary:
The whole section is required and should reflect the information provided in Module 3.
- 2.5 Clinical Overview:
-2.5.2 “Overview of Biopharmaceutics”: The summary of the comparative bioequivalence/bioavailability study reports should be provided under this section. In addition,

critical analysis of any important issues related to bioavailability that might affect efficacy and/or safety of the to-be-marketed formulation(s) (e.g., dosage form/strength proportionality and influence of food on exposure) should be provided under this section.

2.1 Table of Contents of Module 2-5
2.2 Introduction
2.3 Quality Overall Summary
Introduction
2.3.S Drug substance
2.3.S.1 General Information
2.3.S.2 Manufacture
2.3.S.3 Characterization
2.3.S.4 Control of Drug Substance
2.3.S.5 Reference Standards or Materials
2.3.S.6 Container/Closure System
2.3.S.7 Stability
2.3.P Drug Product
2.3.P.1 Description and Composition of the Drug Product
2.3.P.2 Pharmaceutical Development
2.3.P.3 Manufacture
2.3.P.4 Control of Excipients
2.3.P.5 Control of Drug Product
2.3.P.6 Reference Standards or Materials
2.3.P.7 Container/Closure System
2.3.P.8 Stability
2.3.A Appendices
2.3.A.1 Facilities and Equipment
2.3.A.2 Adventitious Agents Safety Evaluation
2.3.A.3 Novel Excipients
2.3.R Regional Information
2.4 Nonclinical Overview
2.5 Clinical Overview
2.5.1 Product Development Rationale
2.5.2 Overview of Biopharmaceutics
2.5.3 Overview of Clinical Pharmacology
2.5.4 Overview of Efficacy
2.5.5 Overview of Safety
2.5.6 Benefits and Risks Conclusions
2.5.7 References
2.6 Non-Clinical Written and Tabulated Summaries
2.6.1 Introduction
2.6.2 Pharmacology Written Summary
2.6.2.1 Brief Summary
2.6.2.2 Primary Pharmacodynamics

2.6.2.3 Secondary Pharmacodynamics
2.6.2.4 Safety Pharmacology
2.6.2.5 Pharmacodynamic Drug Interactions
2.6.2.6 Discussion and Conclusions
2.6.2.7 Tables and Figures
2.6.3 Pharmacology Tabulated Summary
2.6.4 Pharmacokinetics Written Summary
2.6.4.1 Brief Summary
2.6.4.2 Methods of Analysis
2.6.4.3 Absorption
2.6.4.4 Distribution
2.6.4.5 Metabolism (interspecies comparison)
2.6.4.6 Excretion
2.6.4.7 Pharmacokinetic Drug Interactions
2.6.4.8 Other Pharmacokinetic Studies
2.6.4.9 Discussion and Conclusions
2.6.4.10 Tables and Figures
2.6.5 Pharmacokinetics Tabulated Summary
2.6.6 Toxicology Written Summary
2.6.6.1 Brief Summary
2.6.6.2 Single-Dose Toxicity
2.6.6.3 Repeat-Dose Toxicity
2.6.6.4 Genotoxicity
2.6.6.5 Carcinogenicity
2.6.6.6 Reproductive and Developmental Toxicity
2.6.6.7 Local Tolerance
2.6.6.8 Other Toxicity Studies (if available)
2.6.6.9 Discussion and Conclusions
2.6.6.10 References
2.6.7 Toxicology Tabulated Summary
2.7 Clinical Summary
2.7.1 Summary of Biopharmaceutic and Associated Analytical Methods
2.7.1.1 Background and Overview
2.7.1.2 Summary of Results of Individual Studies
2.7.1.3 Comparison and Analyses of Results Across Studies
2.7.1.4 Appendix
2.7.2 Summary of Clinical Pharmacology Studies
2.7.2.1 Background and Overview
2.7.2.2 Summary of Results of Individual Studies
2.7.2.3 Comparison and Analyses of Results Across Studies
2.7.2.4 Special Studies

