Guidance for Submission

Version 4.0

Drug Sector

March 2014

Guidance for Submission

Version 4.0

Drug Sector

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

Please visit SFDA's website at http://www.sfda.gov.sa/En/Drug for the latest update

Drug Sector

Vision & Mission

Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

الرؤية

أن يكون قطاع الدواء رائداً إقليميا في الرقابة على الأدوية ومستحضرات التجميل، ويقدم خدماته بمهنية متميزة تسهم في حماية وتعزيز الصحة في المملكة العربية السعودية.

Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

الرسالة

حماية الصحة العامة من خلال ضمان أمان وجودة وفعالية وتوفر الأدوية البشرية والبيطرية والمنتجات الحيوية وسلامة مواد التجميل عبر تطبيق نظام وطني للرقابة متوافق مع أفضل الممارسات الدولية وتقديم المعلومات الدوائية المبنية على أسس علمية للعامة والمهنيين الصحيين.

Document Control

Version	Date	Author(s)	Comments
1.0	11/05/2009	Licensing department	Initial draft for internal consultation
1.1	20/05/2009	Licensing department	Draft revision
1.2	06/06/2009	Licensing department	Draft revision
1.3	28/06/2009	Licensing department	Revisions after management discussion
2.0	08/07/2009	Licensing department	Published for comments
2.1	20/7/2010	Regulatory Affairs	Internal revision
2.2	18/9/2011	Regulatory Affairs	External consultation
2.3	2/12/2011	Regulatory Affairs	Final revision
2.4	7/12/2011	Regulatory Affairs	Approved by management
3.0	17/12/2011	Regulatory Affairs	Published
3.1	08/05/2012	Regulatory Affairs	Updated and Published version
3.2	10/10/2012	Regulatory Affairs	Updated version
4.0	**16/03/2014**	**Regulatory Affairs**	**Final version posted**

Table of Contents

1   Introduction

The Drug Sector in the Saudi Food & Drug Authority (SFDA) has developed this document, "Guidance for Submission" to assist applicants and industry in the preparation and submission of drug applications for new Marketing Authorization (MA) as well as renewals and variations to existing products to the SFDA. The guidance provides an outline of the way the Framework will be managed with respect to drug applications by the SFDA.

It is intended to provide clarification to applicants of the way in which the Drug Sector in the SFDA manage information and material submitted in accordance with the *Regulatory framework for Drug Approvals (version 5.0).* Also, it provides assistance to comply with the requirements of filing and maintenance of their application.

Industry representatives, as well as the staff of the SFDA responsible for the drug application management, will follow this guidance and operational directions in various areas, including the handling of application information, procedure related to drug assessment, clarification and performance target of drug assessments.

To maintain its consistency and enhanced transparency, this guidance will be updated regularly to reflect the current practices in regulatory sciences. It is expected that this guidance and any amendments to it will create efficiency in the drug application management and reduce the number of clarification requests.

It should be noted that the SFDA has the right to request any information and data within the context of this guidance in order to assess adequately the safety, efficacy and quality of any medicinal products available in the Kingdom of Saudi Arabia. The SFDA is committed to ensuring that such requests are justifiable and decisions are clearly documented.

2   Scope

This guidance document applies to all **drug submission types**:

- Generics

- New drugs

- Biologics

- Radiopharmaceuticals

- Herbal & Health products

- Veterinary products

- Renewal of MA

- Variations

All submitted information and material will be screened to ensure that it is complete and of suitable quality to be reviewed. The same management principles will be applied consistently to all submission types.

This guidance document covers the preparation and filling requirements for submissions in paper-based CTD and electronic format. It is based on the ICH CTD and the eCTD Specifications, and the SFDA Regulatory Framework for Drug Approval.

3 Registration Process

Important Note:

- *All days mentioned throughout this document are __WORKING__ days (subject to change).*

All Applications will be subjected to the following procedures:

1. Online Filing of Application

The applicant shall fill up the appropriate application form in the SDR system. Once completed, application form cannot be submitted unless the payment is received by SADAD. A reference number will be assigned to the application once submitted to facilitate the communication with the SFDA. Then, the applicant will be given an opportunity to book an appointment to hand over the drug application (figure 1). An automatic reminder will be sent 3 days before the appointment. The applicant can reschedule 3 weeks before the chosen appointment. If it is missed, the applicant has to book a new appointment again by requesting a completion appointment by email (sdr.drug@sfda.gov.sa).
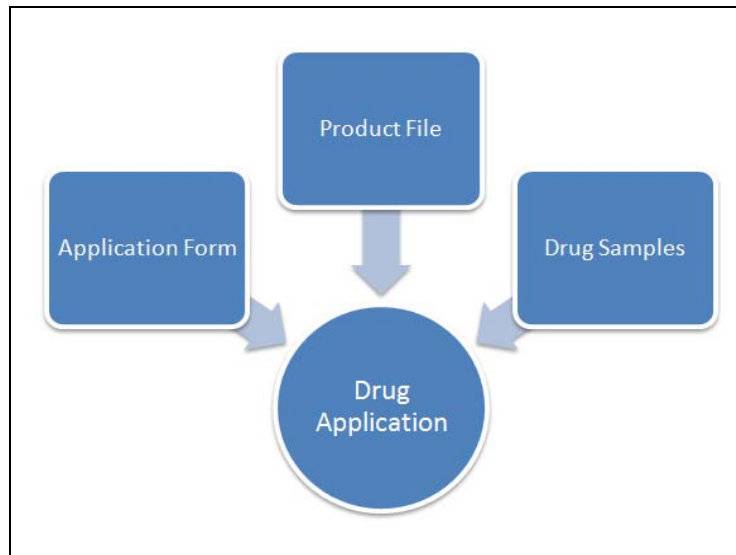

Figure 1: A "Drug Application" includes the application form, the product file and the drug samples

2. Acceptance of Drug Application

Upon receipt of the drug application in the appointment day, a checklist for 'Phase I Validation' will be used to verify that the information and materials provided are complete.

a. Drug application Without Deficiencies:

The applicant will be notified of the acceptability by printing an Acknowledgement Letter. Then, the drug application will be forwarded to the product manager for further processing and assessment. Once these applications are accepted, they will be assessed in the order in which they are received.

b. Drug application With Deficiencies:

If deficiencies are identified, an Acknowledgment Letter stating the deficiencies will be issued. The applicant will be required to submit the requested information within 90 days from the date of the letter.

- The applicant shall send an e-mail to the Drug sector (sdr.drug@sfda.gov.sa) requesting an appointment to complete the deficiencies.

- If the applicant has provided the requested information within 90 days, the application will be accepted and the drug application will be forwarded to the product manager for further processing and assessment.

- If the applicant has provided the requested information within 90 days, but it was found to be still incomplete, the applicant can complete the missing within the rest of the 90 days.

- If the applicant fails to provide the requested information within 90 days, the drug application will be rejected.

3. Phase II Validation

After accepting the drug application from the applicant, the submitted information and material will be validated to ensure that it has suitable quality to be assessed. However, if deficiencies are identified, the applicant will be

asked to submit the required information, and it will follow one of the following cases:

- If the applicant has provided the requested information within 90 days, the product file will be forwarded for further processing and assessment. The applicant will be notified by e-mail.

- If the applicant has provided the requested information within 90 days but it was found to be still incomplete, SFDA will study the case and may extend the period for another maximum 30 days. The applicant will be notified by e-mail.

- If the applicant fails to provide the requested information within 90 days, the drug application will be rejected.

4. Assessment of Application

All applications will be assessed in terms of quality, safety and efficacy – as needed – depending on the type of the product.

If issues are identified during the assessment, these issues will be resolved through electronic Inquiry Forms. Although there is no limitation of inquiries, it is expected that these issues be resolved by two to three inquiries. Responses to inquiries are required within 90 days.

5. Pricing

The pricing will be calculated according to the pricing rules outlined in the pricing guideline.

6. Testing

All drug products will be subjected to appropriate testing according to the type of the application and dosage form. Moreover, the applicant is requested to deliver the samples to SFDA headquarters as part of the drug application. There will be no direct contact between the applicant and SFDA's laboratory.

7. Inspection

The inspection department will communicate with the applicant to decide the appropriate time for inspection – if needed, depending on the schedules of the inspectors. After the inspection is done, an inspection report will be written and a copy of this report will be sent to the applicant. In case of deficiencies, further details will follow.

8. Stop-clock

The stop-clock starts whenever SFDA issues an Inquiry Form. Inquiries may be raised at any time from the Phase II Validation to SFDA decision. The stop-clock ends whenever SFDA receives complete and acceptable responses from the applicant.

If the applicant faces difficulties in responding to inquiries within the specified time, applicant should contact SFDA as soon as possible. A drug application will be considered rejected if the stop-clock time exceeds the SFDA deadline.

