GUIDANCE DOCUMENT FOR SUBMISSION OF APPLICATION ON FORM-5F (CTD) FOR REGISTRATION OF PHARMACEUTICAL DRUG PRODUCTS FOR HUMAN USE

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This draft guideline is uploaded on the official website of DRAP dated on --------, for seeking comments and suggestions from stakeholders on the draft document. Stakeholders can submit their comments and suggestions within 15 days of uploading this document using prescribed format, (further information on comments submission can access on this link. Comments and suggestions can be forwarded via email to Director Pharmaceutical Evaluation and Registration **dir.pe.reg@dra.gov.pk** copying at **iqra.aftab@dra.gov.pk**.

Drug Regulatory Authority of Pakistan
Islamabad - Pakistan.

1 HISTORY

This is the second edition of these guidelines. In light of decisions taken by the Registration Board to further ensure the safety, efficacy, and quality of drugs and to achieve WHO Maturity Level 3 (ML3) this document has been revised with following key changes:

Edition	Date	Section	Description of Change	Approved by
1	1st October, 2020	General Guidance of applicants	Addition of CTD Pre-Submission Screening Checklist.	Registration Board
2		1.5.14	Submission of Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP) to mandatory from optional.	Registration Board
		3.2.R.3	Submission of Product Interchangeability (Bioequivalence study reports), where applicable, as per Notification No-F-348-DRB-Addl-Dir (PE&R-I)/2025 dated 17th July, 2025 to mandatory from optional.	Registration Board
		Module 3	Incorporation of sub-section numbering for sub headings in Module 3.	-
		Introduction	Updated.	-
		Purpose	Added.	-
		Address	Changed address of DRAP from TF complex to Prime Minister's National Health Complex, Chak Shehzad, Park Road.	-
		Format	Updated format of guidelines in accordance with QMSC/SOP/DD015 (Version 3).	-

2 APPLICATION[1] - Guidance for Industry

This document is applicable to the applicants who intends to apply for registration / Marketing Authorization of pharmaceutical drug products (Local and Imported) for human use.

3 PURPOSE

3.1 This document is aimed: -

3.1.1 To provide clear instructions to applicants on how to prepare and submit registration applications using Form-5F in the Common Technical Document (CTD) format.

3.1.2 To standardize the content, structure, and format of dossiers to ensure consistency, completeness, and regulatory compliance.

3.1.3 To facilitate efficient evaluation and review of pharmaceutical products by the regulatory authority by aligning submissions with internationally recognized CTD requirements.

3.1.4 To ensure the safety, quality, and efficacy of pharmaceutical drug products intended for human use through comprehensive documentation.

3.1.5 To align national regulatory practices with WHO standards, including progression toward WHO Maturity Level 3 (ML3).

3.1.6 To reduce deficiencies, delays, and queries during the registration process by clearly outlining mandatory requirements, documentation, and data expectations.

3.1.7 To support transparency in the drug registration process for applicants and stakeholders.

[1] **The Guidance document is prepared by Drug Regulatory Authority of Pakistan for better illustration of ~~practices and principles of various steps involved in collection and evaluation of data for process validation.~~ However, content of guidance document only reflects the current thinking perspective of the Authority on the subject and does not create or confer any rights for or on any person and does not operate to bind the Authority or the public.**

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4 INTRODUCTION

4.1 Responsibility for the quality, safety and efficacy of pharmaceutical drug product lies first and foremost with the manufacturer.

4.2 Guidance documents are meant to provide assistance to industry and regulators on HOW to comply with legal laws, rules and regulations. Additionally, guidance documents are administrative tool not having force of law and, as such, allow for flexibility in approach. Alternative methods to the principles and practices outlined in this document MAY BE acceptable if they are supported by appropriate and sufficient justification in the light of international guidelines adopted by reference regulatory authorities.

4.3 Registration Board and Pharmaceutical Evaluation and Registration Division have the right to request any other information not specifically described in this document, in order to adequately assess the safety, efficacy or quality of a pharmaceutical drug product.

4.4 This guidance is developed to assist manufacturers and importers in developing their applications for registration of product and provide guidance to regulators in assessment. DRAP has adapted CTD format for registration of all such drugs vide SRO-713(l)/2018 dated 8th June 2018. The detailed guidance regarding the data requirement for CTD format has been provided in ICH M-4 guidelines. DRAP is introducing the CTD in a progressive manner, therefore, initial guidance to applicants would be helpful for harmonization and appropriate data submission to achieve consistency and uniformity of application.

4.5 This guidance document is developed on the basis of best available knowledge and scientific data / evidence and should be read *in conjunction with the accompanying notifications and the relevant sections of other applicable guidance documents*.

5 LEGAL REQUIREMENTS

5.1 Rule 26 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, as amended vide S.R.O 713(I)/2018 dated 8th June, 2018, under 26(1) section mandates the use of CTD format for the submission of registration application for human drugs. It provides the standard formats and requirements for submission of registration application dossier on Form 5F (Common Technical Documents) for registration of Human drugs.

5.2 Section 7 (c) (ix) of DRAP Act 2012, mandated the systematic implementation of internationally recognized standards of World Health Organization, International Conference on Harmonization (ICH), and Food and Drug Administration guidelines etc.

5.3 These guidelines conform to DRAP Act 2012, Drugs Act 1976 and rules framed there under and some parts have been adopted from WHO guidelines on registration / market authorization procedures.

6 ACRONYMS

API	Active Pharmaceutical Ingredient
BAN	British Approved Name
BCS	Biopharmaceutics Classification System
BP	British Pharmacopoeia
BSE	Bovine Spongiform Encephalopathy
CAS	Chemical Abstract Service
CEP	Certificate of Suitability
CoA	Certificate of Analysis
CPP	Critical Process Parameters
CQA	Critical Quality Attribute
CTD	Common Technical Document
DML	Drug Manufacturing License
DRAP	Drug Regulatory Authority of Pakistan
EPAR	European Public Assessment Report
FDA	Food & Drug Administration of United States
GCP	Good Clinical Practices
GLP	Good laboratory Practices
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonization
INN	International nonproprietary name
IR	Infrared
JP	Japanese Pharmacopoeia
LR&A	Licensing, Registering & Advertising
MS	Mass Spectrometry
NMR	Nuclear Magnetic Resonance
OSD	Oral Solid Dosage form
PAR	Public Assessment Report
Ph.Eur	European Pharmacopoeia
Ph.Int	International Pharmacopoeia
PMDA	Pharmaceuticals and Medical Devices Agency of Japan
RRA	Reference Regulatory Authority
SAE	Serious Adverse Events
TSE	Transmissible Spongiform Encephalopathies
USAN	United States Adopted Name
USP	United States Pharmacopoeia
UV	Ultraviolet-Visible
WHO	World Health Organization

7 GENERAL GUIDANCE FOR APPLICANTS

- ✓ All applications must be submitted electronically through the eAPP system on Form 5F by Registering on the eApp portal at eapp.dra.gov.pk using valid credentials.
    1. Module 1 (Regional and Administrative Information part) shall be prepared as provided in Form-5F without deleting any component. Applicant shall mention "Not applicable" with proper justification for those parts which are not related to any particular application.
    2. Module 2: Quality Overall Summary (QOS) shall be prepared to summarize the quality; nonclinical and clinical information presented in modules 3, 4 and 5 using ICH template or WHO template provided hereinafter without deleting any component / table of the template. Applicant shall mention "Not applicable" with proper justification for those parts which are not related to any particular application.
    3. Module 3: (Quality) (as per ICH M4Q)
    4. Module 4:((Non-clinical Study Reports) (as per ICH M4S) Optional
    5. Module 5: (Clinical Study Reports (as per ICH M4E) Optional

Each section / sub section of CTD application shall be properly bookmarked.