2.7.2.5 Appendix
2.7.3 Summary of Clinical Efficacy
2.7.3.1 Background and Overview of Clinical Efficacy
2.7.3.2 Summary of Results of Individual Studies
2.7.3.3 Comparison and Analyses of Results Across Studies
2.7.3.3.1 Study Populations
2.7.3.3.2 Comparison of Efficacy Results Across All Studies
2.7.3.3.3 Comparison of Results in Sub-Populations
2.7.3.4 Analysis of Clinical Information Relevant to Dosing Recommendations
2.7.3.5 Persistence of Efficacy and/or Tolerance Effects
2.7.3.6 Appendix
2.7.4 Summary of Clinical Safety
2.7.4.1 Exposure to the Drug
2.7.4.1.1 Overall Safety Evaluation Plan and Narratives of Safety Studies
2.7.4.1.2 Overall Extent of Exposure
2.7.4.1.3 Demographic and Other Characteristics of Study Population
2.7.4.2 Adverse Events
2.7.4.2.1 Analysis of Adverse Events by Organ System or Syndrome
2.7.4.2.2 Narratives
2.7.4.3 Clinical Laboratory Evaluations
2.7.4.4 Vital Signs, Physical Findings, Observations Related to Safety
2.7.4.5 Safety in Special Groups and Situations
2.7.4.5.1 Intrinsic Factors
2.7.4.5.2 Extrinsic Factors
2.7.4.5.3 Drug Interactions
2.7.4.5.4 Use in Pregnancy and Lactation
2.7.4.5.5 Overdose
2.7.4.5.6 Drug Abuse
2.7.4.5.7 Withdrawal and Rebound
2.7.4.5.8 Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability
2.7.4.6 Post-Marketing Data
2.7.4.7 Appendix
2.7.5 References
2.7.6 Synopses of Individual Studies

C. Module 3 Requirements:

Module 3: Quality

The whole section is required, and the information should be presented according to the

structured format described in this guideline.

3.1 Table of Contents of Module 3
3.2 Body of data
3.2.S Drug Substance
3.2.S.1 General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties
3.2.S.2 Manufacture
3.2.S.2.1 Manufacturer(s)
3.2.S.2.2 Description of Process and Process Controls
3.2.S.2.3 Control of Materials
3.2.S.2.4 Control of Critical Steps and Intermediates
3.2.S.2.5 Process Validation and/or Evaluation
3.2.S.2.6 Manufacturing Process Development
3.2.S.3 Characterization
3.2.S.3.1 Elucidation of Structure and Other Characteristics
3.2.S.3.2 Impurities
3.2.S.4 Control of Drug Substance
3.2.S.4.1 Specifications
3.2.S.4.2 Analytical Procedures
3.2.S.4.3 Validation of Analytical Procedures
3.2.S.4.4 Batch Analyses
3.2.S.4.5 Justification of Specification
3.2.S.5 Reference Standards or Materials
3.2.S.6 Container/Closure Systems
3.2.S.7 Stability
3.2.S.7.1 Stability Summary and Conclusions
3.2.S.7.2 Post-approval Stability Protocol and Commitment
3.2.S.7.3 Stability Data
3.2.P Drug Product
3.2.P.1 Description and Composition of the Drug Product
3.2.P.2 Pharmaceutical Development
3.2.P.2.1 Components of the Drug Product
3.2.P.2.1.1 Drug substance
3.2.P.2.1.2 Excipients
3.2.P.2.2 Drug Product
3.2.P.2.2.1 Formulation Development
3.2.P.2.2.2 Overages
3.2.P.2.2.3 Physiochemical and Biological Properties