9. SFDA Decision

The final decision is made based on the outcome of SFDA's assessment, pricing, testing and inspection. The decision can be one of the following:

- **Approval**: when the drug application has satisfied the registration requirements for quality, safety and efficacy.
- **More information is needed**: when the drug application has minor deficiencies.
- **Rejection**: when the drug application has not satisfied the registration requirements.

10. Appeal Process

The applicant will have the right to appeal within 60 calendar days against the SFDA decision. The relevant guidance will be published.

4   Structure and Content of Submission

4.1 Structure and Content of Submission:

The SFDA will require all applicants to submit their applications in accordance to the ICH Common Technical Document (CTD) format. For more information on the CTD, please refer to appendix E.

The dossier requirements for each application will differ, depending on the type of application. For more details refer to appendix B.

It is important to remember that the CTD provides a format for an MAA and does not indicate the content of a dossier and which studies should be performed. Regional and national requirements may affect the content of the dossier; therefore the dossier will not necessarily be identical for all regions.

Relevant guidelines are updated and published in the Drug Sector website, such as Stability guideline, should be followed in providing the information or studies.

4.2 Module 1: Regional Administrative Information

This module includes the required regional information specific to GCC, such as administrative information and certificates. For more information, please refer to appendix A.

5   Presentation of the Product File

A softcopy (electronic-based) of the product file shall be submitted by the applicant along with a hardcopy (paper-based) of selected documents of Module 1 ONLY[1]. The softcopy shall be either:

a.   eCTD[2], or

b.   An electronic version of the product file in NeeS[3] format (appendix C)

5.1 Hardcopy and Softcopy Requirements:

For the **hardcopy** (selected documents of Module 1)**,** it should be bound into one volume (flat file). The flat file specifications:

  ➢ A4 lightweight flat file

  ➢ Clear front and opaque back cover with removable title strip, and with a two hole flat bar filing mechanism

  ➢ Label: should contain the following information (figure 2):
      1.   Reference number (generated from SDR system)
      2.   Company name
      3.   Product trade name
      4.   Product Generic name
      5.   Date of submission (DD/MM/YYYY)
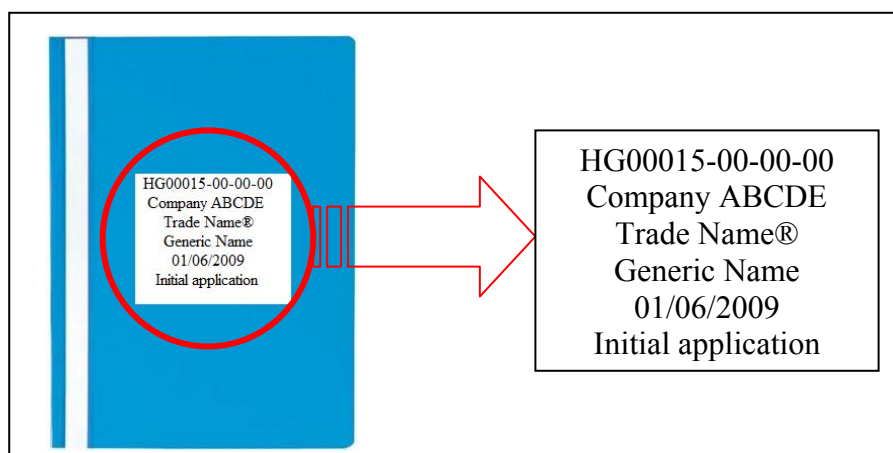   6.   Type of submission (e.g. initial, renew or variation)

Figure 2: Label information on the M1 hardcopy

---

[1] Refer to appendix A for more details
[2] eCTD is mandatory from 3/1/2015
[3] NeeS: Non-eCTD electronic Submission

For the **softcopy** (electronic-based), each CD or DVD and its hard plastic cover submitted should include the following label information, clearly presented and printed on the media with the font of 12 Times New Roman (or equivalent):

- The reference number
- The company name
- The product Trade name
- The Generic name
- The submission type of each submission(s) contained on the CD/DVD (e.g. initial)
- The sequence number(s) of the submissions contained on the CD/DVD (e.g. 0002)

5.2 Number of copies:

Applicants should submit:

a) THREE (3) softcopies (full submission)
b) and ONE hardcopy of selected documents of Module 1 for all drug submission types.

The submitted copies should be identical. The submission shall be in ONE media only (CD or DVD) i.e. if the submission size was above 750MB then the applicant has to use a DVD.

5.3 Media:

The electronic submission may only be submitted in CD or DVD (single or dual layer). The disc must not be bootable or have auto-start programs.

Currently both CD-ROM and DVD ISO 9660 are considered an acceptable media standard.

However, the SFDA will not accept any hardware (laptops, desktops, thumb drives, hard drive, floppy discs, etc.) from applicants in connection with the electronic submission.

5.3.1 System compatibility:

The electronic submission (as provided) must be directly readable and usable on SFDA hardware and software.

Although it is the policy of the SFDA to maintain desktop configurations and IT infrastructure in line with common office standards, the electronic information provided in the submission must not only be readable on the latest operating system, but support a reasonable number of backward versions of windows operating systems.

5.4 Security:

There are various aspects related to security. The physical security of the submission during transportation/transmission is the responsibility of the applicant. Once received within the SFDA, security and submission integrity is the sole responsibility of the SFDA. In this respect, it should be noted that the SFDA will take appropriate measures to prevent loss, unauthorized duplication and/or access or theft of regulatory information presented both on paper and electronic media that are distributed throughout the SFDA.

5.4.1 Password protection:

One-time security settings or password protection of electronic submissions for security purposes is not acceptable during transportation/transmission from the applicant to the SFDA.

Applicants should also not include any file level security settings or password protection for individual files in the electronic submission.

Applicants should allow printing, annotations to the documents, and selection of text and graphics. The Internal security and access control processes in the SFDA maintain the integrity of the submitted files.

5.4.2 Virus protection:

The applicant is responsible for checking the submission for viruses. Checking must be performed with an up-to-date and well-recognized Anti-virus application.

After receipt of the submission at the SFDA, a similar internal virus check will be performed. If a virus is detected it can constitute grounds for refusal of the electronic submission.

6 Document Requirements

6.1 Legibility and Size:

All documents should be legible. The page size, including tables, shall be uniform.

6.2 Page divider/tab:

A page divider or tab (with the header of the section printed) should be used to separate selected section in module 1.
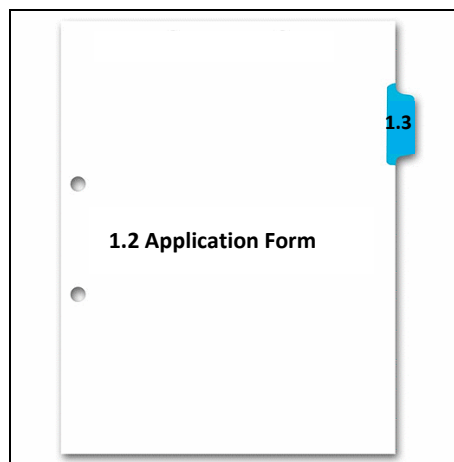

Figure 3: an example of a tab divider

6.3 Language:

Information and documents supporting a drug application – such as certificates and approval letters– must be either in Arabic or English. If documents are neither in Arabic nor English, a translation to English (from an authorized translation office) and authentication from the Saudi Embassy in the COO are required.

6.4 Authentication:

Authentication – also known as legalization – refers to the process whereby the origins of a document are attested. Authentications of documents are made to SFDA by the Health authority and/or the Ministry of Foreign affairs in the country of origin, in addition to the Saudi Arabia Embassy or Consulate where the document was issued. For more details, please refer to appendix A.

7 Inquiries

An applicant may receive an inquiry from SDR system. When the answers are ready, applicant shall do the following:

1. **In SDR:**

   a. Respond electronically to SDR inbox to close the inquiry *(Reason: to stop the clock)*

2. **In the softcopy[4]:**

   a. Provide SFDA with the following:

      i. Section 1.9 in module 1: should include a document which lists the inquiries (questions) with the corresponding narrative text response for each question. This section will not be used for supporting technical documentation which will be included to the relevant modules. Each question should be followed by the name of section, page number and a hyperlink where the answer can be found in the concerned module.

      ii. Relevant section(s) added in the right place of the submission

   b. Prepare a CD/DVD including the above document(s) in the form of:

      i. NeeS submission: follow the instructions in **appendix C** of this guidance.

      ii. eCTD submission[5]: follow the guideline "**GCC M1 Specifications**" published in the website.

Taking into account, the labelling of the CD as mentioned in page 15 of this guidance.

---

[4] Dossiers concerning herbal, health or veterinary products are *excluded*
[5] eCTD will be mandatory in 3 Jan 2015

Notes:

- No **hardcopy** is required with the submission.

- Only full answers of the inquiries are accepted.