NOTE ON SCREENING

- ✓ After submission of application, it will be screened as per CTD pre-submission screening checklist as provided below to assess for the acceptability of the application. Application shall be received for full evaluation if all the below mentioned documents are submitted and will be considered from that date. If the application is incomplete, it will be returned back for completion.

CTD Pre-submission screening checklist for Pharmaceutical Products

	Form 5-F:
1.	Requisite fee :
2.	Valid DML / DSL:
3.	Evidence of approval of section/manufacturing facility by the Central Licensing Board.:
4.	Evidence of approval status in RRA:

5. Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).
For Module-3, in <u>Drug Substance</u> part:
3.2.S.2.1: Manufacturer(s) site address
3.2.S.4.4: Certificate of Analysis (COA) of both drug substance(s) manufacturer and drug product manufacturer:
3.2.S.7: Stability data of 3 batches at accelerated and real time conditions:
For Module-3, in <u>Drug Product</u> part: 3.2.P.2.2.1: Pharmaceutical Equivalence through Comparative Dissolution Profile (where applicable) [Explanation: Pharmaceutical Equivalence is mandatory for each dosage form/product while Comparative Dissolution Profile is required as applicable]
3.2.P.5.1: Specifications of drug product:
3.2.P.5.3: Validation / verification of analytical procedures summary / reports:
3.2.P.8.3: Stability data:(At least 3 months)
3.2.R Product Interchangeability (Bioequivalence study reports) (where applicable)
FOR IMPORTED PRODUCTS (Following additional documents) Original, legalized and valid CoPP / Free sale and GMP certificate
Original, Valid Sole agency agreement / authorization letter

8 MODULE 1: (ADMINISTRATIVE PART)

1.1 Covering Letter and Fee Deposit Slip

a) Covering letter on the Applicant company / manufacturer / importer letter head in context to the application for the registration of the Pharmaceutical Drug Product shall be submitted, which shall be dully signed by owner/ authorized person on behalf of company/ manufacturer/ importer as per below mentioned format:

"I / We ……..... of ……hereby apply for registration of the drug, namely ……details of which are enclosed."

b) A scanned copy of original cash deposit slip of prescribed fee as per prevailing S.R.O., for specified category shall be attached and submitted therewith through the integrated payment gateway.

1.2 Table of Contents (From Module 1 to Module 5)

a) A comprehensive Table of Contents shall contain Module and sub module heading with page number on the pharmaceutical dossier. The contents of all the Module from 1 to 5 shall be covered. Comprehensive Table of Contents is different form individual table of contents in the beginning of each Module.

b) Also, a complete list of all documents provided in the registration dossier by Module, Section and sub-section shall be included.

1.3 Applicant Information

1.3.1. Name, address and contact details of Applicant / Marketing Authorization Holder:

a) In this section, administrative information related to the applicant is required.

b) It is necessary to provide the complete particulars of the applicant, which shall contain:

i. Name of Licensed Pharmaceutical Manufacturer / Licensed Importer having Drug Sale License by respective licensing authority

ii. Manufacturing Site Address of Pharmaceutical unit or address of the godown / warehouse in case the applicant is Drug Sale license Holder

iii. Contact details, including postal address, telephone contact number, Fax number, website and email address.

1.3.2. Name, address and contact details of manufacturing site

There could be following three situations:

a) **The applicant is manufacturer**

Provide the details including name, DML number and complete address of the manufacturing site of the applicant (manufacturer).

b) **Contract Manufacturing (The applicant is not manufacturer for the applied product)**

Provide the details including name, DML number and complete address of the manufacturing site of the manufacturer.

c) **Import (The applicant is importer for the applied product)**

Provide the details including name and complete address of the manufacturing site and name of marketing authorization Holder/ Product License Holder for the applied product.

In case multiple manufacturing sites are involved, provide details for each.

1.3.3. Specify whether the Applicant is:

*** Manufacturer**

*** Importer**

*** Is involved in none of the above (contract giver)**

This point requires the status of applicant for the instant product.

The applicant must select one of the above mentioned options. A manufacturer will provide all the requisite information as per Registration procedure of Pakistan, subsequently mentioned in 1.3.4-1.3.5.

- An importer shall provide Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country.
- "c" is for Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976.

1.3.4. Valid Drug Manufacturing License (DML) of manufacturer / Applicant or Drug Sale License, whichever is applicable.

a) For drug to be locally manufactured, copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.

b) For drugs to be imported, copy of valid Drug Sale License (DSL) issued by relevant licensing authority. The address of applicant mentioned on Drug Sale License (DSL) shall match with the information provided in sub-section 4.3.1 and sole agency agreement / letter of authorization between applicant and marketing authorization holder (abroad).

1.3.5. Evidence of approval of manufacturing facility / Approved Section from Licensing Authority

a) To be provided if option **a** or **c** is selected in sub-section 1.3.3

b) Approval letter of the section (Dosage form) in which manufacturing of the applied product is to be carried out needs to be submitted or panel inspection report conducted for renewal of DML or grant of GMP certificate. In case of contract manufacturing, the same documents from the contract manufacturer shall be submitted.

c) GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.

1.3.6. List of already approved registered drugs in this section

The submission against this point is optional

1.3.7. Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance

The submission against this point is optional**.**

1.3.8. Manufacturer's Site Master File and Credential (for importer)

The submission against this point is optional.

1.4 Type of Application

1.4.1. Application is for the registration of:

New Drug Product (NDP)

Generic Drug Product (GDP)

a) New Drug Product (*Product not already registered in Pakistan*) includes New Molecule/ New strength / New Formulation.

b) It is important to specify here whether the applicant has submitted the CTD for a New Drug Product Registration or a Generic Drug Product.

1.4.1 Pharmaceutical product is intended for:

Domestic sale

Export sale

Domestic and Export sales

a) Applicant needs to clarify whether the applied product (drug product) is intended for sale in domestic market or both for domestic and export market.

b) For Export only registrations application on Form 5F (CTD) is already exempted by the Authority vide its Circular No. F.1-21/2019-Add:Dir. (PE&R) dated06-02-2019.

1.4.2. For imported products, please specify one of following:

Finished Pharmaceutical Product Import

Bulk Import and local repacking (specify status of bulk)

Bulk Import Local Repacking for Export purpose only

This point only pertains to registration applications of drug products for import.

The applicant / importer needs to specify whether the import is of finished pharmaceutical product or of bulk product. In case of bulk import local repack, the applicant also needs to provide following documents:

a) Evidence and GMP status of packing facility for the bulk imported drug to be repacked and batch release.

b) Agreement between the importer and the firm responsible for local repacking in Pakistan.

1.4.3. Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976.

*** Domestic Manufacturing**

*** Export Purpose Only**

a) Provide notarized copy of Contract manufacturing agreement.

b) Provide documents confirming number of approved sections of the applicant (DML holder).

c) Provide details of already registered drug products of contract giver on contract manufacturing.

1.5 Detailed Information of Drug, Dosage From & Labeling Claims

1.5.1. Generic name with chemical name & synonyms of the applied drug.

The following necessary information shall be provided in this sub-section:

a) (Recommended) International Non-proprietary name (INN):

b) Compendia name, if relevant:

c) Chemical name(s):

d) Chemical Abstracts Service (CAS) registry number: (where applicable)

The submission of following is **optional**

a) Company or laboratory code:

b) Other non-proprietary name(s) (e.g. national name, USAN, BAN):

1.5.2. Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit

a) Strength of Active ingredient shall be stated clearly. In case API is in the form of salt, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.

b) For example, each tablet contains, each ml contains in case of Injectable. However, description like each ampoule / vial contains shall be avoided, or in case of syrup / suspension / dry powder for suspension each 5 ml (after reconstitution) contains etc.