3.2.P.2.3 Manufacturing Process Development
3.2.P.2.4 Container Closure System
3.2.P.2.5 Microbiological Attributes
3.2.P.2.6 Compatibility
3.2.P.3 Manufacture
3.2.P.3.1 Manufacturer(s)
3.2.P.3.2 Batch Formula
3.2.P.3.3 Description of Manufacturing Process and Process Controls
3.2.P.3.4 Controls of Critical Steps and Intermediates
3.2.P.3.5 Process Validation and/or Evaluation
3.2.P.4 Control of Excipients
3.2.P.4.1 Specifications
3.2.P.4.2 Analytical Procedures
3.2.P.4.3 Validation of Analytical Procedures
3.2.P.4.4 Justification of Specifications
3.2.P.4.5 Excipients of Human or Animal Origin
3.2.P.4.6 Novel Excipients
3.2.P.5 Control of Drug Product
3.2.P.5.1 Specifications
3.2.P.5.2 Analytical Procedures
3.2.P.5.3 Validation of Analytical Procedures
3.2.P.5.4 Batch Analyses
3.2.P.5.5 Characterization of Impurities
3.2.P.5.6 Justification of Specifications
3.2.P.6 Reference Standards or Materials
3.2.P.7 Container/Closure System
3.2.P.8 Stability
3.2.P.8.1 Stability Summary and Conclusions
3.2.P.8.2 Post-Approval Stability Protocol and Stability Commitments
3.2.P.8.3 Stability Data
3.2.A Appendices
3.2.A.1 Facilities and Equipment
3.2.A.2 Adventitious Agents Safety Evaluation
3.2.A.3 Excipients
3.2.R Regional Information
3.3 Literature References

The following are recommendations for the presentation of the information in the Quality Module for different scenarios that may be encountered:

- For a drug product containing more than one drug substance: one complete “3.2.S” section

should be provided for one drug substance, followed by other complete "3.2.S" sections for each drug substance.

- For a drug substance from multiple manufacturers: one complete "3.2.S" section should be provided for the drug substance from one manufacturer, followed by other complete "3.2.S" sections for each drug substance manufacturer.

- For a drug product with multiple strengths: one complete "3.2.P" section should be provided with the information for the different strengths provided within the subsections.

- For a drug product with multiple container closure systems (e.g. bottles and unit dose blisters): one complete "3.2.P" section should be provided with the information for the different presentations provided within the subsections.

- For multiple drug products (e.g. tablets and a parenteral product): a separate dossier is required for each drug product.

- For a drug product supplied with reconstitution diluent(s), the information on the diluent should be provided in a separate part "3.2.P" if the diluent is co-packaged with the drug product. However, if the diluent is not co-packaged with the drug product, the compatibility of the diluent with the drug product should be discussed in section 3.2.P.2.6.

D. Module 4 Requirements:

Module 4: Non-Clinical Study Reports

Generally, not applicable for generic products, however some exceptions may apply.

4.1 Table of Contents of Module 4
4.2 Study Reports
4.2.1 Pharmacology
4.2.1.1 Primary Pharmacodynamics
4.2.1.2 Secondary Pharmacodynamics
4.2.1.3 Safety Pharmacology
4.2.1.4 Pharmacodynamic Drug Interactions
4.2.2 Pharmacokinetics
4.2.2.1 Analytical Methods and Validation Reports
4.2.2.2 Absorption
4.2.2.3 Distribution
4.2.2.4 Metabolism
4.2.2.5 Excretion
4.2.2.6 Pharmacokinetic Drug Interactions
4.2.2.7 Other Pharmacokinetic Studies
4.2.3 Toxicology
4.2.3.1 Single-Dose Toxicity