8 Renewal

An applicant shall submit a renewal request every five years – on drug products that have already received a marketing authorization from the SFDA – at least six months before the certificate expires through the following steps:

1. **In SDR:**

   a. Choose the required drug under "*Registered Products*" section and press '**Renewal**' button

   b. Complete the form and submit it electronically

   c. Save a copy of the application form (for preparing the softcopy)

2. **In the softcopy[6]:**

   Prepare a CD/DVD including the required document in the form of:

   a. NeeS submission: follow the instructions in **appendix C** of this guidance.

   b. eCTD submission[7]: follow the guideline "**GCC M1 Specifications**" published in the website.

Notes:

- The hardcopy should consist only of the documents selected in the attachment A.

- The requirements of renewal are available in the SFDA's website.

---

[6] Dossiers concerning herbal, health or veterinary products are *excluded*
[7] eCTD will be mandatory in 3 Jan 2015

9 Variations

An applicant can submit a variation request – on drug products that have already received a marketing authorization from the SFDA – through the following steps:

1. **In SDR[8]:**

   a. Choose the required drug under "*Registered Products*" section and press '**Variation**' button.

   b. Complete the form and submit it electronically

   c. Save a copy of the application form (for preparing the softcopy)

2. **In the softcopy[9]:**

   Prepare a CD/DVD including the required document in the form of:

   a. NeeS submission: follow the instructions in **appendix C** of this guidance.

   b. eCTD submission[10]: follow the guideline "**GCC M1 Specifications**" published in the website.

Notes:

- No hardcopy is required with the submission except for the *cover letter*.

- The requirements of variation are available in the SFDA's website.

---

[8] The variation in SDR will be announced soon
[9] Dossiers concerning herbal, health or veterinary products are *excluded*
[10] eCTD will be mandatory in 3 Jan 2015

10 Gulf Cooperation Council – Drug Registration (GCC-DR)

If a product is registered in the Executive Board of the Health Ministers' Council for GCC States (GCC-DR), it can be registered in SFDA in a short time as long as the applicant will do the followings[11]:

1. Fill up the product application form in SDR system (refer to the published *"Guidance on how to use SDR"*) including:

    a. Paying the required fees

    b. Scheduling an appointment

2. In the appointment, submit the followings:

    a. The hardcopy of the documents selected in the attachment A, except sample form. The GCC certificate should be attached to the cover letter.

    b. Three (3) copies of the softcopy – CD/DVD (according to appendix C) of the full submission,

    c. One sample for pricing in the final packaging in addition to the PIL.

Note:

- GCC certificate can be a copy of the original.

---

[11] According to the SFDA circular no. 12338 dated 20/5/1431H

11 Appendices

Appendix A: GCC Module 1 Administrative Information

Section	Requirements	1✳	2✳	3✳	4✳	HC[12]
1.0	Cover letter	✔	✔	✔		✔
1.1	Table of contents					
1.2	Application Form		✔	✔		✔
1.3	Product Information					
1.3.1	Summary of Product Characteristics (SPC)					
1.3.2	Labeling					
1.3.3	Patient information leaflet (PIL)					
1.3.3.1	Arabic leaflet					
1.3.3.2	English leaflet					
1.3.4	Artwork (Mock-ups)					
1.3.5	Samples	✔	✔	✔		✔
1.4	Information on the experts					
1.4.1	Quality					
1.4.2	Non-Clinical					
1.4.3	Clinical					
1.5	Environmental Risk Assessment					
1.5.1	Non-Genetically Modified Organism (Non-GMO)					
1.5.2	GMO					
1.6	Pharmacovigilance					
1.6.1	Pharmacovigilance System	✔				
1.6.2	Risk Management Plan	✔				
1.7	Certificates and Documents					
1.7.1	GMP Certificate					
1.7.2	CPP or Free-sales[13]				✔	✔
1.7.3	Certificate of analysis – Drug Substance & Finished Product	✔[14]	✔[14]	✔[14]		
1.7.4	Certificate of analysis – Excipients					
1.7.5	Alcohol-content declaration	✔	✔	✔		
1.7.6	Pork-content declaration	✔	✔	✔		
1.7.7	Certificate of suitability for TSE					
1.7.8	The diluents and coloring agents in the product formula	✔	✔	✔		
1.7.9	Patent Information					
1.7.10	Letter of access or acknowledgment to DMF					✔
1.8	Pricing					
1.8.1	Price list	✔	✔	✔	✔	✔[15]
1.8.2	Other documents related					
1.9	Responses to questions					
	Additional data					

✳**1:** Company original paper (not a photocopy)

✳**2:** Signature of authorized person

✳**3:** Company official stamp

✳**4:** Authentication

---

[12] Hard-copy

[13] Not required for local manufacturers

[14] Only for Finished Product

[15] In the initial submission, a price list without authentication can be *accepted*, but provide one upon requested

Appendix B: Data Requirements

The data requirements for each application will differ, depending on the drug submission type. However, all the required data should be in accordance with the CTD structure.

Please refer to the following documents published in the website:

- Data requirements for Human Drugs Submission – *Content of the Dossier*

- Data requirements Update for Herbal and Veterinary Products

- The GCC Data Requirements for the Renewal of Marketing Authorization

- The GCC Guidelines for Variation Requirements

Appendix C: Electronic Version of the Paper-Based Submission

The electronic version of the submission is based on the ICH CTD and the SFDA Regulatory Framework for Drug Approval. This appendix details the requirements for the submission of Non-eCTD electronic Submissions (NeeS).

NeeS applications should be regarded as an **interim** format and that applicants should be actively planning their move to full eCTD submissions. A separate guidance document covering eCTD submission is published on the SFDA website.

The GCC-DR will also accept NeeS and eCTD in 2014 and 2015 respectively. Therefore, SFDA did minor changes on the m1 folder structure by adding "gc" folder.

Important Note: *dossiers concerning <u>herbal</u>, <u>health</u> or <u>veterinary</u> products are **excluded** at this moment.*

1. Structure of Submission:

Documents provided must be structured in accordance with the Common Technical Document (CTD), which for paper submission became mandatory in Saudi Arabia from January 2010.

For NeeS applications, the eCTD folder structure is used with the addition of ToC(s) as appropriate. The breakdown of the electronic submission should be in conformity with the ICH Granularity Document and the ICH and GCC eCTD file naming conventions should be followed.

The difference from an eCTD is that the two relevant XML files, the *index.xml* and *gc-regional.xml* for the backbone of Modules 2 to 5 and Module 1 for the GCC, respectively and the *util* folder are not present, so navigation through a NeeS is based on electronic Tables of Content, bookmarks and hypertext links.

Typically, a NeeS application will cover all **dosage forms** and strengths of a product with any one invented name.

1.1 Table of Contents and bookmarks:

Table of Contents (TOCs) should still always be provided by the applicant. It should always be submitted in PDF format. All documents in the NeeS dossier should be referenced from a hyperlinked Table of Contents (TOC).

Hyperlinks for each document should always be provided to the first page of the appropriate file. In the case of small dossiers (e.g. for certain variations), especially when only one module beside module 1 is concerned, it should be acceptable to only include a main TOC referring directly to the content documents. However, for larger submissions, the main TOC should always be linked to module TOCs which

are then further linked to the documents in each module. The module TOCs should not include hyperlinks to documents in other modules.

The file containing the main Table of Contents for the CTD should be named *ctd-toc.pdf* and be located in the top level folder for the Non eCTD submission. The files containing the module Tables of Content should be named *m1-toc.pdf*, *m2-toc.pdf*, *m3-toc.pdf*, *m4-toc.pdf* and *m5-toc.pdf* and be located in the corresponding top level module folder.

Where document TOCs are included they should be located within the same file as the rest of the document. For each document, provide bookmarks for every entry in the document's Table of Contents to the appropriate location, or where a Table of Contents does not exist, provide bookmarks to a sufficiently detailed level, typically to Level 3 or 4 headings, as considered appropriate.

An additional function might be provided to allow easy navigation back to the Table of Contents. This can be achieved through the use of a bookmark linked back to the previous level. This additional function is not mandatory, but when provided it will facilitate the assessment.
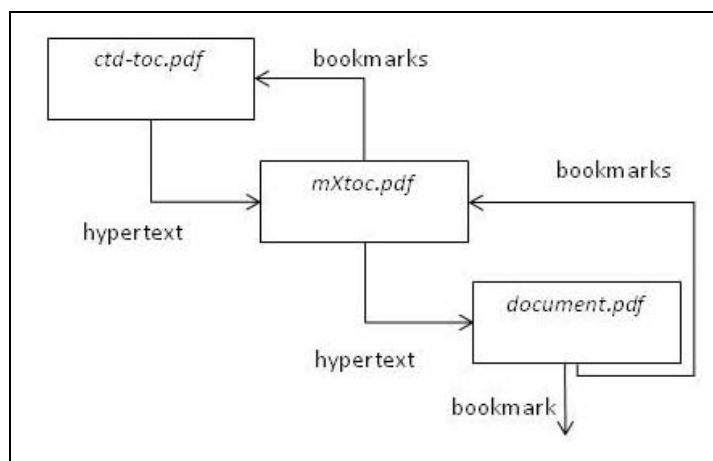

Figure 4: Principle for hypertext link use in TOC

1.2 Submission numbering:

The use of a four digit number in the top level folder name in which the ctd-toc.pdf file is placed is highly recommended. The number does not have to be unique or sequential but it is recommended that a sequential number is used whenever possible.