1.5.3 The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance.

a) The proposed brand name shall be justified keeping in view the LASA (Look alike and Sound alike) with specific emphasis on prefix, mid-name and suffix.

b) An undertaking in this regard that the applicant shall be responsible to change the name in case the name resembles with already approved / registered names.

1.5.4 Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned.

a) The applicant needs to submit the proposed pack size as well as demanded price for each pack size.

1.5.5 Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API)

a) Indicate Pharmacological class of the API (drug substance) with proper reference.

b) Also, state the WHO ATC code for each distinct therapeutic indication.

1.5.6 Pharmacopoeial reference / Status of applied formulation

Mention the reference specifications of the finished product (drug product) from the following list

- USP
- BP
- Int. Ph.
- JP

Pharmacopoeia of any Reference Regulatory Authority

- Manufacturer's specifications.
- Specifications as per Innovator's product
- Any other (specify exact reference)
- Any other pharmacopoeia as mentioned in Drug specification rules. (Specify the exact reference).

1.5.7 Route of administration

The applicant needs to specify the exact route of administration for the applied drug product. In case of multiple route of administration, specify all routes of administration.

1.5.8 For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price.

If the applicant has selected Generic Drug Product (GDP) in sub-section 1.4.1, the reference of already registered product including the following details needs to be submitted.

- Brand name
- Manufacturer/Registration holder
- Registration number

If the applicant has selected New Drug Product (NDP) in sub-section 1.4.1 "Not applicable since this is a new drug" needs to be mentioned against this point.

1.5.9 The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention.

Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently.

The list of reference countries with official website links, as approved by the Registration Board in its 275th meeting and as updated from time to time.

1.5.10 Dosage form of applied drug

Dosage form of applied drug shall be mentioned clearly, with complete description of a unit like "Film Coated Tablet" & "Sugar Coated Tablet" etc.

1.5.11 Proposed label [outer (secondary) & inner (primary)] & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens

The submission against this point is optional.

1.5.12 Description of Batch numbering system

The submission against this point is optional.

1.5.13 Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).

The submission against this point is optional.

1.5.14 Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).

The submission against this point is mandatory. The applicant shall submit as part of Form 5F as per **Annex-A** of the DRAP Guidance document on SUMMARY OF PRODUCT CHARACTERISTICS GUIDELINES, that includes:

i. Name of drug product.
ii. **Qualitative and quantitative composition**: *<Clarify API's strength including its salt form or equivalency with respect to quantity of the active moiety (if applicable). The declaration of strength should appear only in Section 2 of the SmPC (Qualitative and Quantitative Composition) in a standardized format (active substance per dosage unit or per volume). For reference see DRAP Guidance document on SUMMARY OF PRODUCT CHARACTERISTICS GUIDELINES .>*
iii. Pharmaceutical form.
iv. **Clinical particulars:**
<For products on which DRAP has implemented interchangeability requirements as part of registration application, the clinical particulars shall be same as approved for the reference product by Reference Regulatory Authorities (RRA).>
v. *< Any clinical manifestations and effects on plasma levels and AUC of parent compounds or active metabolites and/or on laboratory parameters shall be mentioned for the applied products in concurrence with the BE studies performed by the applicant. In case of those products which does not currently fall under DRAP's BE notification, the submission of this information is optional.>*
vi. Pharmacological properties.
vii. **Pharmaceutical properties:**
< In addition to the requisite information as outlined in the DRAP Guidance document on SUMMARY OF PRODUCT CHARACTERISTICS GUIDELINES, the details of diluents and reconstitution procedures should be included in the SmPC of such products which require reconstitution.>
viii. Marketing authorization/ Registration holder.
ix. Marketing authorization/Registration number.
x. Date from which marketing is authorized.
xi. Date of revision of the text.

1.5.15 – 1.5.20 Commitments

I / we hereby undertake that:

1.5.15 After registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan

within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.

1.5.16 We shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.

1.5.17 In case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.

1.5.18 We will follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. *(For drug products to be imported, this commitment must be submitted by manufacturer abroad as well).*

1.5.19 In case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.

1.5.20 We will perform process validation and stability studies till the assigned shelf life for the first three consecutive batches of commercial scale, stability study of at least one batch every year in accordance with the protocols and continue real time stability study till assigned shelf life of the applied product.

a) We will be responsible to change the brand name in case the name resembles with already approved / registered names.

b) We will be responsible to change the label design if it resembles with any of the previously registered drug.

I / We hereby undertake that the above given information is true and correct to the best of my / our knowledge and belief.

1.5.21 Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.

The submission against this point is optional.

1.5.22 Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.

The submission against this point is optional.

1.6 Miscellaneous Information

1.6.1 Information on Prior-related Applications

The submission against this point is optional.

1.6.2 Appendix

1.6.3 Electronic Review Package

The applicant shall submit electronic review package in CD / USB including Quality Overall Summary.

1.6.4 QIS (Quality Information Summary)

The submission against this point is optional

1.6.5 Drug Substance related Document including following:

a. Name and address of API manufacturer.

b. Approval of manufacturing facility of API by regulatory body of country and validity.

For applications of locally manufactured drug product(s), the one of the following documents shall be submitted.

i. Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin.

ii. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.

iii. CEP certificate.

For applications of imported drug product(s), the submission against this point is not required.

c. Vendor qualification / audit is

Document based

Site inspection based

Reason for point c.

9 MODULE 2: (OVERVIEWS AND SUMMARIES)

2.3 Quality Overall Summary (QOS)

- The applicants of innovator drug products can submit QOS either as per WHO QOS-PD template or as per ICH template for consideration by the Registration Board.
- For drug products other than innovator's product, Quality Overall Summary (QOS) shall be provided in WHO QOS-PD Template or template provided below.

INTRODUCTION

Summary of product information:

Non-proprietary name(s) of the Drug Product	
Proprietary name(s) of the Drug Product	
International non-proprietary name(s) of the Drug Substance, including form (salt, hydrate, polymorph)	
Applicant name and address	
Dosage form	
Strength	
Route of administration	
Proposed indication(s)	
Primary Contact person responsible for this application	**Title:** **First name:** **Family Name:**
Contact person's job title	
Contact person's details	
Corresponding address	
Town/City/Country	
Contact person's email address	
Contact person's phone number	

Note: Provide contact details of the person who is responsible for this application and have all the technical and administrative details related to this application.

Other Introductory information:

Related dossiers (e.g. Drug Product(s) with the same Drug Substance(s) submitted to DRAP:

Brand Name	Date of submission in DRAP	Drug Substance, strength, dosage form (eg. Abacavir (as sulphate) 300 mg tablets)	Drug Substance manufacturer (including address if same supplier as current dossier)

Identify available literature references for the Drug Substance and Drug Product:

Publication(s)	Monograph exists/does not exist/exists in other combination only	Most recent edition/volume consulted
Drug substance status in pharmacopoeias:		
USP	<e.g. Monograph exists>	<e.g. USP 42>
BP	<e.g. Monograph exists>	<e.g. BP 2019>
Ph.Eur.	<e.g. Monograph exists>	<e.g. Ph.Eur. 10.0>
Ph.Int.	<e.g. monograph exists>	<e.g. Ph.Int. 9th Edition 2019>
Other (e.g. JP)	<e.g. Monograph exists>	<e.g. JP 17th Edition>
Drug product status in pharmacopoeias:		
USP	<e.g. Monograph exists>	<e.g. USP 42>
BP	<e.g. Monograph exists>	<e.g. BP 2019>
Ph.Int.	<e.g. monograph exists>	<e.g. Ph.Int. 9th Edition 2019>
Other (e.g. JP)	<e.g. Monograph exists>	<e.g. JP 17th Edition>
Other reference texts (e.g. public access reports): Mandatory for new drugs or drug products for which official monograph does not exist		
<e.g. WHOPARs, EPARs, FDA review, PMDA review report>	<e.g. WHOPAR HAXXX>	<e.g. EMA PAR of June 2018>

Do not delete any row in the above table. For drug products for which official monograph do not exist, the information regarding other references (e.g. public assessment reports) is mandatory to mention.