4.2.3.2 Repeat-Dose Toxicity
4.2.3.3 Genotoxicity
4.2.3.3.1 In vitro Studies
4.2.3.3.2 In vivo Studies
4.2.3.4 Carcinogenicity
4.2.3.4.1 Long Term Studies
4.2.3.4.2 Short- or medium-term studies
4.2.3.4.3 Other studies
4.2.3.5 Reproductive and Development Toxicity
4.2.3.5.1 Fertility and Embryonic Development
4.2.3.5.2 Embryo-Fetal Development
4.2.3.5.3 Pre- and Post-natal Development & Maternal Function
4.2.3.5.4 Offspring, Juvenile, Second & Third-Generation Studies
4.2.3.6 Local Tolerance
4.2.3.7 Other Toxicity Studies
4.2.3.7.1 Antigenicity
4.2.3.7.2 Immunogenicity
4.2.3.7.3 Mechanistic Studies (not included elsewhere)
4.2.3.7.4 Dependence
4.2.3.7.5 Metabolites
4.2.3.7.6 Impurities
4.2.3.7.7 Other
4.3 Literature References

E. Module 5 Requirements:

Module 5: Clinical Study Reports

It is anticipated that only the following relevant sections of Module 5 will normally be required.
- 5.1 Table of contents for Module 5
- 5.2 Tabular listing of all clinical studies
- 5.3 Clinical study reports
* 5.3.1 Reports of biopharmaceutical studies
* 5.3.1.2 Comparative BA & BE Study Reports
The comparative bioavailability/bioequivalence study reports should be presented in Module 5 under section 5.3.1.2 “Comparative BA & BE Study Reports”, preferably in clear text/searchable format.

*5.3.1.3 In vitro/In vivo Correlation (IV/IVC) study reports: if available.

*5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human studies: Bioanalytical or analytical methods for BA/BE or in vitro dissolution studies should ordinarily be provided in the clinical study reports. However, where a method is used in multiple studies, the method and its validation should only be included once in section 5.3.1.4 and referenced in the appropriate individual clinical study reports.

*5.3.7 Case Report Forms and Individual Patient Listings: only Case Report Forms (CRFs) for subjects who experienced serious adverse events should be included. All CRFs should be available upon request.

-5.4 Literature references

Module 5 Clinical Study Reports
5.1 Table of Contents of Module 5
5.2 Tabular Listing of All Clinical Studies
5.3 Clinical Study Reports
5.3.1 Reports of Biopharmaceutic Studies
5.3.1.1 Bioavailability (BA) Study Reports
5.3.1.2 Comparative BA & BE Study Reports
5.3.1.3 In vitro/In vivo Correlation (IV/IVC) study reports
5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human studies
5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials
5.3.2.1 Plasma Protein Binding Study Reports
5.3.2.2 Reports of Hepatic Metabolism and Drug Interactions studies
5.3.2.3 Reports of Studies Using other Human Biomaterials
5.3.3 Reports of Human Pharmacokinetic Studies
5.3.3.1 Healthy Subject PK and Tolerability
5.3.3.2 Patient PK and Initial Tolerability
5.3.3.3 Intrinsic Factor PK Study Reports
5.3.3.4 Extrinsic Factor PK Study Reports
5.3.3.5 Population PK Study Reports
5.3.4 Reports of Human Pharmacodynamic (PD) Studies
5.3.4.1 Healthy Subject PD and PK/PD Study Reports
5.3.4.2 Patient PD and PK/PD Study Reports
5.3.5 Reports of Efficacy and Safety Studies
5.3.5.1 Study reports of Controlled Clinical Studies pertinent to the claimed Indication
5.3.5.2 Study reports of Uncontrolled Clinical Studies
5.3.5.3 Reports of Analyses of Data from More than One Study
5.3.5.4 Other Study Reports
5.3.6 Reports of Post-Marketing Experience
5.3.7 Case Report Forms and Individual Patient Listings
5.4 Literature Reference

4.4. Laboratory Analysis:

It is mandatory to have product samples analyzed by NHRA-authorized laboratories for new registration applications prior to the first importation of the product.

In case the product failed in lab analysis initially, another request for analysis will be made. If the product failed again in lab analysis it will be rejected after discussion in the licensing committee.

Documents to be submitted are as follows:

i. Samples of the product.
ii. Certificate of analysis for the sample submitted.
iii. Reference standard for the active ingredients and related substances along with their certificate of analysis.
iv. Product composition certificate.
v. Complete method of analysis.
vi. Product Specification.
vii. Material safety data.
viii. Documents in CD, DVD or USB.