1.3 Moving to NeeS format applications:

A NeeS format application can be started with any initial, variation or renewal MA application. Once the switch to this electronic format is made it is expected that further applications and responses relating to the particular medicinal product are submitted in the same electronic format.

2. Submission Considerations:

2.1 File and folder structure:

Submissions are a collection of documents and each document should be provided as a separate file. The detailed structure of the NeeS should conform to the ICH Granularity Document and GCC M1 specifications.

Total folder/file path should not exceed 180 characters.

2.2 File Naming:

The eCTD file naming conventions described in the ICH M2 eCTD Specification and GCC Module 1.

Specification should be followed. If an applicant wishes to submit multiple files in one section, where only one highly recommended name is available, this can be achieved using a suffix to the filename, using the file name-var.pdf convention as described in the GCC Module 1 Specifications, where the *-var* component has no dashes or illegal characters (e.g. pharmaceutical-developmentcontainer.pdf).

2.3 Handling of Empty or Missing eCTD Sections:

For new applications (including generic applications), detailed statements justifying the absence of data or specific eCTD sections should be provided in the relevant Quality Overall Summary and/or Non-Clinical/Clinical Overviews (Module 2.3, 2.4, 2.5).

2.4 Correspondence:

In addition to the NeeS application, information may need to be exchanged to assist the processing or handling of the application. Not all such correspondence need to be included in the NeeS dossier.

2.4 File formats:

Detailed guidance on the specific file formats can be found in the ICH eCTD specification document and GCC Module 1 specifications.

2.4.1 PDF:

The majority of documents included in electronic submissions should be in PDF format. Please, see appendix D for more information.

2.6 Bookmarks and hypertext links:

Navigation through an electronic submission is greatly enhanced by the intelligent use of bookmarks and hypertext links. ICH guidance states "It is expected that any document that has a Table of Contents (TOC) will have bookmarks";

Documents without TOCs should have bookmarks included where it aids in the navigation around the document content.

In general terms, bookmarks and hyperlinks should be used to aid navigation. Additional details on creating bookmarks and hypertext links in PDF documents can be found in the ICH eCTD Specification, Appendix 7.

Each document should be referred to from a table of content (the overall TOC or any module TOC as applicable).

2.8 Technical validation of submissions

The technical validation of a NeeS is a separate activity to the content validation of a submission and takes place irrespective of the type of the submission.

A NeeS must pass both the technical validation and the business/content validation and errors found should be fixed by sending an updated NeeS submission.

The following items may be checked during validation:

- Virus check,

- Compliance with general requirements (e.g. PDF file properties),

- Compliance with the eCTD structure templates and naming convention

- Compliance with specific details of pure PDF submissions

- Bookmarks and hyperlinks,

- Security settings or password protection,

- Any other serious defect, incident, etc. associated with the initial processing of the electronic submission.

If any defects (such as non-functioning hyperlinks, hyperlinks to non-existing document…etc) are found, the applicant should submit a new file.

3. Specific Information:

Important note: *DELETE empty folders.*

3.1 Module 1: Table of Contents (ToC)

The ToC should be in the in the same level in main folder as in figure 5.

3.2 Module 1: 1.2 Application Form

The application form should always be provided as a searchable PDF file (except for the last page of signature).

3.3 Module 1: 1.3 Product Information

Product information should be supplied as a searchable PDF files.

3.4 Module 1: 1.9 Responses to questions

The organization of the submission of electronic information in response to a list of questions from SFDA should follow the same basic principles as the first submission.

The written response should be submitted following the response folder and file structure. In this case the written response document should be placed in a folder named for example "*ourdrug/0000/m1/gc/19-responses*".

Appropriate navigation in the submission should follow the same concepts.

4. Illustration:

An illustration of how to create a NeeS submission as follows:

Points to be considered:

- *The maximum length of the name of a single folder or file is 64 characters including extensions*

- *Total folder/file path should not exceed 180 characters.*

- *Folder or file names should be written in lower case only*

1. Create 5 folders and name them as *m1*, *m2*, *m3*, *m4* and *m5* respectively, as in figure 5. (*Note that, the TOC is in the main folder of the drug submission*)
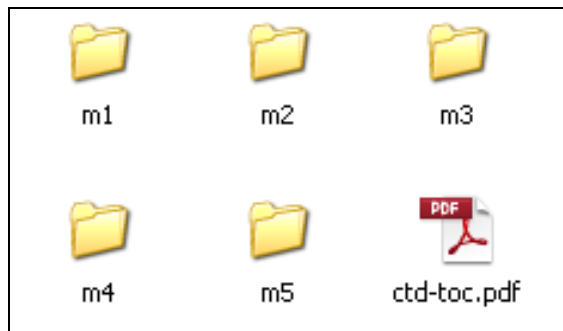

Figure 5: View of the product file after creation of m1 to m5

2. In *m1*, create a folder and name it "*gc*".

3. In *gc* folder, the folders and folder names described in table 1.

Table 1

Section	Description	Folder name
1.0	Cover letter	*10-cover*
1.2	Application Form	*12-form*
1.3	Product Information	*13-pi*
1.3.1	Summary of Product Characteristics (SPC)	*131-spc*
1.3.2	Labeling	*132-labeling*
1.3.3	Patient information leaflet (PIL)	*132- leaflet*
1.3.4	Artwork (Mock-ups)	*134- artwork*

Section	Description	Folder name
1.3.5	Samples	*135- samples*
1.4	Information on the experts	*14-expert*
1.4.1	Quality	*141-quality*
1.4.2	Non-Clinical	*142-nonclinical*
1.4.3	Clinical	*143-clinical*
1.5	Environmental Risk Assessment	*15-environrisk*
1.5.1	Non-Genetically Modified Organism (Non-GMO)	*151-nongmo*
1.5.2	GMO	*152-gmo*
1.6	Pharmacovigilance	*16-pharmacovigilance*
1.6.1	Pharmacovigilance System	*161-phvig-system*
1.6.2	Risk Management Plan	*162-riskmgt-system*
1.7	Certificates and Documents	*17-certificates*
1.7.1	GMP Certificate	*171-gmp*
1.7.2	CPP or Free-sales	*172-cpp*
1.7.3	Certificate of analysis – Drug Substance & Finished Product	*173-analysis-substance*
1.7.4	Certificate of analysis – Excipients	*174-analysis-excipients*
1.7.5	Alcohol-content declaration	*175-alcohol-content*
1.7.6	Pork-content declaration	*176-pork-content*
1.7.7	Certificate of suitability for TSE	*177-certificate-tse*
1.7.8	The diluents and coloring agents in the product formula	*178-diluent-coloring-agents*
1.7.9	Patent Information	*179-patent-information*
1.7.10	Letter of access or acknowledgment to DMF	*1710-letter-access-dmf*
1.8	Pricing	*18-pricing*
1.8.1	Price list	*181-price-list*
1.8.2	Other documents related	*182-other-doc*
1.9	Responses to questions	*19-responses*
	Additional data	*additional-data*

