THE COMMON TECHNICAL DOCUMENT (CTD)

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ICH

هو عباره عن **guidelines** الي توحد المتطلبات التنظيمي لتطوير وتسجيل الدواء في الدول حتى يقلل الوقت. والتكاليف اللازمه لتطوير الدواء ويضمن **safe, effective, meet pharmaceuticals quality**

يجي تحته موضوع **CTD** الي هي جزء من **ICH guidelines**(إذا تم اتباعه رح يطلع عنا **product** (رح يكون **format** الملف الي ممكن نقدمه في كل العالم ولكن لكل بلد **requirements** معين من حيث **introduction** فلما نعمل **authorization** للملف والسلطات توافق عليه وتسجله معناه انو الدواء **safe and effective and meet pharmaceuticals (quality**

يتم تنظيم المعلومات فيه على شكل **moudule** كمان شوي نشرحهم

تكوين إمنين

هي مجموعه من الوثائق تخلينا اذا اتبعنا **format** تبعتها نقدر نعمل **regesteration** مش بدوله معينه انما بكل العالم

MARKETING AUTHORIZATION APPLICATION

- Proof of:
  - **Efficacy**
  - **Safety**
  - **Pharmaceutical quality**

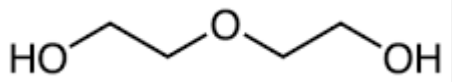
ووذكرنا مشكله **thalidomide** وانه من بعدها بلشت عمليات **regulation and safety** وانبثق عنها **ICH guidelines** التابعه اله ولما بلشنا نشوف ايش في **gap** وشو هي المشاكل الي تعمل **compromised the quality and safety and effective the drug**

بالاعتماد على شغلهم زمان الي هو من ايام **thalidomide** وبعد ما شافو شو ممكن يصير مشاكل ايش الأخطاء الي صارت. بلشو يعملو **risk assessment and risk management**

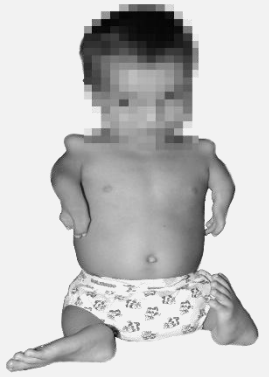
THE NEED FOR REGULATORY AUTHORITIES

Examples

- In 1938, one pharmaceutical firm added diethylene glycol to a pediatric drug dosage form without ever testing it, killing a number of children.



- Thalidomide (1957): Birth defects in more than 10000 children.



- Many products have been approved and later removed from the market for **safety** reasons, including alosetron HCl (Lotrovec), astemizole (Hismanal), bromfenac sodium (Duract), cerivastatin (Baycol), cisapride (Propulsid), dexfenfluramine HCl (Redux), fenfluramine HCl (Pondimin), grepafloxacin HCl (Raxar), mibefradil (Posicor), natalizumab (Tysabri), pemoline (Cylert), phenylpropanolamine (Propagest, Dexatrim), rofecoxib (Vioxx), terfenadine (Seldane), and troglitazone (Rezulin).

THE NEED FOR REGULATORY AUTHORITIES

- The realization that it was important to have an independent evaluation of medicinal products before they are allowed on the market.
- The need to assemble all Quality, Safety and Efficacy information in a common format
- **Overview**
- Transparency
- Identification of gaps
- Common review process
- Exchange of information

THE INTERNATIONAL COUNCIL FOR HARMONISATION(ICH) OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

- Started in 1990.
- **Harmonization** of regulatory requirements was pioneered by the European Community (EC), in the 1980s, as the EC (now the European Union) moved towards the development of a single market for pharmaceuticals.
- The success achieved in Europe demonstrated that harmonization was feasible. At the same time there were discussions between Europe, Japan and the US on possibilities for harmonization.
- In 2015 ICH became an international association, a legal entity under Swiss law.

THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

Founding Regulatory Members

- **The European Countries(EC)**
- **EU** Commission of the European Communities
- **EFPIA** European Federation of Pharmaceutical Industries Association

- **USA**
- **FDA** Food and Drug Administration
- **PhRMA** Pharmaceutical Research and Manufacturers of America

- **Japan**
- **MHLW** Ministry of Health, Labour and Welfare
- **JPMA** Japanese Pharmaceutical Manufacturers Association

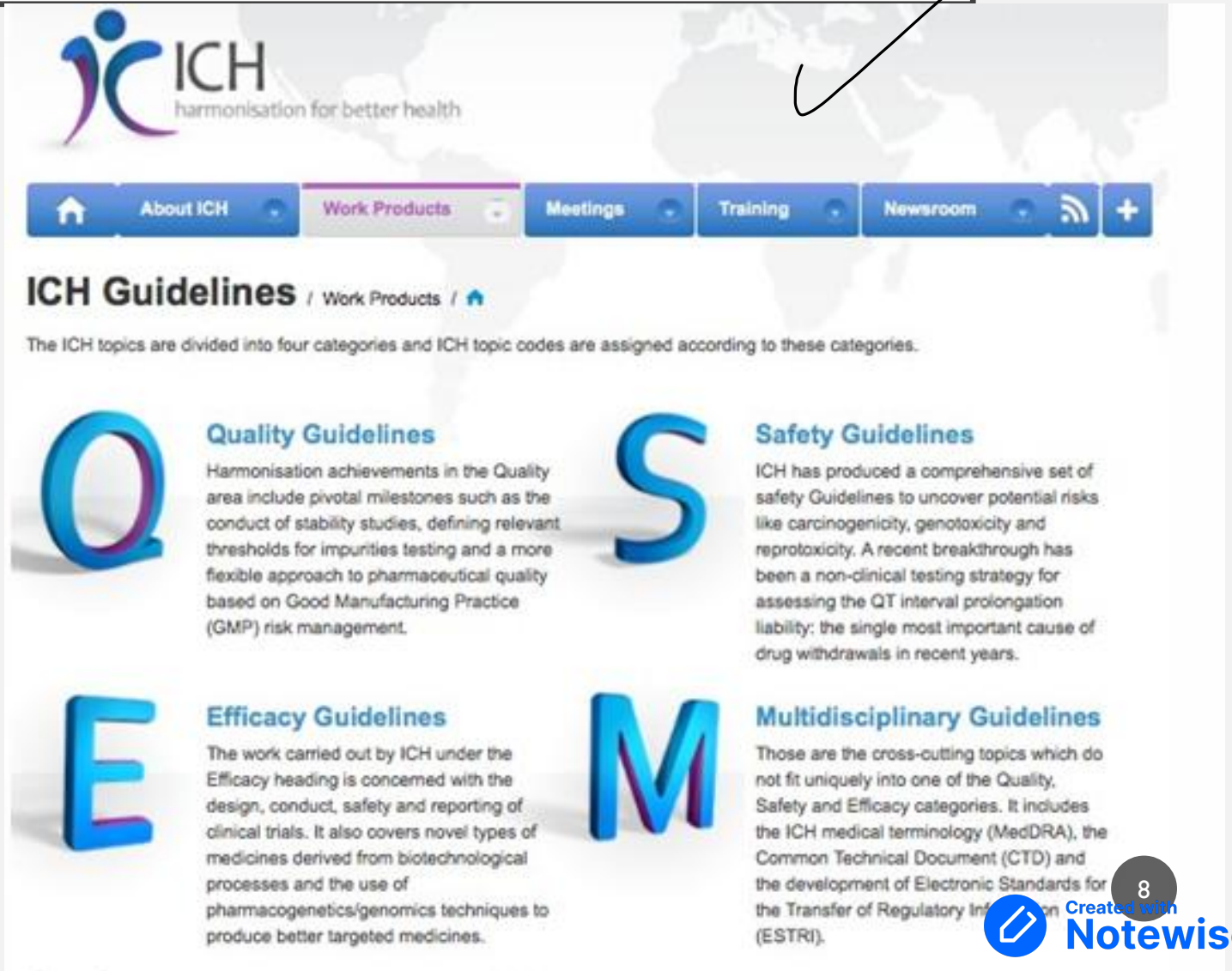
THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

- In June 2024, the ICH welcomed **ANMAT (Argentina)** and **JFDA (Jordan)**
- In 2025, the (ICH) comprises **23 Members** and **38 Observers**

هدول وهمان

ICH GUIDLINES

Quality Q1-Q12
33 guidelines
Q4 Pharmacopoeias - additional
Safety S1-S11
19 guidelines
Efficacy E1-E19
35 guidelines
Multidisciplinary
10 guidelines