Minimum quantity of sample required for analysis:

	Dosage form	**Quantity**
1.	Capsules & Tablets	100 nos
2.	Oral liquids	10 bottles
3.	Parenteral (ampoule)	50 nos
4.	Parenteral (vials)	25 nos
5.	Parental solution up to 500ml	5 nos
6.	Parental solution above 500ml	2 nos
7.	Suppositories	50 nos
8.	Creams and ointments	10 nos
9.	Inhalers	10 nos
10.	Powders	20 nos
11.	Ophthalmic preparations	20 nos

12.	Nasal drops	10 nos
13.	Ear drops	10 nos
14	PREFILLED SYRENGES (4mL)	20 nos
15	SHACHETS (2Gm)	50 nos

**Quantity is approximate and subject to change depending on the nature & size of the product itself.*

4.5. Addition of Pack Size

Addition of pack size is considered as a new registration. Following are the requirements for the same.

I. New pack size can only be accepted if the product is already registered and has a valid product license.
II. Baseline update sequence is the minimum requirement for registration.
III. Laboratory analysis is exempted.
IV. Fees as per resolution 17 of 2016 is applicable, subject to relevant revision in resolution.
V. Declaration of no change in the quality of the product.

Different volume of vials/ampoules & oral solutions and addition of new strength of the registered strength are not considered as addition in pack size.

4.6. Submission & Validation

To submit a new medicine licensing application, the applicant must complete the submission and payment of application fees through the online portal 'ADWEYA'. NHRA staff will review the attached documents and verify that the information provided in the online application matches the submitted documents. Only complete and valid submissions will be accepted.

The applicant must select the required registration pathway, either the normal registration pathway or the fast-track registration pathway.

4.6.1 Fast Track Pathway:

NHRA staff will review the submitted application to ensure that all required documents are complete and available. Only valid applications that meet the following requirements will be accepted:

a. Proof of product registration from one of the following reference authorities:
   i. GHC Central
   ii. SFDA
   iii. USFDA
   iv. EMA
   v. Swissmedic
   vi. MHRA (UK)

b. Batch releasing site registration:
   The batch releasing site must be registered with NHRA and approved by one of the above-mentioned reference authorities.

c. Medicine dossier in eCTD format.

Once the application is accepted for submission, the applicant may proceed with uploading the eCTD dossier.

4.6.2 Normal Registration Pathway:

This pathway follows all previously stated criteria. NHRA staff will review the submitted application to verify that all required documents are complete and available. Only complete and valid applications will be accepted.

Once the application is accepted for submission, the applicant may proceed with uploading the full eCTD dossier.

4.7. Assessment & Queries

Each application is assessed in accordance with NHRA standard operating procedures and where queries arise, a request for further information will be sent to the applicant. The applicant is requested to respond to such requests in a timely manner and in accordance with any decided timeline.

The assessment of the application shall be conducted by the designated NHRA staff in accordance with the service level agreement (SLA) timelines specified in the table below, excluding any applicable stop-clock periods:

Registration Process	Service Level Agreement
Normal registration Pathway	35 Working Days
Fast track registration pathway	3 Working Days

NHRA will not be held responsible for the delay or cessation of registration process if the applicant fails to respond to NHRA request in a timely manner.

4.8. Approval

After completion of assessment-laboratory analysis and pricing of medicine a decision to approve or disapprove a product for licensing is made by the medicine licensing committee. Upon approval from the committee the applicant must pay the required fees prior to collection of the license.

Medicine license is valid for 5 years.