2.3.S Drug Substance

<For drug products having more than one drug substances, a separate section 2.3.S shall be provided for each drug substance >

2.3.S.1 General Information

2.3.S.1.1 Nomenclature

(a) (Recommended) International Non-proprietary name (INN):

(b) Compendial name, if relevant:

(c) Chemical name(s):

(d) Other non-proprietary name(s) (e.g. national name, USAN, BAN):

(e) Chemical Abstracts Service (CAS) registry number:

2.3.S.1.2 Structure

(a) Structural formula, including relative and absolute stereochemistry:

(b) Molecular formula:

(c) Relative molecular mass:

<For drug substance(s) existing as salts the molecular mass of the free base or acid shall also be provided>

2.3.S.1.3 General Properties

(a) Physical description (e.g. appearance, colour, physical state):

(b) Solubilities:

In common solvents:

Quantitative aqueous pH solubility profile (pH 1.2 to 6.8) at 37°C:

Medium (e.g. pH 4.5 buffer)	**Solubility (mg/ml)**
<pH = pKa, if pKa is between 1.2 and 6.8>	**<e.g. pKa = 13.1, therefore solubility result at this pH is not required>**

(c) Physical form (e.g. polymorphic form(s), solvate, hydrate):

Polymorphic form:

Solvate:

Hydrate:

(d) Other:

Property	

pH	
pK	
Partition coefficients	
Melting/boiling points	
Specific optical rotation (specify solvent)	
Refractive index (liquids)	
Hygroscopicity	
UV absorption maxima/molar absorptivity	

2.3.S.2 Manufacture

2.3.S.2.1 Manufacturer(s)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing, storage) of each manufacturer, including contractors and each proposed production site or facility involved in these activities:

Name and address (including block(s)/unit(s))	**Responsibility**

(b) Approval of Drug Substance / Drug Manufacturing License (DML) / Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin:

<The copy of certificate shall be provided in Module-1 section 1.6.5(b)>

2.3.S.2.2 Description of Manufacturing Process and Process Controls

The submission against this point is optional.

2.3.S.2.3 Control of Materials

The submission against this point is optional.

2.3.S.2.4 Controls of Critical Steps and Intermediates

The submission against this point is optional.

2.3.S.2.5 Process Validation and/or Evaluation

The submission against this point is optional.

2.3.S.2.6 Manufacturing Process Development

The submission against this point is optional.

-

2.3.S.3 Characterization

2.3.S.3.1 Elucidation of Structure and other Characteristics

(a) List of studies performed (e.g. IR, UV, NMR, MS, elemental analysis) and conclusion from the studies (e.g. whether results support the proposed structure):

<For Drug substance(s) that are not described in an officially recognized pharmacopoeia, the studies carried out to elucidate and/or confirm the chemical structure normally include elemental analysis, infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR) and mass spectra (MS) studies>

<For Drug substance(s) that are described in an officially recognized pharmacopoeia, it is generally sufficient to provide copies of the IR spectrum>

(b) Discussion on the potential for isomerism and identification of stereochemistry (e.g. geometric isomerism, number of chiral centres and configurations):

<Generally applicable for those drug substance(s), for which isomerism may impact the quality, safety or efficacy of the drug product>

(c) Summary of studies performed to identify potential polymorphic forms (including solvates): <including identification of and data on the drug substance lot used in stability studies>

<Generally applicable for those drug substance(s), for which polymorphic form may impact the quality, safety or efficacy of the drug product>

(d) Summary of studies performed to identify the particle size distribution of the API: <including identification of and data on the drug substance lot used in stability studies>

<Generally applicable for those drug substances, for which particle size may impact the quality, safety or efficacy of the drug product>

2.3.S.3.2 Impurities

(a) Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation:

i. List of Drug Substance / API-related impurities (e.g. starting materials, by-products, intermediates, chiral impurities, degradation products), including chemical name, structure, origin and acceptable limits:

Drug Substance / API-related impurity (chemical name and compendial name)	**Structure**	**Origin**	**Acceptable limit / Acceptance criteria**

ii. List of process-related impurities (e.g. residual solvents, reagents):

Process-related impurity (compound name)	**Acceptable limit / Acceptance criteria**

2.3.S.4 Control of the Drug Substance

2.3.S.4.1 Specification

(a) Drug Substance specifications of the Drug Product manufacturer:

Standard (e.g. USP, BP, Ph.Int., Ph.Eur., JP, in-house)		
Specification reference number and version		
Test	**Acceptance criteria**	**Analytical procedure (Type/Source/Version)**
Description		
Identification		
Impurities		
Assay		
etc.		

Provide Drug Substance Specifications of the Drug Product manufacturer. Avoid deleting this table and inserting specifications table provided by the Drug Substance / API manufacturer.

2.3.S.4.2 Analytical Procedures

(a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing):

<Provide brief tabulated summary of analytical procedures instead of attaching detailed analytical methods of Drug Substance manufacturer>

Detailed analytical procedures shall be provided in Module 3 under section 3.2.S.4.2

2.3.S.4.3 Validation of Analytical Procedures

(a) Summary of the validation information (e.g. validation parameters and results):

<Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s)>

Detailed data of verification of analytical procedures shall be provided in Module 3 under section 3.2.S.4.3

2.3.S.4.4 Batch Analyses

<Provide summarized results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer >

<Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacturer shall also be submitted>

(a) Summary of batch analyses release results *of the Drug Product manufacturer* for relevant batches used during product development and stability studies:

Test	**Acceptance Criteria**	**Results**		
		<batch x>	**<batch y>**	**etc.**
Description				
Identification				
Impurities				
Assay				
etc.				

<A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)>

2.3.S.4.5 Justification of Specification

<A discussion shall be provided on the inclusion of certain tests, evolution of tests, analytical procedures and acceptance criteria, and differences from the officially recognized compendial standard(s)>

2.3.S.5 Reference Standards or Materials

(a) CoA of primary / secondary reference standard including source and lot number:

<For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable>

2.3.S.6 Container Closure System

(a) Description of the container closure system(s) for the shipment and storage of the Drug Substance:

Packaging component	Materials of construction

2.3.S.7 Stability

2.3.S.7.1 Stability Summary and Conclusions

(a) Summary of accelerated and long-term stability study testing parameters:

Accelerated stability study				
Storage condition (◦C, % RH)	**Batch number**	**Batch size**	**Container closure system**	**Completed testing intervals**

Long term / Real time stability study				
Storage condition (◦C, % RH)	**Batch number**	**Batch size**	**Container closure system**	**Completed testing intervals**

(b) Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate):

Container closure system	Storage conditions / Storage statement	Re-test period*

* indicate if a shelf-life is proposed in lieu of a re-test period (e.g. in the case of labile Drug Substance).

2.3.S.7.2 Post-approval Stability Protocol and Stability Commitment

The submission against this point is optional.

2.3.S.7.3 Stability Data

(a) Summary of the stability results observed for the accelerated and long-term studies:

The actual stability results shall be provided in *Module 3* section 3.2.S.7.3.