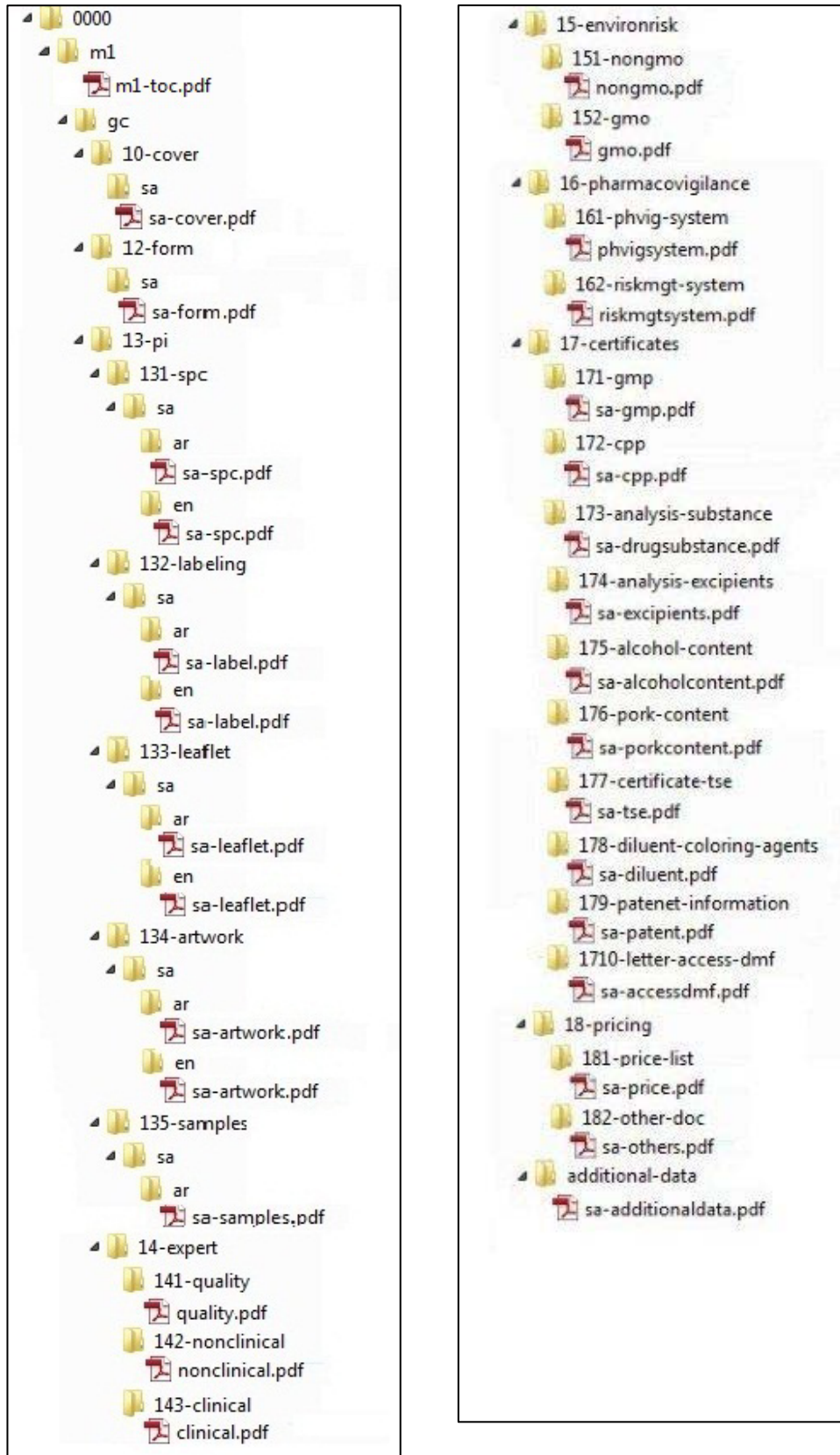A screenshot for module 1 is presented in figure 6.

Figure 6: A screenshot for module 1 hierarchy

4. In *m2*, *m3*, *m4* and *m5* the folders and folder names should follow the same structure as in "Appendix 3: General Considerations for the CTD Modules" in the **Electronic Common Technical Document Specification V 3.2.2[16],** published in the ICH website.

Notes:

- In figure 6, this is an example of module 1 only. Not all submission has to have all details.

- In response to *Questions*, the 1.9 folder should be present (figure 7)
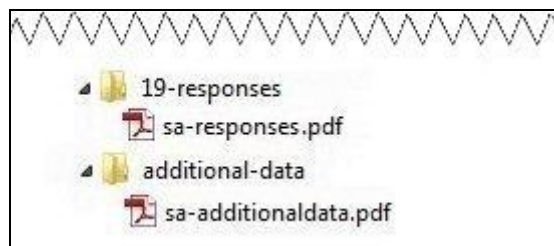

Figure 7: an illustration on the appearance of 1.9

Appendix D: File Formats

General requirements:

Generally, the relevant information must be structured according to the requirements of the Common Technical Document (CTD). The following files formats are accepted:

- PDF

- For graphics: Joint Photographic Experts Group (JPEG), Portable Network Graphics (PNG), Scalable Vector Graphics (SVG) or Graphic Interchange Format (GIF).

Portable Document Format:

PDF is an open, de facto, published format created by Adobe Systems Incorporated (http://www.adobe.com). It is not necessary to use a product from Adobe or from any specific company to produce PDF documents. PDF is accepted as a standard for documents defined in this specification. The following recommendations support the creation of PDF files that agencies can review effectively. To ensure that PDF files can be accessed efficiently, **PDF files should be no larger than 100 megabytes**. Optimize PDF files for fast web view.

The following points can be made in relation to PDF files:

- Files must be legible with PDF version 1.4 or higher

- PDF files produced from an electronic source document are highly preferred over PDF files produced from scanned paper, since those 'electronic' PDF files provide the maximum functionality to the reviewers in terms of search and print capabilities, and copy and paste functionality. The overviews/summaries in the CTD Module 2 should always be generated from an electronic source document.

- If scanning is unavoidable, readability and file size must be balanced; the following is recommended: resolution 300 dpi (photographs up to 600 dpi), avoid gray scale or color where possible, use only lossless compression techniques.

- If colors other than black are used, the colored pages must be tested on a black and white printer for acceptable reproduction and legibility prior to submission.

- Print area for pages must fit on an A4 sheet of paper; margins must allow binding in multi-ring binders without affecting readability.

- Landscape-oriented tables must automatically appear in landscape on screen.

Text Searchable Files:

Applicants are requested to ensure that all submissions contain the maximum amount of text searchable content. Documents with searchable text will aid the assessor, or any other user, in searching for specific terms and also in copying and pasting information into another document, such as an assessment report. The SFDA recognizes that not all documents need to be text searchable. This appendix provides some guidance about what must be text searchable and the ways to ensure that files are created appropriately.

Documents that must always be text searchable:

The PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then they **must be** OCR'd.

- Key administrative documents in Module 1 including, the cover letter, application form, SPC, labeling and PIL documents

- The main body of text of Risk Management Plans

- Any document in Module 2 of the submission (QOS, Nonclinical Overview and Summaries, Clinical Overview and Summaries).

- The main body of text in any reports, methods, analytical procedures, etc. supplied in Module 3 of the submission

- The main body of text and main tables in modules 4 and 5.

Documents that do not need to be text searchable:

The PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then there is no need for OCR.

- Any original Certificate of Pharmaceutical Product

- Any original Certificate that confirm that the product is free from BSE/TSE

- Any original GMP certificate

- Any original certificate of analysis

- Any manufacturer's licenses

- Any certificates of suitability

- Any Manufacturing Authorization

- Any literature references sourced from journals, periodicals and books (except when these are used in a bibliographic application so support the main claims of the application).

- Any page with a signature that does not contain other information key to the understanding of the submission

- Applicants should consider providing signatures on separate pages from key text in reports, overviews, etc.

Use of Electronic Signatures:

The use of advanced electronic signatures (digital signatures) will be crucial in achieving pure electronic communication between the pharmaceutical industry and regulatory agencies, particularly for authentication of electronic submissions and documents contained therein. Saudi Arabia is therefore developing a long-term strategy to implement digital signatures. Currently however, the use of digital signatures for electronic submissions within the kingdom of Saudi Arabia is not fully supported and digital signatures should therefore not be used.

Appendix E: ICH Common Technical Document

Common Technical Document (CTD)

The Common Technical Document is an internationally agreed format for the preparation of a marketing authorization (MA) that is to be submitted to the regulatory authorities in the three ICH regions (USA, EU and Japan) and in some other countries and regions. The CTD provides a common format for the preparation of a well-structured dossier. It uses a modular framework described in ICH Topic M4[17]. This guidance document should be read in conjunction with the most recent version of the ICH CTD guidance documents.

It is important to remember that the CTD provides a format for an MAA and does not indicate the content of a dossier and which studies should be performed. Regional and national requirements may affect the content of the dossier; therefore the dossier will not necessarily be identical for all regions.

The CTD is applicable for all types of products (new chemical entities, biologicals, herbals etc.)

The CTD is organized into five modules (figure 4). Module 1 is region specific. Modules 2, 3, 4, and 5 are intended to be common for all regions.