4.9. General Notes

1. Medicine license is specific to a particular name, formulation, dosage form, strength, pack size with a particular set of approved indications and directions for use.
2. The medicine must be licensed and marketed in the country of origin for at least one year before submission of the medicine licensing application, subject to relevant revision in resolution.
3. When required Bioequivalence study must be according to ICH guideline.
4. When required Stability study must be according to ICH guideline.
5. Multiple API sources (for each API) will be accepted upon the first registration.
6. Multiple Bulk manufacturers, primary and secondary packagers will be accepted at the time of registration.
7. A printout of the GMP certificate from Eudra GMP website and a screen shot of the USFDA inspected establishment record will be accepted by NHRA without legalization.
8. GMP certificates have to be valid for at least 3 months at the time of submission.
9. CPP certificates to be valid for at least 3 months at the time of submission.
10. The name of the product in the CPP to be as proposed to bahrain.
11. Change in formulation (salt type) is considered as new registration not variation.
12. Addition of batch releasing site to an already registered product will result in generating a new registration number to the product with the new batch releasing site – to be considered as new registration with the applicable fees.
13. The local distributor cannot be considered as MAH/Scientific office for international manufacturers.
14. The local manufacturing site can be considered as MAH or collaborate with a scientific office to act as MAH on their behalf.
15. The company should make sure that their products' name is not similar to an already registered product to avoid any Sound alike medicines error.
16. For GHC registered products, they will be considered as GHC registered if the product is submitted within 6 months of registration in GHC, otherwise it will be considered as National

submission.

17. e-PIL (electronic – patient information leaflet) is accepted by NHRA, for further information please refer to the relevant published information.

18. Change in Batch releaser (or Bulk Manufacturer) name is not accepted during the new registration submission; the MAH should either submit variation for name change after registration or cancel the site registration and submit for site registration with new name.

19. Medicines can be classified into one of the following categories at the time of licensing (method of sale):

i. **Prescription Only Medicines (POM)** – available only on a prescription**.**
ii. **Pharmacy only (P)** – available under the supervision of a pharmacist.
iii. **General Sale (GS)** – available in general retail outlets**.**

5. Import, Export & Invoice Clearance

Importation/Exportation of medicine is governed by Bahrain Pharmacy decree-law no. (18) Of 1997 amended by decree-law # (20) of 2015 which states that “the importation/exportation of medicines must be through authorized legal entity”.

The document should be read together with Invoice clearance procedure: Drug Utilization Review (DUR) published on NHRA website.

References

1. Decree-Law No. (18) of 1997 With Respect to the Practice of Pharmacists and Pharmaceutical Centers
2. Decree-Law No. (20) of 2015 Amending Decree-Law No. (18) of 1997 on the Organization of the Pharmacy Profession and Pharmaceutical Centers
3. 2022
4. Decree No. (04) of 2013 Regarding the Pricing of Drugs or Pharmaceuticals and the Determination of Profits to be Traded
5. Decision No. (09) of 2016 On Classification of Pharmaceutical Preparations and Identification of Healthy Foods
6. Decree No. (17) of 2016 on NHRA Application Fees
7. Legislative Decree No. (41) of 2017 Issuing a Track and Trace System for the Supply Chain of Medicine
8. Resolution No. (63) of 2019 on Requirements and Procedures for Practicing Pharmacy Professions and Licensing of Pharmaceutical Facilities
9. Saudi Arabia Food and Drug Authority, http://www.sfda.gov.sa
10. Gulf Health Council, http://ghc.sa/en-us/Pages/Home.aspx#
11. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), https://www.ich.org/
12. https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview
13. https://nuclearmedicineeurope.eu/nuclear-medicine/
14. World Health Organization (WHO) https://www.who.int/
15. Resolution No. (46) of 2023 Amending some of the provisions of the Medicines and Pharmaceutical Products registration regulations and pricing issued by Resolution No. (32) of 2020

Annex I

New Medicine Application Form

Part 1 – Administrative data					
Local agent full name and address					
Contact information					
Name:					
Tel:		Fax:		e-mail	
Commercial registration (CR) number of local agent					
Address of storage premises					
Marketing Authorization Holder's (MAH) name and address in country of origin					
Marketing Authorization Holder's (MAH) name and address for Bahrain					
Contact information of responsible person (MAH)					