2.3.P Drug Product

2.3.P.1 Description and Composition of the Drug Product

(a) Description of the Drug Product:

<e.g The proposed XYZ 50-mg tablets are available as white, oval, film coated immediate release tablets, debossed with'50' on one side and a break line on the other side>

(b) Composition of the Drug Product:

i. **Composition, i.e. list of all components of the Drug Product and their amounts on a per unit basis and percentage basis (including individual**

components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**	
		Quant. per unit or per mL	**%**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>			
Subtotal 1			
<complete with appropriate title e.g. Film-coating >			
Subtotal 2			
Total			

(c) Description of accompanying reconstitution diluent(s), if applicable:

<Provide summarized information (including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug product>

(d) Type of container closure system used for the Drug Product and accompanying reconstitution diluent, if applicable:

<The container-closure used for the drug product (and accompanying reconstitution diluent, if applicable) shall be briefly described, with further details provided under 3.2.P.7 Container-closure system>

2.3.P.2 Pharmaceutical Development

2.3.P.2.1 Components of the Drug Product

2.3.P.2.1.1 Drug Substance

(a) Discussion of the:

i. **compatibility of the Drug Substance(s) with excipients listed in 2.3.P.1:**

<If the qualitative composition of the formulation is not similar to innovator / reference product, the drug-excipient compatibility studies shall be provided>

ii. **key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product:**

iii. **for fixed-dose combinations, compatibility of Drug Substance(s) with each other:**

<For combination products, which are not approved by any reference regulatory authority, the compatibility of drug substances with each other shall be discussed>

2.3.P.2.1.2 Excipients

(a) Discussion of the choice of excipients listed in 2.3.P.1, their concentrations and characteristics that can influence the Drug Product performance):

2.3.P.2.2 Drug Product

2.3.P.2.2.1 Formulation Development

(a) Summary describing the development of the Drug Product:

<Brief discussion on the formulation development procedure adopted for the currently applied Drug Product>

(b) Pharmaceutical equivalence:

<The comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted and discussed>

For innovator drug products, the submission of pharmaceutical equivalence is not required.

i. Summary of the results of comparative dissolution profile (where applicable):

<The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 shall be submitted and discussed>

<For comparative dissolution profile, the guidelines specified in WHO Technical Report Series No. 992, 2015, Annex 7, Appendix 1 Recommendations for conducting and assessing comparative dissolution profiles and USFDA Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms - Dissolution Profile Comparisons may be followed>

For innovator drug products, the submission of comparative dissolution profile is not required.

2.3.P.2.2.2 Overages

(a) Justification of overages in the formulation(s) described in 2.3.P.1:

<Generally overages are not acceptable unless fully justified>

2.3.P.2.2.3 Physicochemical and Biological Properties

(a) Discussion of the parameters relevant to the performance of the Drug Product (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties):

2.3.P.2.3 Manufacturing Process Development

(a) Discussion of the development of the manufacturing process of the Drug Product (e.g. optimization of the process, selection of the method of sterilization):

<The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified>

<Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided.>

2.3.P.2.4 Container Closure System

(a) Discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the Drug Product (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the Drug Product):

<A brief description of container closure shall be included>

(b) For a device accompanying a multi-dose container, a summary of the study results demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume for the lowest intended dose):

<e.g. for Dry Powder Inhalers supplied with rotacaps, the studies including uniformity of delivered dose, aerodynamic particle size distribution etc. shall be provided>

2.3.P.2.5 Microbiological Attributes

(a) Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies):

<Antimicrobial (preservative) effectiveness studies to be performed as per recommendations of pharmacopoeia>

2.3.P.2.6 Compatibility

(a) Discussion of the compatibility of the Drug Product (e.g. with reconstitution diluent(s) or dosage devices, co-administered Drug Product(s)):

<Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product>

2.3.P.3 Manufacture

2.3.P.3.1 Manufacturer(s)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing:

Name and address **(include block(s)/unit(s))**	**Responsibility**

(b) Good Manufacturing Practices (GMP) certificate of all manufacturing sites mentioned above:

<For applications of locally manufactured drug products, GMP certificate of all sites shall be provided in Module 1>

<For applications of imported drug products, Certificate of Pharmaceutical Product or GMP certificate of all manufacturing sites shall be provided in Module 1>

2.3.P.3.2 Batch Formula

(a) List of all components of the Drug Product to be used in the manufacturing process and their amounts on a per batch basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Proposed commercial batch size(s) (e.g. number of dosage units)	
Component and quality standard	**Quantity per batch**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>	
Subtotal 1	
<complete with appropriate title e.g. Film-coating >	
Subtotal 2	
Total	

2.3.P.3.3 Description of Manufacturing Process and Process Controls

(a) Flow diagram of the manufacturing process:

<A flow diagram shall 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 shall be identified>

<The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified>

2.3.P.3.4 Controls of Critical Steps and Intermediates

(a) Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates:

Step (e.g. granulation, compression, coating)	Controls	
	Tests	Acceptance criteria

<Tests and acceptance criteria of the critical steps identified in Description of Manufacturing Process and Process Controls shall be provided, to ensure that the process is controlled>

2.3.P.3.5 Process Validation and/or Evaluation

(a) Summary of the proposed process validation protocol for the critical steps or critical assays used in the manufacturing process:

<For applications of locally manufactured drug products, a brief description of process validation including the proposed protocol based upon the process steps and controls mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be described. It shall be noted that first three consecutive batches of commercial scale will be subjected to the process validation in accordance with the protocol>

<For applications of imported drug products, process validation reports including the protocols and results for critical process steps mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be provided>

2.3.P.4 Control of Excipients

<If the excipient(s) are in pharmacopoeia there is no need to provide detailed specifications or its analytical procedures. However for excipients of non-compendial standards, specifications as well as analytical procedures shall be provided>

2.3.P.4.1 Specifications

(a) Summary of the specifications for in-house standard excipients:

<The specifications for excipients of non-compendial standard shall be provided>

2.3.P.4.2 Analytical Procedures

(a) Summary of the analytical procedures for in-house standard excipients:

<Copies of analytical procedures of non-compendial excipient shall be submitted>

2.3.P.4.3 Validation of Analytical Procedures

(a) Summary of the validation information for the analytical procedures for in-house standard excipients:

2.3.P.4.4 Justification of Specifications

(a) Justification of the specifications for the analytical procedures for in-house standard excipients:

2.3.P.4.5 Excipients of Human or Animal Origin

<For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE>

2.3.P.4.6 Novel Excipients

<For excipient(s) used for the first time in a drug product or by a new route of administration, full details of specification and testing method shall be provided>

2.3.P.5 Control of Drug Product

2.3.P.5.1 Specification(s)

(a) Specification(s) for the Drug Product:

Standard (e.g. USP, BP, Ph.Int., JP, in-house)			
Specification reference number and version			
Test	**Acceptance criteria (release)**	**Acceptance criteria (shelf-life)**	**Analytical procedure (type/source/version)**
Description			
Identification			
Impurities			
Assay			
etc.			

<Specifications shall include the degradation products and related substances>

2.3.P.5.2 Analytical Procedures

(a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing):

<Provide brief tabulated summary of analytical procedures including key method parameters and conditions instead of attaching detailed analytical methods of Drug Product>

Detailed analytical procedures shall be provided in Module 3 under section 3.2.P.5.2

2.3.P.5.3 Validation of Analytical Procedures

(a) Summary of the validation information (e.g. validation parameters and results):

<For in-house methods, analytical method validation shall be performed>

<All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy>

<Brief summary of validation / verification shall be provided here, instead of attaching detailed protocols and results of analytical method validation>

Summarized tabulated results of validation / verification shall be provided in 2.3.R.2.