- Module 1: Administrative Information and prescribing Information

- Module 2: Common Technical Document Summaries

- Module 3: Quality

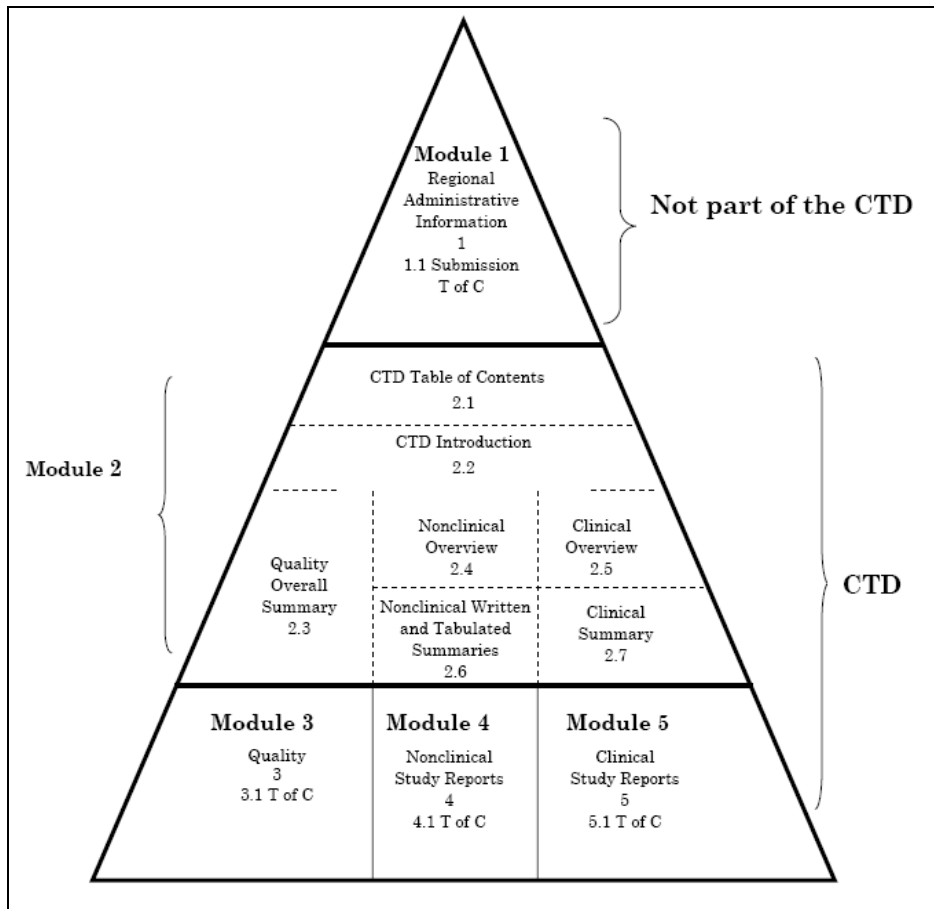- Module 4: Non-Clinical Study Reports

- Module 5: Clinical Study Reports

---

[17] http://www.ich.org/

Figure 8: Diagrammatic representation of the organization of the ICH CTD[18]

eCTD

The eCTD is defined as an interface for industry to agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission.

The eCTD is an electronic version of the CTD. The structure, folder and file names correspond to those of the CTD. As a submission format, however, it contains additional technical components which enable the lifecycle of individual files in the application, and the lifecycle of the product itself, to be managed.

An eCTD has the following components: Folder structure, Contents (files) and XML backbone.

[18] Source: adapted from the ICH guideline "*ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE*" Jan, 2004

The folder structure has a hierarchical organization reflecting that of the CTD, and it holds the scientific and technical contents of the eCTD (divided into many files which are the same as those in the non-eCTDs, usually in PDF format).

The XML backbone is recognisable as 'index.xml' at the root level of the submission folder of an eCTD and provides two useful functions:

- It provides a hyperlinked table of contents of the entire submission when viewed in a web browser with a suitable style sheet

- It provides descriptive information ('metadata') on the files that make up the actual contents of the eCTD.

Appendix F: Target Performance Timelines

Target performance timelines from the date of acceptance to SFDA decision, excluding the stop-clock for various submission types are as follows:

The timelines stated (in working days) are subject to change.

Process	Total Performance Target[19]
Marketing Authorization Application for Generics	165 days
Marketing Authorization Application for New Drugs	290 days
Marketing Authorization Application for New Drugs not registered in an SRA *(New)*	415 days
Marketing Authorization Application for Biologicals	290 days
Marketing Authorization Application for Biologicals not registered in an SRA *(New)*	415 days
Marketing Authorization Application for Radiopharmaceuticals	290 days
Marketing Authorization Application for Veterinary drugs	175 days
Marketing Authorization Application for Herbal products	155 days
Renewal of Marketing Authorization	70 days
Variation to a Marketing Authorization Type IA	60 days
Variation to a Marketing Authorization Type IB (New)	120 days
Variation to a Marketing Authorization Type II	145 days

---

[19] Working days

Appendix G: Required Quantities of Samples

The following table shows the required quantities of the samples for different sample types (in alphabetic order):

No.	Sample Type	Volume	Quantity
1	Ampoules, Vials & PFS[20]	<0.5 mL	50 sample
2	Ampoules, Vials & PFS	0.5-1 mL	25 sample
3	Ampoules, Vials & PFS	1-2 mL	20 sample
4	Ampoules, Vials & PFS	2-5 mL	15 sample
5	Antiseptic	1 L	6 bottles
6	Antiseptic	3 L	4 bottles
7	Antiseptic	5 L	4 bottles
8	BCG vaccine	-	50 bottles
9	Blood bags	-	8 bags
10	Bottles	$\geq$ 5 mL	12 bottles
11	Capsule	-	200 capsules
12	Drops	0.5-1 mL	30 bottles
13	Drops	1-10 mL	30 bottles
14	Drops	15 mL	20 bottles
15	Infusion sets	-	6 packs
16	Inhalers	-	20 samples
17	Ointment & Creams	-	20 tubes
18	Oral syrup, suspension or emulsion	< 250 mL	15 bottles
19	Oral syrup, suspension or emulsion	> 250 mL	15 bottles
20	Patches	-	50 patches
21	Raw materials	-	2 packs
22	Sachets	-	100 sachets
23	Solution	< 250 mL	15 bottles
24	Solution	250-500 mL	10 bottles

---

[20] PFS: Pre-filled syringes

No.	Sample Type	Volume	Quantity
25	Solution	0.5-5 L	8 bottles
26	Solution	5-10 L	5 bottles
27	Suppositories & Vaginal Pessaries	-	150 supp's
28	Tablets	-	200 tablets

Important Notes:

- The **batch number** of the provided samples must conform with the finished product certificate of analysis (1.7.3).

- The applicant should provide **working standards** not less than 500 mg with its storage condition specifications (expiry date not less than one year) and a certificate of analysis that proof the potency of the standard

- The applicant should provide **two additional samples** in the final packaging (plus PIL) for the pricing and evaluation for the human drugs. One additional sample only if the product is registered in GCC, or a herbal or health product.

- Samples should have at least 1 year from the meeting date.

- If the applicant couldn't know the required samples, please contact the SFDA at the email: sdr.drug@sfda.gov.sa

- The SFDA has the right to ask for additional quantities as needed.

- The SFDA has the right to ask for analysis tools and/or primary reference standards as needed.

Appendix H: References

SFDA Reference Documents:

- Regulatory Framework for Drug Approvals

- GCC Module 1 Specifications

- GCC Guidelines for Bioequivalence

- GCC Guidelines for Stability testing of API's and FPP's

- GCC Guidance for Presenting the SPC, PIL and Labeling Information

The latest versions of SFDA's guidance documents are available on the website at the following address:
http://www.sfda.gov.sa/en/drug/Pages/default.aspx

ICH Reference Documents:

M4 : The Common Technical Document

- Organization of The Common Technical Document for the Registration of Pharmaceuticals for Human Use

- Implementation Working Group – Questions & Answers (R3)

- Electronic Common Technical Document Specification (version 3.2)

- The Common Technical Document for The Registration of Pharmaceuticals for Human Use: Quality – M4Q(R1)

- The Common Technical Document for The Registration of Pharmaceuticals for Human Use: Safety – M4S(R2)

- The Common Technical Document for The Registration of Pharmaceuticals for Human Use: Efficacy – M4E(R1)

These documents and more are found at the ICH website at the following address:
http://www.ich.org/

Appendix I: Price List

Price Certificate Form (Form 30)

General information						
	Product Name		Concentration		Pack Size	
	Pharmaceutical Form		Company Name & Nationality			

Country of Origin	Ex-Factory Price (In Country of Origin's currency)	Wholesale Price (In Country of Origin's currency)	Public Price (In Country of Origin's currency)	Proposed CIF to KSA (In Country of Origin's currency)	Note

THE OTHER PRICE IN COUNTRIES WHERE THE PRODUCT IS MARKETED

No	Country Name	Pack Size	Ex-Factory Price	Currency	CIF Price	Currency	Public Price	Currency	Notes
1	Algeria								
2	Australia								
3	Argentina								
4	Bahrain								
5	Belgium								
6	Canada								
7	Cyprus								
8	Denmark								
9	Egypt								
10	France								
11	Germany								
12	Greece								
13	Holland								
14	Hungary								
15	Ireland								
16	Italy								
17	Jordan								
18	Kuwait								
19	New Zealand								
20	Oman								

No	Country Name	Pack Size	Ex-Factory Price	Currency	CIF Price	Currency	Public Price	Currency	Notes
21	Portugal								
22	Lebanon								
23	Japan								
24	South Korea								
25	Spain								
26	Sweden								
27	Switzerland								
28	Turkey								
29	U.A.E								
30	U.K.								