NEW DRUG DEVELOPMENT AND APPROVAL PROCESS

Preclinical testing	Clinical trials research and development	FDA	Post-marketing surveillance
Synthesis – Identify a lead compound **Characterization** – Physicochemical properties **Toxicity and bioactivity** – *In vitro* (cell culture) – *In vivo* (short term) – ADME/Tox	**Phase I** – Healthy volunteers (20–80) – Safety profiles – Drug tolerance **Phase II** – Patients (100–300) – Controlled, randomized trials – Double-blinded – Short-term side effects – Decision on final dosage form **Phase III** Patients (1000–3000) – Expanded and uncontrolled trials – Monitor adverse reactions – Confirm effectiveness – Decision on physician labeling	Review and approval	**Phase IV** – Postmarketing testing – Report adverse effects – Report product defects
Average 3.5 years	1.5 + 2 + 4 = 7.5 years	6–10 months	
Evaluation of thousands of compounds	<1% Enter trials	1 Approved	
	IND submission	NDA filing	NDA approval

Time course for the development of a new drug

بعد ما نخلص عمليه **pre clinical** الي هو (اخترع الدواء من اول من الصفر وبعدها نشوف **identity of drug** لانه اذا فيها مشاكل **(phesychemical and drug assessment** وهاي مهمه لل مستحيل الدواء يوصل للسوق بروح على**FDA** وبعطيهم ملف اسمه **new investigation drug** ونقعد احنا واياهم نتناقش فيه وبعد ما يوافقو عليه رح ابلش اعمل **clinical study**

NID
احنا هانكون عارفين شو هو Dose

بمرحله **NDI**هو مش **drug** لساتة تحت **investigation** وهون نمسك ملف ونحط **probability** تبعت وهون لسا ما نحكي عن **dose** بس نعمل **submission** لملف اسمة **NID** عشان لما يشوفو نتفق احنا واياهم وانه رح نعمل **dosing** وهاد يكون عشان ال **study** ورح نبلش هون يعدلو علية او يرفضوه او يقبلو فية ولما يوافقو نبلش **clinical trial** الي يكون من ضمنها **phase 1** الي يتضمن موضوع **dose**

COMMON TECHNICAL DOCUMENT (CTD)

- **CTD** is a set of specification for application file for the registration of Medicines and designed to be used across Europe, Japan and the United States.
- It is an internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries.
- In July 2003, the CTD became the mandatory format for new drug applications in the EU and Japan, and the strongly recommended format of choice for NDAs submitted to the FDA.

ADVANTAGES OF CTD

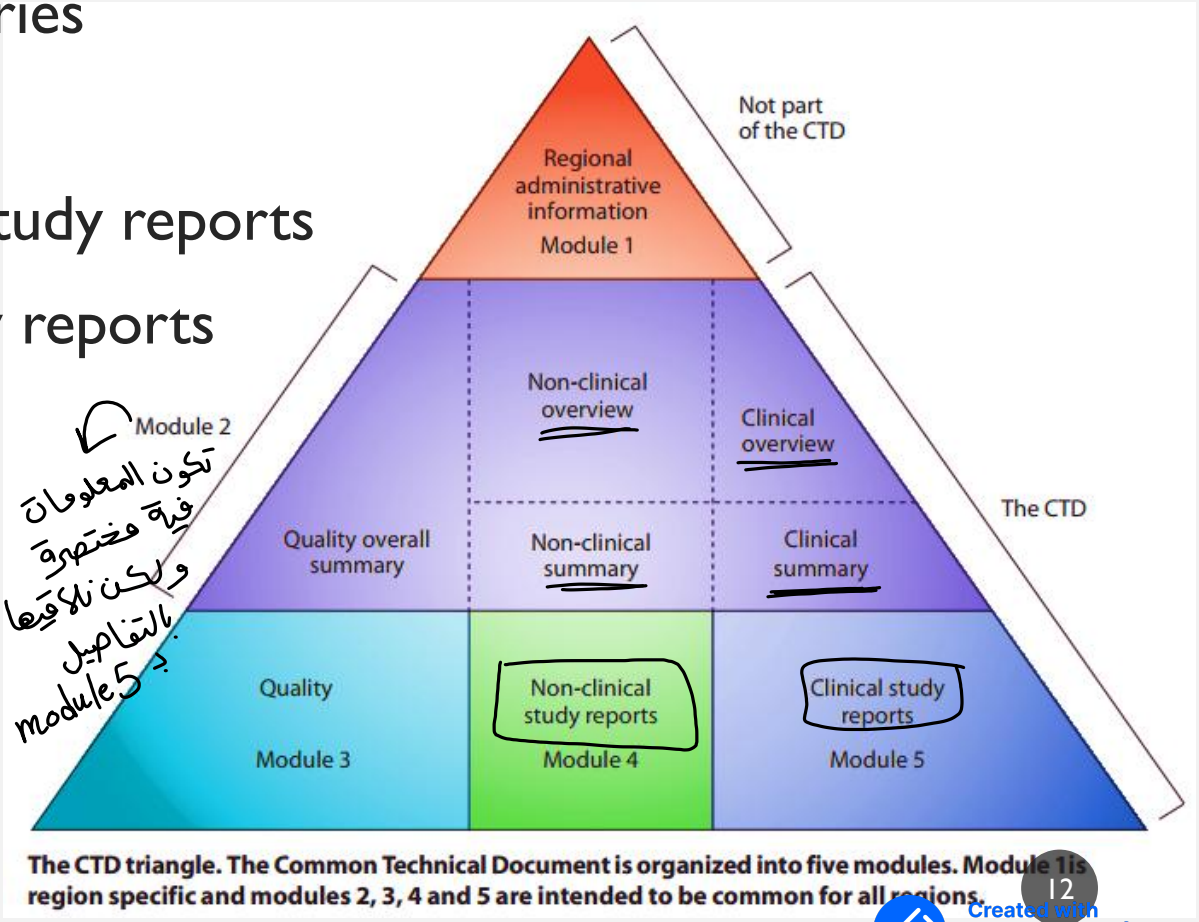
- It has facilitated the regulatory review processes
- It has eliminated the need to reformat the information for submission to the different ICH regulatory authorities
- It facilitated simultaneous submission in three regions
- It is applicable to all type of products (NCE, Radio, Vaccines, herbals)
- It led to harmonised electronic submission that, in turn, enabled implementation of good review practices.
- Faster availability of new medicines