2.3.P.5.4 Batch Analyses

(a) Description of the batches:

Batch number	**Batch size**	**Date of manufacturing**	**Use (e.g. pharmaceutical equivalence or stability)**

(b) Summary of batch analyses release results for relevant batches (e.g. comparative bioavailability or biowaiver, stability):

Test	**Acceptance criteria**	**Results**		
		<batch x>	**<batch y>**	**etc.**
Description				
Identification				

Test	Acceptance criteria	Results		
		<batch x>	<batch y>	etc.
Impurities				
Assay				
etc.				

2.3.P.5.5 Characterization of Impurities

<Those impurities that are degradation product shall be included in the specifications>

2.3.P.5.6 Justification of Specification(s)

<The justification of specification(s) for non-pharmacopeial products must be provided. Justification of specification of non-pharmacopeial product shall be based on batch analysis results>

2.3.P.6 Reference Standards or Materials

(a) Specifications of primary / secondary reference standard including source and lot number for primary reference standards:

<For testing of Pharmacopeial Drug Product(s), the use of primary reference standard is recommended, however for non-pharmacopeial Drug Product(s), a secondary reference standard is acceptable>

2.3.P.7 Container Closure System

(b) Description of the primary container closure systems, including unit count or fill size, container size or volume:

Description of primary container closure (including materials of construction)	Unit count or fill size (e.g. 60s, 100s etc.)	Container size (e.g. 5 ml, 100 ml etc.)

2.3.P.8 Stability

2.3.P.8.1 Stability Summary and Conclusions

(a) Summary of accelerated and long-term stability study:

Accelerated stability study				
Storage condition (◦C, % RH)	**Batch number**	**Batch size**	**Container closure system**	**Completed testing intervals**

Long term / Real time stability study				
Storage condition (◦C, % RH)	**Batch number**	**Batch size**	**Container closure system**	**Completed testing intervals**

(b) Summary of additional stability studies (if applicable): *<e.g. in-use studies for drug products which are to be reconstituted before use>:*

(c) Proposed storage statement and shelf-life:

Container closure system	Storage statement	Shelf-life

(d) Proposed in-use storage statement and in-use shelf-life:

Storage statement	Shelf-life

All the data and statements provided in this section shall be based on ICH and WHO guidelines

2.3.P.8.2 Post-approval Stability Protocol and Stability Commitment

(a) Stability protocol for *Commitment batches* (e.g. storage conditions, batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	Details	
Storage condition(s) (◦C, % RH)		
Batch number(s) / batch size(s)	*<not less than three production batches in each container closure system>*	
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		

Parameter	Details
Container closure system(s)	

<For applications of imported drug product(s) where stability study data till complete shelf life is submitted, post-approval stability protocols and commitment is not required>

2.3.P.8.3 Stability Data

(a) Conclusion of the stability studies:

The actual stability results shall be provided in Module 3 section 3.2.P.8.3

2.3.A Appendices

2.3.A.1 Facilities and Equipment

<Provide a list of manufacturing and testing facilities / equipment available with reference to the applied drug product>

2.3.A.2 Adventitious Agents Safety Evaluation

The submission against this point is optional.

2.3.A.3 Excipients

<For excipient(s) used for the first time in a drug product or by a new route of administration, full details of manufacture, characterization, and controls, with cross references to supporting safety (non-clinical and/or clinical) data shall be provided>

2.3.R Regional Information

2.3.R.1 Production Documentation

2.3.R.1.1 Executed Production Documents

<Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>

2.3.R.1.2 Master Production Documents

<For applications of locally manufactured drug product(s), provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product>

<For applications of imported drug product(s) the submission of master production documents is not required>

2.3.R.2 Analytical Procedures and Validation Information for Drug Product

<Provide analytical method validation / verification results in the table below>

ANALYTICAL PROCEDURES AND VALIDATION INFORMATION SUMMARIES			
HPLC Method Summary		**Volume/Page:**	
Method name:			
Method code:		**Date:**	
Column(s) / temperature (if other than ambient):			
Mobile phase (specify gradient program, if applicable):			
Detector (and wavelength, if applicable):			
Flow rate:			
Injection volume:			
Sample solution preparation and concentration (expressed as mg/ml, let this be termed "A"):			
Reference solution preparation and concentration (expressed as mg/ml and as % of "A"):			

System suitability solution concentration (expressed as mg/ml and as % of "A"):	
System suitability tests (tests and acceptance criteria):	
Method of quantification (e.g. against API or impurity reference standard(s)):	

Validation Summary		**Volume/Page:**			
Analytes:					
Typical retention times (RT)					
Relative retention times ($RT_{Imp.}/RT_{API\ or\ Int.\ Std.}$):					
Relative response factor ($RF_{Imp.}/RF_{API}$):					
Specificity:					
Linearity / Range:	**Number of concentrations:** **Range (expressed as mg/ml and as % "A"):** **Slope:** **Y-intercept:** **Correlation coefficient (r^2) :**				
Accuracy:	**Conc.(s) (expressed as mg/ml and as % "A"):** **Number of replicates:** **Percent recovery (avg/RSD):**				
Precision / Repeatability: (intra-assay precision)	**Conc.(s) (expressed as mg/ml and as % "A"):** **Number of replicates:** **Result (avg/RSD):**				
Precision / Intermediate Precision: (days/analysts/equipment)	**Parameter(s) altered:** **Result (avg/RSD):**				
Limit of Detection (LOD): (expressed as mg/ml					

and as % "A")		
Limit of Quantitation (LOQ): (expressed as mg/ml and as % "A")		
Robustness:	**Stability of solutions:** **Other variables/effects:**	
Typical chromatograms or spectra may be found in:		
Company(s) responsible for method validation:		

2.4 Non-Clinical Overview

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.4 is optional.

2.5 Clinical Overview

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.5 is optional.

2.6 Non-Clinical Written and Tabulated Summaries

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.6 is optional.

2.7 Clinical Summary

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.7 is optional.

10 MODULE 3: (QUALITY / CMC)

A properly completed Module 3 will facilitate preparation of the Quality Overall Summary (QOS) and will expedite the submission review process.

3.2.S Drug Substance

3.2.S.1 General Information

3.2.S.1.1 Nomenclature

Information on the nomenclature of the drug substance shall be provided. For example: INN, compendial name, USAN, BAN, CAS registry name where applicable.

3.2.S.1.2 Structure

The structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass shall be provided. For APIs existing as salts or esters the molecular mass of the free base or acid shall also be provided.

3.2.S.1.3 General Properties

The physical and chemical properties of the API shall be discussed, including the physical description, solubility in common solvents (e.g. water, alcohols, dichloromethane and acetone), quantitative aqueous pH solubility profile (e.g. pH 1.2–6.8, dose/solubility volume), polymorphism, pH and pKa values, ultraviolet (UV) absorption maxima and molar absorptivity, melting point, refractive index (for a liquid), hygroscopicity and partition coefficient.

This list is not intended to be exhaustive but provides an indication as to the type of information that could be included. Such information can be obtained either from the open part of drug master file or from manufacturer as well as from reference literature.

3.2.S.2 Manufacture

The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided. It is important that the site of the manufacturer as well as its role and responsibility with respect to manufacturing, packing and testing shall be clearly identified. The name and address of the site shall be given. If the manufacturing, processing, packaging or testing is performed by an outside contractor or third party contractor, this shall be clearly identified and copy of quality agreement shall be included.

A certificate of compliance with GMP shall be provided in the Module-1.

3.2.S.3 Characterization

3.2.S.3.1 Elucidation of Structure and other Characteristics

Drug substances /Active Pharmaceutical Ingredients that are not described in an officially recognized pharmacopoeia, the studies carried out to elucidate and/or confirm the chemical structure normally include elemental analysis, infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR) and mass spectra (MS) studies. Other tests could include X-ray powder diffraction (XRPD) and differential scanning calorimetry (DSC). Drug substance /Active Pharmaceutical Ingredients that are described in an officially recognized pharmacopoeia it is generally sufficient to provide copies of the IR spectrum.