We:	: تشهد شركة
Certify That all Prices in this Form are Correct and Accurate	أن جميع الأسعار الواردة في هذا النموذج صحيحة.
Name of the Person Authorized to Sign on Behalf of the Company	اسم الشخص المفوض بالتوقيع عن الشركة
Stamp	ختم الشركة

Appendix J: Cover Letter

هذا النموذج يساعد المتقدم على كتابة خطاب تغطية	
This is a template to assist the applicant in writing a cover letter	

سعادة نائب الرئيس التنفيذي لشؤون الدواء   سلمه اللّه

الهيئة العامة للغذاء والدواء

السلام عليكم ورحمة اللّه وبركاته

نتقدم إلى سعادتكم بطلب الحصول على تسجيل المستحضر الموضحة بياناته أدناه، علما بأنه

تم إرفاق جميع البيانات والدراسات المطلوبة مع هذا الخطاب:

Reference no.		الرقم المرجعي
Trade Name		الاسم التجاري
Generic Name		الاسم العلمي
Strength		التركيز
Dosage Form		الشكل الصيدلاني
Pack size		حجم العبوة
Manufacturer		الشركة الصانعة
Marketing Company		الشركة المسوقة
MAH (Agent)		الوكيل

وتقبلوا سعادتكم خالص التحية والتقدير، ، ،

مدير شركة ....

الاسم:

التوقيع

التاريخ

ختم الشركة

Appendix K: Samples Form

هذا النموذج يساعد المتقدم على كتابة نموذج العينات
This is a template to assist the applicant in writing a sample form

Samples information:

English		Arabic
Reference no.		الرقم المرجعي
Trade Name		الاسم التجاري
Generic Name		الاسم العلمي
Strength		التركيز
Dosage Form		الشكل الصيدلاني
Pack size		حجم العبوة
Storage condition		شروط التخزين
Marketing Company		الشركة المسوقة
Manufacturer		الشركة الصانعة
MAH (Agent)		الوكيل
Sample Quantity		عدد العينات للتحليل
Batch No.		رقم التشغيلة
Expiry Date		تاريخ انتهاء الصلاحية

Reference (Working) Standard:

English		Arabic
API Weight		وزن المادة الفعالة
Storage condition		شروط التخزين
Expiry Date		تاريخ انتهاء الصلاحية
Potency of the standard		درجة النقاوة للمادة القياسية

Appendix L: Abbreviation and Acronyms

API	Active pharmaceutical ingredient
COO	Country of Origin
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
FPP	Finished pharmaceutical product
GCC-DR	Gulf Cooperation Council Drug Registration
MA	Marketing Authorization
MAA	Marketing Authorization Application
NCE	New Chemical Entity
PFS	Prefilled syringe
PIL	Patient Information Leaflet
SA	Saudi Arabia
SADAD	Payment System established by the Saudi Arabian Monetary Agency (SAMA) to be the national Electronic Bill Presentment and Payment (EBPP) service provider for the Kingdom of Saudi Arabia (KSA)
SDR	Saudi Drug Registration system
SFDA	Saudi Food and Drug Authority
SPC	Summary of Product Characteristics

Appendix M: Contact Address

Saudi Food and Drug Authority – Drug Sector

3292 Northern Ring Road – An nafal District

Riyadh 13312 – 6288

Kingdom of Saudi Arabia

Tel: +966-11-203- 8222 extensions: 5301/5302/5101

Fax: +966-11-275-7195

e-mail: sdr.drug@sfda.gov.sa

٩. قرار الهيئة العامة للغذاء والدواء:

سيتم إصدار القرار النهائي بناءً على نتائج تقييم وتسعير وتحليل المستحضر من قبل الهيئة العامة للغذاء والدواء. وقد تكون نتيجة القرار ما يلي:

- **موافقة:** يتم إصدار قرار الموافقة عندما يكون الطلب قد استوفى كافة الشروط والمعايير الخاصة بالجودة والسلامة والفاعلية.

- **يحتاج للمزيد من التوضيح:** يكون ذلك في حال كانت هنالك بعض الملاحظات على الطلب المقدم كنقص في البيانات المطلوبة.

- **مرفوض:** يتم إصدار قرار برفض الطلب المقدم في حال عدم ملائمة الطلب المقدم للشروط المطلوبة.

١٠. طلب الاستئناف:

يملك مقدم الطلب الحق في تقديم استئناف حول قرار الهيئة العامة للغذاء والدواء خلال مدة لا تتجاوز الستين يوماً. وسيتم إصدار دليل إرشادي حول هذا الأمر في وقت لاحق.

٦. التحليل:

سيتم إخضاع جميع المستحضرات الصيدلانية للتحاليل المناسبة وفقاً لنوع الدواء (الذي تم تقديمه بغرض التسجيل) والشكل الصيدلاني. علاوة على ذلك، يجب على مقدم الطلب تسليم عينات من الدواء المراد تسجيله إلى المقر الرئيسي للهيئة العامة للغذاء والدواء. ويجب على مقدم الطلب أن يعي عدم إمكانية التواصل بشكل مباشر مع المختبر الخاص بالهيئة.

٧. التفتيش:

تقوم إدارة التفتيش بالتواصل مع مقدم الطلب من أجل تحديد الوقت المناسب لإجراء زيارة التفتيش (حسب الحاجة) شريطة أن يكون ملائماً لجدول الأعمال الخاص بالمفتشين. وبعد الانتهاء من عملية التفتيش، سيتم كتابة تقرير حول هذه الزيارة وإرسال نسخة منه إلى مقدم الطلب. وفي حال وجود أي ملاحظات، سيزود مقدم الطلب بها لاستيفائها.

٨. إيقاف التقييم بشكل مؤقت:

يتم إيقاف التقييم بشكل مؤقت عندما تقوم الهيئة العامة للغذاء والدواء بإصدار نموذج للاستعلام. وقد يتم رفع هذه الاستفسارات إلى الإدارة لاتخاذ قرار حولها. ويتم العمل في تقييم المستحضر مرة أخرى بعد أن تتلقى الهيئة العامة للغذاء والدواء إجابات كاملة ومقبولة من قبل مقدم الطلب.

يجب على مقدم الطلب التواصل مع الهيئة العامة للغذاء والدواء في أقرب وقت ممكن في حال مواجهته صعوبة في الإجابة على الاستفسارات الخاصة بالهيئة في الوقت المحدد. وسيتم اعتبار الطلب مرفوضاً في حال عدم الإجابة على هذه التساؤلات في الوقت المحدد.

٣. مرحلة التأكيد الثانية:

بعد قبول طلب تسجيل المستحضر المقدم، سيتم التحقق من المعلومات المقدمة للتأكد من مدى جودتها لإجراء عملية التقييم. فإذا تم ملاحظة عدم استيفاء الشركة لجميع البيانات المطلوبة في الطلب المقدم سيتم الطلب بأن يقوم بإكمال البيانات الناقصة. وقد تنطبق هذه الخطوة على إحدى الخطوات التالية:

- في حال تم تسليم البيانات المطلوبة من قبل مقدم الطلب خلال ٩٠ يوماً، سيتم قبول الطلب المُقدم وإبلاغ صاحبه عن طريق البريد الإلكتروني، مع إرساله للإدارات المعنية بغرض تقييمه.

- في حال تم تسليم البيانات المطلوبة من قبل مقدم الطلب خلال ٩٠ يوماً وتم ملاحظة أن الطلب غير مكتمل حتى الآن، ستقوم الهيئة العامة للغذاء والدواء بدراسة هذه الحالة التي قد يتم من خلالها إعطاء مقدم الطلب مهلة أخرى لا تتجاوز الثلاثين يوماً وإبلاغه بهذا القرار بواسطة البريد الإلكتروني.

- أما في حال لم يقم مقدم الطلب بإرسال البيانات المطلوبة خلال ٩٠ يوماً، فسيتم رفض الطلب المقدم.

٤. تقييم الطلب المقدم:

ستقيم جميع الطلبات المقدمة بناءً على مدى جودتها وسلامتها وفاعليتها – حسب الحاجة وتعتمد هذه التقييمات على نوع المستحضر.

وفي حال وجود أي نواقص أثناء عملية التقييم، سيتم إرسالها لمقدم الطلب عن طريق نماذج الاستعلامات الإلكترونية. ويتوقع أن تتم معالجة هذه المشاكل بواسطة استعلامين أو ثلاثة، على الرغم من عدم وجود قيود على عدد الاستعلامات المتاحة. ويجب الاستجابة على الاستعلامات (الأسئلة أوالاستفسارات) خلال ٩٠ يوماً.

٥. التسعير:

سيتم تسعير المستحضر ووضع السعر المناسب له وفقاً لقواعد التسعير المذكورة في دليل قواعد تسعير المستحضرات.