Part 2 – Product Particulars				
1.	Name of the product:			
2.	Strength:			
3.	Pharmaceutical form:			
4.	Pack size:			
5.	Description of dosage form:			
6.	Primary packaging			
7.	Pharmacotherapeutic group:		ATC code:	
8.	Proposed shelf-life (in months)			
9.	Storage condition for Bahrain			
10.	Active substance(s) - including relevant quality standard i.e., Ph. Eur. USP etc.):	Unit*		Unit*
11.	Excipient(s) – including relevant quality standard i.e., Ph. Eur. USP etc.):	Unit*		Unit*
**Quantity/dose unit or % quantity*				
12.	Release specification reference number and approval date			

13.	Is the finished product composition as that registered and marketed in country of origin?	
Yes ☐ No ☐ If no, please clarify.		
14.	Batch release MSRN number	Registration date
15.	Bulk manufacture MSRN number (If applicable)	Registration date
16.	Trade name of the product in the country of origin	
17.	Registration number of the marketing authorization for the product in the country of origin and the date of authorization	
18.	State if the product is licensed by any of the following authorities with the grant date: GHC, US FDA, HEALTH CANADA, TGA, EMA or regulatory authorities of Denmark, France, Germany, Italy, Ireland, Netherland, Sweden, UK or Switzerland.	
19.	Has the product license withdrawn, cancelled, or rejected in any of the above-mentioned authorities?	
Yes ☐ No ☐ If yes, please clarify.		
20.	Name and address of the manufacturer(s) involved in all stages of manufacture and activities carried out by each:	

Manufacturer Name	Country	Manufacturer Address
API manufacturer name		
Bulk Manufacturer		
Primary Packaging		
Secondary Packaging		
Batch release of finished product		

21.	Method of sale & supply in country of origin
22.	Package leaflet revision date and number
23.	Invoicing company name with full address
24.	Shipping point with full address (if applicable)
25.	Bioequivalence center name and address (FOR GENERIC application)
25 a	Reference product
25 b	Shelf life of reference product
25 c	MAH and country of reference product

I/we apply for a medicine license in respect of the product for which details are provided above.
It is hereby confirmed that all information relevant to the product have been supplied in the file as appropriate and they are all correct (must be filled by the MAH).

Name of signatory		Signature	
Designation		Date	

Annex II

New Medicine Registration Appointment Request

Local Agent Name:			
Product Name in Bahrain:			
Strength:			
Dosage Form:			
Pack Size:			
API(S) **Name**(S) & **Concentration**(S)			
API Manufacturing Site(s)	**Country**	**Site Address**	**GMP Expiry**
FP Bulk Manufacturing Site(s)	**Country**	**Site Address**	**GMP Expiry**
FP 1RY Packaging Site(s)	**Country**	**Site Address**	**GMP Expiry**
FP 2RY Packaging Site(s)	**Country**	**Site Address**	**GMP Expiry**
FP Batch Releasing Site	**Country**	**Site Address**	**GMP Expiry**
NHRA Manufacturing Site Registration Certificate for The FP Batch Releaser			
Registration Number:		**Registration Date**:	
NHRA Manufacturing Site Registration Certificate for Bulk Manufacturer(s) (if applicable)			
Registration Number:		**Registration Date**:	
CPP Issuing Country & Authority	**Legalization**		**Product Registration Number & Date**
	☐Yes ☐No		
MAH in Country of Origin			

Bioequivalence Center Details (FOR GENERIC ONLY)		
Center Name:	**Country:**	
MAH for Bahrain		
***Name of Agent's Authorized Person:**	***Signature:**	***Date:**
_____	_____	_____

Annex III

Price Form

General information					
Product Name		Strength		Pack Size	
Active Substance		Form			
Company Name & Nationality					

Country of Origin				
Ex-Factory Price (In USD)	**Wholesale Price** (In USD)	**Public Price** (In USD)	**Proposed CIF to Bahrain** (In USD)	Notes