Discussion on the potential for isomerism and identification of stereochemistry, studies performed to identify potential polymorphic forms and particle size distribution of the Drug substance shall be submitted, where these parameters may impact the quality, safety or efficacy of the drug product.

3.2. S.3.2mpurities

List of Drug Substance / API-related impurities and process-related impurities shall be submitted along with acceptance limits.

3.2.S.4 Control of Drug Substance

3.2.S.4.1 Specification

Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.

3.2.S.4.2 Analytical procedures

Detailed analytical procedures for the testing of drug substance shall be provided.

3.2.S.4.3 Validation of analytical procedures

Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.

3.2.S.4.4 Batch analysis

Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.

A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).

3.2.S.4.5 Justification of specifications

A discussion/justification shall be provided on the inclusion of certain tests, evolution of tests, analytical procedures and acceptance criteria. Any differences from the officially recognized compendial standard(s) shall also be justified.

3.2.S.5 Reference Standards or Materials

For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable.

COA of primary / secondary reference standard including source and lot number shall be provided.

3.2.S.6 Container Closure System

Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component.

Other information on the container closure system(s) (e.g. suitability studies) may be submitted.

3.2.S.7 Stability

- The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted.
- For locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV a conditions.
- In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.
- Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.

3.2.S.7.1 Stability Summary and Conclusions (name, manufacturer)

Should include the study conditions, including all of the storage conditions (temperature, humidity, light) in which the drug substance is evaluated, analytical methods, specifications, summary of results, and conclusions. Reference ICH Guidelines: Q1A, Q1B, and Q5C

3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment (name, manufacturer)

It refers to the continuation of the stability study, including the number of lots to be included in the study each year and the tests to be performed.

Reference ICH Guidelines: Q1A and Q5C

3.2.S.7.3 Stability Data (name, manufacturer)

Results of the stability studies (Real time & Accelerated) should be presented in an appropriate format.

3.2.P Drug Product

3.2.P.1 Description and Composition of the Drug Product

a) Description of the dosage form

The description of the Drug product shall include the physical description, available strengths, release mechanism (e.g. immediate or modified (delayed or extended)), as well as any other distinguishable characteristics, e.g.

"The proposed XYZ 50-mg tablets are available as white, oval, film coated tablets, debossed with '50' on one side and a break line on the other side.

b) Composition

List of all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications).

* *Overages are not acceptable unless fully justified*

If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride").

c) **Description of accompanying reconstitution diluent(s)**

Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.

d) Type of Container Closure:

The container-closure used for the Drug Product (and accompanying reconstitution diluent, if applicable) shall be briefly described, with further details provided under 3.2.P.7 Container-closure system

3.2.P.2 Pharmaceutical Development

A brief information on the pharmaceutical development shall be included. This information specify the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed.

3.2.P.2.1 Components of the Drug Product

Drug substance

Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product.

Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product.

For fixed-dose combinations, compatibility of Drug Substance(s) with each other shall be discussed, where in the applied formulation is not approved any reference regulatory authority.

Excipients

Discussion of the choice of excipients, their concentrations and characteristics that can influence the Drug Product performance shall be provided.

3.2.P.2.2 Formulation Development

a) A brief description of formulation development shall be given.

b) *Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.

c) Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 shall be submitted and discussed.

d) Justification of overages in the formulation(s) shall be submitted.

e) Discussion of the parameters relevant to the performance of the Drug Product (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties).

* For innovator drug products, the submission of pharmaceutical equivalence and comparative dissolution profile is not required.

3.2.P.2.3 Manufacturing Process Development

The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified.

Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided.

3.2.P.2.4 Container Closure System

Discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP) shall be provided.

For a device accompanying a multi-dose container, study results demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume for the lowest intended dose) shall be submitted.

3.2.P.2.5 Microbiological Attributes

Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.

3.2.P.2.6 Compatibility

Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.

3.2.P.3 Manufacture

3.2.P.3.1 Manufacturer

The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.

The list of manufacturers or companies shall specify the actual addresses of production or manufacturing site(s) involved (including block(s) and unit(s)), rather than the administrative offices.

For applications of locally manufactured drugs, GMP certificate of all sites shall be provided. For applications of imported drugs, Certificate of Pharmaceutical Product or GMP certificate of all manufacturing sites shall be provided.

3.2.P.3.2 Batch formula

A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.

If the drug product is formulated using an active moiety, then the composition for the drug substance shall be clearly indicated (e.g. “1 kg of active ingredient base = 1.075 kg active ingredient hydrochloride”).

3.2.P.3.3 Description of manufacturing process and process controls

A flow diagram shall 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 shall be identified.

Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section.

The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified.

3.2.P.3.4 Controls of critical steps and intermediates

Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled.

3.2.P.3.5 Process validation and/or evaluation

For applications of locally manufactured drug products, a brief description of process validation including the proposed protocol shall be described. A commitment to perform process validation on first three consecutive batches of commercial scale shall be provided in Module-1.

For applications of imported drug products, process validation reports including the protocols and results for critical process steps mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be provided.

3.2.P.4 Control of Excipients

3.2.P.4.1 Specifications

The specifications for excipients shall be provided. If the excipient(s) are in pharmacopoeia there is no need to provide detailed specifications or its analytical procedures. However for excipients of non-compendial standards, specifications as well as analytical procedures shall be provided.

The colors permitted for use are limited to those listed in the FDA "Inactive ingredient guide", "Japanese pharmaceutical excipients" or the European Union (EU) "List of permitted food colors".

For proprietary mixtures, the composition sheet provided by the supplier shall be submitted.

3.2.P.4.2 Analytical procedures

Copies of analytical procedures of non-compendial excipient shall be submitted.

3.2.P.4.3 Validation of analytical procedures

Validation information for the analytical procedures for in-house standard excipients shall be submitted.

3.2.P.4.4 Justification of specifications

Justification of the specifications for the analytical procedures for in-house standard excipients shall be provided.

3.2.P.4.5 Excipients of Human or Animal Origin

For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE.

3.2.P.4.6 Novel Excipients

For excipient(s) used for the first time in a drug product or by a new route of administration, full details of specification and testing method shall be provided.

3.2.P.5 Control of Drug Product

3.2.P.5.1 Specification(s)

A copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure shall be provided. Specifications shall also include the details of impurities (as applicable).

3.2.P.5.2 Analytical procedures

Detailed analytical procedures used for testing the drug product shall be provided.

3.2.P.5.3 Validation of analytical procedures

For in-house methods, analytical method validation shall be performed.

All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy.

3.2.P.5.4 Batch analysis

The copies of complete analysis of at least two batches shall be provided.

3.2.P.5.5 Characterization of impurities

Those impurities that are degradation product shall be included in the specifications.

3.2.P.5.6 Justification of specifications

The justification of specification(s) for non-pharmacopeial products must be provided. Justification of specification of non-pharmacopeial product shall be based on batch analysis results.

3.2.P.6 Reference Standards or Materials

For testing of Pharmacopeial Drug Product(s), the use of primary reference standard is recommended, however for non-pharmacopeial Drug Product(s), a secondary reference standard is acceptable.

COA of primary / secondary reference standard including source and lot number shall be provided.

3.2.P.7 Container Closure System

A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.