٢. قبول الطلب المُقدم:

عند استلام الطلب في الموعد الذي تم تحديده مسبقا لاستلام الطلب، سيتم استخدام قائمة تسمى (مرحلة التأكيد الأولية) للتأكد من اكتمال جميع المستدات والمتطلبات.

أ. طلب تسجيل المستحضر المُكتمل:

سيتم إصدار موافقة على استلام الطلب بخطاب مطبوع. بعد ذلك سيتم إرسال الطلب إلى مدير المستحضر لتقييمه والقيام بإجراءات أخرى. وبمجرد قبوله، سيتم تقييمه وفقاً لأولوية استلامه.

ب. طلب تسجيل المستحضر غير المُكتمل:

سيتم إصدار خطاب يتم فيه ذكر المستدات أو الملاحظات الناقصة في الطلب المُقدم. ويجب على مقدم الطلب أن يسلم البيانات المطلوبة خلال ٩٠ يوماً من تاريخ إصدار الخطاب.

- بإمكان المتقدم إرسال بريد إلكتروني على العنوان (sdr.drug@sfda.gov.sa) لطلب موعد لاستكمال النواقص.

- في حال تم تسليم البيانات المطلوبة من قبل مقدم الطلب التسجيل خلال ٩٠ يوماً، سيتم قبول الطلب المُقدم وإصدار خطاب القبول، مع إرساله إلى مدير المستحضر لتقييمه والقيام بإجراءات أخرى.

- وفي حال تم تسليم البيانات المطلوبة من قبل مقدم الطلب خلال ٩٠ يوماً وتم ملاحظة أن الطلب غير مكتمل حتى الآن، فسيكون عليه إكمال المتطلبات خلال الفترة المتبقية.

- أما في حال لم يقم مقدم الطلب بإرسال البيانات المطلوبة خلال ٩٠ يوماً، فسيتم رفض الطلب المقدم.

٣   عملية التسجيل

ستكون جميع الطلبات خاضعة للإجراءات التالية :

١. تعبئة الطلب إلكترونياً:

يجب على المتقدم أن يقوم بتعبئة النموذج الخاص بنوع المستحضر عن طريق النظام الإلكتروني لتسجيل الأدوية السعودي (سدر)، ولا يمكن حجز موعد إلا بعد أن تتم عملية دفع المقابل المالي. وبعد الانتهاء من عملية تقديم الطلب، سيحصل مقدم الطلب على رقم مرجعي يكون مرجعاً له كي يتم تسهيل عملية التواصل بينه وبين الهيئة. بعد ذلك سيتم منح مقدم الطلب فرصة لكي يقوم بحجز موعد لتسليم طلبات المستحضر (كما هو مبين في الشكل رقم ١). ويتم التذكير بالموعد إلكترونيا (عن طريق البريد الإلكتروني أو إحدى وسائل الاتصال) قبيل الموعد بثلاثة أيام. كما يمكن للمتقدم أن يعدل في موعده بحيث يكون قبيل الموعد المحدد مسبقاً بثلاثة أسابيع. وفي حال عدم حضور مقدم الطلب في موعده المحدد، عليه القيام بحجز موعد آخر عن طريق إرسال بريد إلكتروني للعنوان (sdr.drug@sfda.gov.sa).
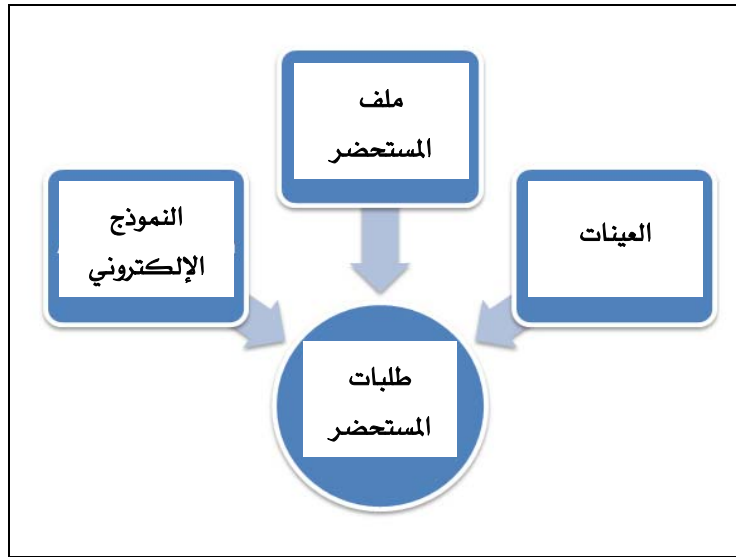
الشكل رقم ١: "طلبات المستحضر" تتكون من ملف المستحضر والنموذج الإلكتروني والعينات

٢   الهدف

تتطبق التعليمات والمعلومات الموجودة في هذا الدليل على جميع أنواع التسجيل الدوائي:

- المستحضرات الجنيسة
- المستحضرات الجديدة
- المستحضرات الحيوية
- المستحضرات الصيدلانية الإشعاعية
- المستحضرات العشبية والصحية
- المستحضرات البيطرية
- تجديد رخصة التسويق
- التعديلات

سيتم الإطلاع على جميع المعلومات المقدمة للتأكد من اكتمال الوثائق اللازمة ومراجعتها بعناية. وسوف تطبق نفس المبادئ المتعلقة على جميع أنواع التسجيل الدوائي. يغطي هذا الدليل جميع الإجراءات وكيفية إكمال المتطلبات الخاصة بالطلبات المقدمة ورقياً والمتوافقة مع المستندات التقنية الموحدة لتسجيل المستحضرات الصيدلانية، بالإضافة إلى الطريقة الإلكترونية. وهذه العملية مبنية على المبادئ المذكورة في المؤتمر الدولي للموائمة والمستندات التقنية الموحدة لتسجيل المستحضرات الصيدلانية، بالإضافة إلى الخواص الخاصة بالمستندات التقنية الموحدة لتسجيل المستحضرات الصيدلانية إلكترونياً وآلية العمل التي يتم إتباعها لتسجيل المستحضرات بالهيئة العامة للغذاء والدواء.

١   مقدمة

تم إعداد هذا الدليل من قِبَل قطاع الدواء بالهيئة العامة للغذاء والدواء لإعطاء نبذة للمتقدمين والشركات حول كيفية إعداد وتقديم ملفات المستحضرات الدوائية للحصول على رخصة التسويق أو تجديدها. ويوضح هذا الدليل وبشكل مبسط آلية العمل التي يتم تطبيقها وفقاً للضوابط المتعلقة بالدواء والتي تم إقرارها من قبل الهيئة.

كما يوضح هذا الدليل الطريقة التي تتم بواسطتها إدارة الملفات والمعلومات المقدمة حسب ما ورد في الهيكل الإجرائي لترخيص الأدوية (النسخة الخامسة). وعلاوة على ذلك، فإنه يساعد المتقدمين على الإيفاء بجميع المتطلبات وتعديل الطلبات الخاصة بهم إذا لزم الأمر.

سيقوم ممثلي الشركات وموظفي الهيئة العامة للغذاء والدواء المسئولين عن إدارة الطلبات المقدمة، بإتباع ما ورد في هذا الدليل وتطبيقاته العملية في المجالات المختلفة والتي قد تشتمل على إدارة المعلومات الخاصة بالطلب المقدم، والإجراءات المتعلقة بتقييم المستحضر، والتوضيحات المتعلقة بالإضافة إلى تقدير الفترة الزمنية التي قد يحتاجها المستحضر لدراسته.

واستمرارا لمبدأي الشفافية والاتساق الذي تم بموجبه كتابة هذا الدليل، فسوف يتم تحديث البيانات بشكل منتظم حسب آخر التطبيقات العملية المتعلقة بالتنظيمات الدوائية. يتوقع أن يكون هذا الدليل (وأي تعديلات قد تطرأ عليه) ذا فاعلية ومفيداً في إدارة الطلبات المتعلقة بالمستحضرات، وواضحاً بحيث يقلل من التساؤلات الموجودة لدى لمقدمي الطلبات والشركات.

يجب التنويه بأن للهيئة العامة للغذاء والدواء الحق في طلب أي معلومات أو بيانات ترتبط بهذا الدليل من أجل تقييم سلامة وجودة وفاعلية أي مستحضر متوفر بالمملكة العربية السعودية بشكل ملائم. وتلتزم الهيئة بضمان أن يتم تبرير وتوضيح مثل هذه التساؤلات مع توثيق النقاشات التي تدور حولها.

الدليل الإرشادي للتسجيل

النسخة ٤٫٠

قطاع الدواء

الهيئة العامة للغذاء والدواء

المملكة العربية السعودية

الرجاء زيارة الموقع الإلكتروني للهيئة http://sfda.gov.sa للحصول على آخر المعلومات

هذه الصفحة تركت فارغة عمداً

الدليل الإرشادي للتسجيل

النسخة ٤٫٠

قطاع الدواء
Drug Sector

جمادى الأولى ١٤٣٥هـ