هل رح يختلف الملف تبع تسجيل الدواء اذا كان نفس الدواء ولكن شكله الصيدلاني مختلف .... لا لانه نفس ال **component** يعني **format CTD** ثابت ولكن المعلومات الي تخص كل واح منهم تختلف

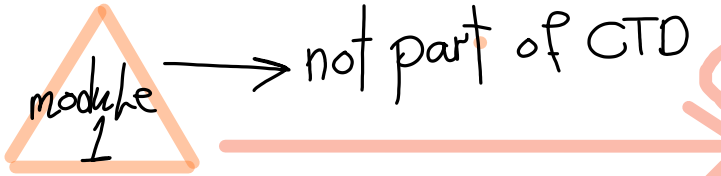
بنقدر بنسجل باي دوله تابعه لل**ICH** اذا غيرنا **module 1** ولكن مش، دايما يتغير انما نغير حسب الدوله شو عندها حسب اذا اشي **spacefication** او نموذج معين بدوله الي بدي اياها

ORGANIZATION OF CTD

- Module 1: Administrative Information
- Module 2: CTD summaries
- Module 3: Quality
- Module 4: Nonclinical study reports
- Module 5: Clinical study reports

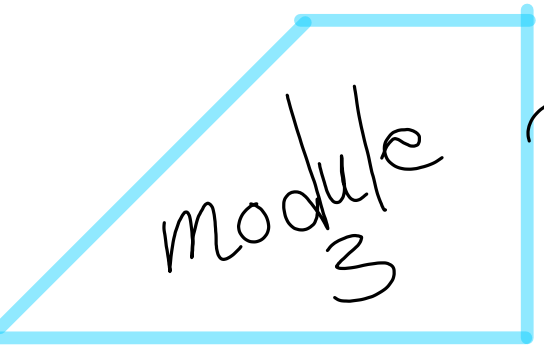


The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.