3.2.P.8 Stability

For the pre-market authorization stability studies for a period of 6 months accelerated and real time in proposed container closure system is required in accordance with the Zone IVa conditions. Based on the satisfactory results, a two years shelf life will be granted. For selection of number and size of batches applicant may follow , any of the following options:

a) ICH/WHO guidelines.

b) At least 2 batches having the following minimum batch size considering the scientific reliability

- OSDs : 5000 Units
- Oral Liquid/Suspension : 2000
- Injectable : 2000
- Aerosol and any other specialized preparations : 500

c) At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life.

3.2.P.8.1 Stability summary and conclusion (Finished pharmaceutical product):

Summary of stability batches with details of storage conditions, batch numbers, batch size, testing intervals and container closure system along with proposed storage statement and shelf-life shall be provided.

Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.

3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment:

For applications of locally manufactured drug product(s), stability protocol for commitment batches (e.g. storage conditions, batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s) shall be provided. A written commitment (signed and dated) to continue long-term testing over the shelf-life shall be included in Module-1.

For applications of imported drug product(s) where stability study data till complete shelf life is submitted, post-approval stability protocols and commitment is not required.

3.2.P.8.3 Stability Data:

Results of the stability studies shall be presented in an appropriate format (provided below).

The actual stability results and reports used to support the proposed shelf-life shall be provided. For quantitative tests (e.g. individual and total degradation product tests and assay tests), actual numerical results shall be provided rather than vague statements such as "within limits" or "conforms". Conduction of stability study data shall be scientifically justified.

Storage Conditions:

a) General case

The general case applies if the drug product is not specifically covered by any other storage condition in the subsequent sections.

Study	Storage condition
Accelerated	40°C ± 2°C / 75% RH ± 5% RH
Long term	30°C ± 2°C / 65% RH ± 5% RH

b) Drug products packaged in semi-permeable containers

Aqueous-based products packaged in semi-permeable containers shall be evaluated for potential water loss in addition to physical, chemical, biological, and microbiological stability.

Other comparable approaches can be developed and reported for non-aqueous, solvent-based products.

Study	Storage condition
Accelerated	40°C ± 2°C / NMT 25% RH
Long term	30°C ± 2°C / 35% RH ± 5% RH

c) Drug products intended for storage in a refrigerator

Study	Storage condition
Accelerated	25°C ± 2°C / 60% RH ± 5% RH
Long term	5°C ± 3°C

d) Drug products intended for storage in a freezer

Study	Storage condition
Accelerated	5°C ± 3°C or 25°C ± 2°C
Long term	- 20°C ± 5°C

Stability data submission:

- For applications of imported drug product(s), real time and accelerated stability data (summary sheets) as per ICH guidelines or till claimed shelf life as per the storage conditions mentioned above shall be provided.
- For applications of locally manufactured drug product(s), the stability study data shall be provided as per the below mentioned format.

Stability study data submission locally manufactured products for CTD:

Stability Study Data Sheet

Product details:

<table>
<tr><td>Product name</td><td colspan="2">ABCD 100mg tablets</td><td>Batch No.</td><td></td></tr>
<tr><td>Description of pack (container closure system)</td><td colspan="2">e.g: Alu-Alu blister of 10’s packed in printed unit carton, further packed in a master shipper.</td><td>Batch Size.</td><td></td></tr>
<tr><td>Parameters and tests mentioned</td><td colspan="2">As per Product Specifications</td><td>Mfg. Date</td><td></td></tr>
<tr><td rowspan="2">Recommended storage conditions</td><td>Accelerated conditions</td><td></td><td rowspan="2">Exp Date</td><td rowspan="2"></td></tr>
<tr><td>Real time conditions</td><td></td></tr>
<tr><td>Date of initiation of stability studies</td><td colspan="2"></td><td>(API) lot no.</td><td></td></tr>
</table>

Accelerated Stability study data:

Storage conditions				
Assessment frequency (Months)		Initial	3	6
Date of Testing				
Tests (as per specifications)	Acceptance Criteria			

Real time stability study data:

Storage conditions				
Assessment frequency (Months)		Initial	3	6
Date of Testing				
Tests (as per specifications)	Acceptance Criteria			

Documents / Data to be provided along with stability study data:

1.	Reference of previous approval of applications with stability study data of the firm (if any)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

3.	Documents for the procurement of API with approval from DRAP (in case of import).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

3.2.A Appendices

3.2.A.1 Facilities and equipment

A list of manufacturing and testing facilities / equipment available with reference to the applied drug product shall be provided.

3.2.A.2 Adventitious agent safety evaluation

The submission against this point is optional.

Excipients

For excipient(s) used for the first time in a drug product or by a new route of administration, full details of manufacture, characterization, and controls, with cross references to supporting safety (non-clinical and/or clinical) data shall be provided.

3.2.R Regional Information

3.2.R.1 Production Documentation Human Blood product with required supporting documents:

The submission against this point is optional.

3.2.R.2 TSE Checklist with required supporting documents:

For excipients of human or animal origin, a certificate stating that all excipients used in the applied drug product, are free from BSE and TSE.

3.2.R.3 Product Interchangeability (Bioequivalence study reports):
The applicant will submit Bio-equivalence studies for molecules mentioned in the notification No-F-348-DRB-Addl-Dir (PE&R-I)/2025 dated 17th July, 2025.

< While summary BE data may be presented in Module 2 of the Form 5F, the detailed study reports must be submitted under Modules 3 and 5 of the CTD, which should be considered mandatory for all applicable cases.>

All Studies including comparative pharmacokinetic studies & comparative clinical trials or any other studies involving human subjects shall only be conducted after approval from the Clinical Studies Committee (CSC) as per the Bio-Study Rules, 2017. *<For imported products, the approval of BE protocols from the regulatory authority of the country of origin/ or where BE studies have been performed shall be submitted.>*

The studies must be performed as per DRAP's GUIDELINE ON REGISTRATION REQUIREMENTS TO ESTABLISH THE INTERCHANGEABILITY OF PHARMACEUTICAL DRUG PRODUCTS.

3.2.R.4 Blank production batch record:

For applications of locally manufactured drug product(s), provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product

For applications of imported drug product(s) the submission of master production documents is not required.

3.3 Literature References

11 Module 4: (Non-clinical / Safety)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 4 is optional.

12 Module 5: (Clinical / Efficacy)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 5 is optional.

Section/subsection wherein data submission is optional:

Registration Board decided that data requirements for following components / part of CTD will be optional.

Chemistry, Manufacturing and Control (CMC) data		
Sub-section of Drug substance	**Sub section in Module 2**	**Sub section in Module 3**
Description of Manufacturing Process and Process Controls	2.3.S.2.2	3.2.S.2.2
Control of Materials	2.3.S.2.3	3.2.S.2.3
Control of critical steps and Intermediates	2.3.S.2.4	3.2.S.2.4
Process Validation and/or Evaluation	2.3.S.2.5	3.2.S.2.5
Manufacturing Process Development	2.3.S.2.6	3.2.S.2.6
Post-approval Stability Protocol and Stability Commitment	2.3.S.7.2	3.2.S.7.2

Non-Clinical and Clinical Data
Module / Section / Sub-section
Module 2.4 Non-Clinical Overview
Module 2.5 Clinical Overview
Module 2.6 Non-Clinical Written and Tabulated Summaries
Module 2.7 Clinical Summary
Module 4: (Non-clinical / Safety)
Module 5: (Clinical / Efficacy)

13 REFERENCES

1. The DRAP Act, 2012.
2. The Drugs Act 1976.
3. The Drugs (Licensing, Registering and Advertising) Rules, 1976.
4. Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6 of WHO Technical Report Series No. 986, 2014).
5. ICH -M4Q (R1) Guidelines.
6. WHO QUALITY OVERALL SUMMARY: PRODUCT DOSSIER (QOS-PD) TEMPLATE

Islamabad
www.dra.gov.pk