Prices in other countries where the product is marketed

No	Country	Pack Size	Ex-Factory Price	currency	CIF Price	currency	Public Price	currency	Notes
GCC Countries									
1	Kuwait								
2	Oman								
3	Qatar								
4	Saudi Arabia								
5	U.A.E								
Other countries									
6	Australia								
7	Belgium								
8	Canada								
9	Denmark								
10	Egypt								
11	France								

No	Country	Pack Size	Ex-Factory Price	Currency	CIF Price	currency	Public Price	currency	Notes
12	Germany								
13	Ireland								
14	Jordan								
15	Spain								
16	Sweden								
17	Switzerland								
18	Turkey								
19	U.K.								

Declaration	
We:	
Certify that all prices in this form are correct and accurate	
Name of the person authorized to sign on behalf of the company	
Signature	
Stamp	

Annex IV

Bioequivalence Study Summary Template

1.Test product information	
Trade name	
Active ingredient(s)	
Therapeutic classification	
BCS Classification	
API source(s) used in bio batch	
Particle size of API used in bio batch	
Polymorphic form of API used in bio batch	
Strength(s) to be registered	
Strength used in the study	
Dosage form	
Type of formulation (immediate release, modified release… etc.)	
Expected production size	
Bio batch information	
Batch type	
Batch size	
Batch number	
Manufacturing site	
Manufacturing date	
Expiry date	
Assay content in the COA	

2.Tabulation for the composition of the proposed formulation(s)					
Component and quality standard	Function	Strength (label claim)			
		Xx mg		Xx mg	
		Quantity/unit	%*	Quantity/unit	%*
Total					

**Each ingredient expressed as a percentage of the total core or coating weight.*

3.Reference product information	
Trade name	
Active ingredient(s)	
Strength	
Type of formulation (immediate release, modified release… etc.)	
Mode of administration (with or without meals)	
Country of purchase	
Batch number	
Expiry date	
Manufacturer/site	
Assay content in the COA	

4.Summary of in vitro dissolution studies			
Testing date			
Apparatus			
Speed of rotation			
Medium			
Volume			
Temperature			
No. Of dosage units used			
Collection times (minutes or hours)			
F2 value in the comparative in vitro dissolution study (test vs. Reference)	At buffer		
	Ph 1.2	Ph 4.5	Ph 6.8
F2 value in the comparative in vitro dissolution study (bio batch vs other strength(s) to be registered)	At buffer		
	Ph 1.2	Ph 4.5	Ph 6.8

5.Bioequivalence summary		
No. Of submitted bioequivalence studies		
Study design		
Period(s) date(s)		
Bioanalysis date		
Study site		
Number of subjects		
Parent data	☐ yes	☐ no
Metabolite data	☐ yes	☐ no

Parameter	Arithmetic mean (cv%)		% ratio of geometric means	Confidence interval stated in study protocol
	Test	Reference		
Auc(0-t)				
Auc(0-~)				
Cmax				
Tmax				
T 1/2				

6.Bioanalytical method summary	
Method description	
Analyte	
Internal standard (is)	
Average recovery of drug (%)	
Average recovery of is (%)	
Bench-top stability (hours/c)	
Stock stability (days/c)	
Processed stability (hours)	
Freeze-thaw stability (cycles)	
Long-term stability (days/c)	
Dilution integrity	

Selectivity		
Standard curve concentrations (units/ml)		
Lloq (units/ml)		
Qc concentrations (units/ml)	*List all the concentrations used*	
Qc intraday precision range (%)	*Per qc*	
Qc intraday precision range (%)	*Per qc*	
Qc intraday precision range (%)	*Per qc*	
Qc intraday precision range (%)	*Per qc*	
Chromatograms for bioanalytical method	☐ yes	☐ no
20% of subject's chromatograms	☐ yes	☐ no
Incurred sample reanalysis (mandatory for studies that were conducted beyond 2013)	☐ yes	☐ no