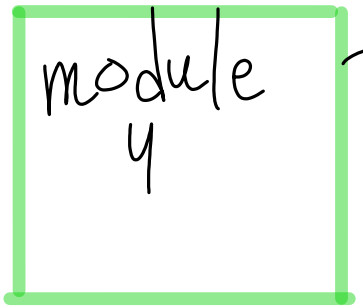
هاد عباره عن **introduction** وهاد يختلف **(requirements)** من بلد لبلد لانه مثلا في دوله معينه بدها سجل الضريبه وفي بلد من رخصة للمهن الخ.... وهاي بتكون **chicklist**

يعني مثلا هاد الدواء دورت ب **literature view** يعني شو في مثله بالسوق وشو،في منه **doseg forme** وبعدين عملت إلهم **summary overview**
(هاي الشغله ما عنا هيها (**stage of NID**) بالأردن لانه احنا يوصلنا الدواء جاهز بس عليهم يسجلوه)
نكمل هسا لما نقدمه لل **FDA** الدواء المخترع جديد لازم يكونو مجهزين **module 1/2** على **stage of investigation drug** وبعدين يكمل **module 3/4**
اي حدا بسجل غير**FDA** او اشي مش **originated** لازم يعمل كل اشي ككل



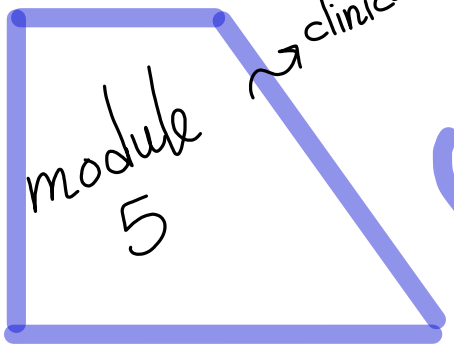
Qulity

بالنسبة لل **quality** كيف صنعنا هاد الدواء وكيف حللناه وشو **formela and**
component تبعته بالمختصر اثبت انو طريقه صنعه صحيحه



non clinical
study report

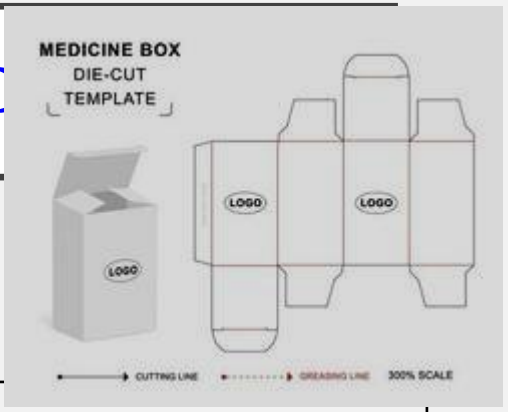
الها دخل **pharmacokinetics, pharmacodynamic** الها دخل
بالدواء ولكن هي **non clinical**



clinical

On details of details
البروتوكولات كيف انعملت ،النتائج

ORGANIZATION OF CTD



Module 1: JFDA Requirements

(www.jfda.jo *F1/RDP-3/2011*)

1.0	**Cover Letter.**
1.1	**Comprehensive Table of Contents (Module 2-5).**
1.2	**Application Forms (JFDA forms):** ← زي طلب التقديم للجامعة
1.2.1	Check List ***(F1/RDP-3/2011)***
1.2.2	Drug Registration form ***(LF 4-RDP-7\2008)***
1.2.3	Technical Committee Form ***(F2/RDP-7\2008)***(5 copies)
1.2.4	Computer application Form ***(F3/RDP-7\2008*)**
1.2.5	JFDA Stability Report Form ***(F5/RDP-7\2008)***
1.3	**Product Information:**
1.3.1	SPC (Summary of product characteristics), Labeling, Package leaflet.
1.3.2	Mock-up.
1.3.3	Specimen (One Registration sample).

ممنوع نستخدم اللون الأحمر في اشي
اسمه **paint of code** هاد الي يستخدم

حتى يتم التأكد انه data إلى محطوطه صحيحة

ORGANIZATION OF CTD

Module 1: JFDA Requirements (www.jfda.jo)

1.4	**Specific Requirements for Different Types of Applications:**
1.4.1	Information for application type (Generic, Bio-similar ……..).
1.4.2	Information for submission type (Technology Transfer, under license …..)
1.5	**Information related to Pharmacovigilance:**
1.5.1	Pharmacovigilance System.
1.5.2	Risk-management System.
1.6	**Other information:**
1.6.1	List of Similar Product Available in Local Market.
1.6.2	Detailed Comparison between Generic Leaflet & Originator (for generic drugs).
1.6.3	Declaration from the manufacturer about the ingredient/s from human or animal origin included in the composition of the product and their source and the related certificates (*TSE CEP*).
1.6.4	List from manufacturer to declare the worldwide registration status: (registered\Marketed (date), under registration, rejected (with reason)).
1.6.5	Technical Contract (Open part) in case of contract manufacturing.
1.6.6	Health authority approval of the latest Plasma master file (if the product contain plasma derivatives).

معناها انه في شركات تصنع وتعمل development وفي شركات تقلك R&D ما بدي اغلب حالي واعمل contract of فتروح على munfacturing center يعني حدا. بيني وبينه عقد خذ اعملي development او صنعلي ولما تخلص بجي بعمل transfer عشان اصير اصنعها عندي بالمختبر

تكون خالية من اي اشي يعمل جنون البقر

ORGANIZATION OF CTD

Module 1: JFDA Requirements (www.jfda.jo)

1.6.7	**Certificates:**
1.6.7.1	Certificate of Pharmaceutical product (CPP) according to WHO format Certified and Legalized.
1.6.7.2	SmPC certified and legalized from country of origin (excluding generics).
1.6.7.3	Price certificates:(for Exported products)(priced drug): - Public Price Certificate showing Price Structure: Ex.f, WSP, PP,(Certified and Legalized):if vat included specify . - Price structure from median countries (UK, Spain, France, Greece, Italy, Belgium, and Holland). - Export Price letter for Jordan & Export price to Saudi Arabia (if marketed).
1.6.7.4	Prices certificate: (for local products) Suggested Public price\ pharmacist price or hospital price (for priced drug).
1.6.7.5	JFDA approval certificate for the Manufacturing site/s (for the same production line)(or copy of the request letter for approval (date and number))
1.6.7.6	A copy of JFDA committee approval of the B.E or the Comparative Dissolution Profile should be provided (for generic drugs).

European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2002-124-Rev 00

Name of the substance:
WOOL FAT

Name of holder:
NIPPON FINE CHEMICAL CO LTD
4-9, 2-Chome
Bingomachi, Chuo-Ku
Japan-541-0051 Osaka

Site(s) of production:
NIPPON FINE CHEMICAL CO LTD
Kakogawahigashi Plant
377-1, Kitano, Noguchi-Cho, Kakogawa-Shi
Japan-675-0011 Kakogawa

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2002-124-REV 01

After examination of the information provided on the origin of raw material(s) and type of tissue(s) used and on the manufacturing process for this substance on the site(s) of production mentioned above, we certify that the substance **WOOL FAT** meets the criteria described in the current version of the monograph Products with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including supplements.

– nature of animal tissues used in manufacture: Sheep wool

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform encephalopathy agents.

Manufacture of the substance shall take place in accordance with a suitable quality assurance system such as ISO 9001, and in accordance with the dossier submitted.

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : http://www.edqm.eu

ORGANIZATION OF CTD

Module 1: Administrative Information and Prescribing Information

- This module should contain documents specific to each region;
- e.g.
  - application forms
  - the proposed label for use in the region.
- The content and format of this module can be specified by the relevant regulatory authorities.

مثلا عنا موظف التسجل يكون عامل على desktop بدك تجمع هاي requirements وزمان كان بدك تجمعها وتعمل طباعه وتنحطها بملفات وكل modules الها ملف لحال

Module1.

تحكي عن description وهي اصلا regen of spacefic وتحتوي أيضا على tablet of content هي زي الفهرس (document of regen spacefic)

Module2

تحتوي اول اشي على tabel of content بعدين introduction تكتب صفحتين ثلاث عن الدواء او الشركه وشو ضروره انو الدواء لازم ليتسجل وكمان فيها quality overall summary

في عنا اشي اسمه chick list زي نجيبها منR&D كل ما نحط ونجهز شغله نحط عندها صح عنا مثلا شكل العلبه الخارجيه شكل dropper وابعادهم نجيبها من Quality control مختومه من QA

ORGANIZATION OF CTD

Module 2. Common Technical Document Summaries

- Module 2 should begin with a general introduction to the pharmaceutical, including its pharmacologic class, mode of action, and proposed clinical use. In general, the Introduction should not exceed one page.
- Module 2 should contain 7 sections in the following order :
  - CTD Table of Contents
  - CTD Introduction
- Quality Overall Summary (brief summary of the relevant sections and should not exceed 40 pages of text – no tables or figures)
  - Nonclinical Overview (Integrated and critical assessment of the pharmacologic , pharmacokinetic and toxicological evaluation of the pharmaceutical product)
  - Clinical Overview
  - Nonclinical Written and Tabulated Summaries
  - clinical summary → Bio pharmacutical, analytical clinical study

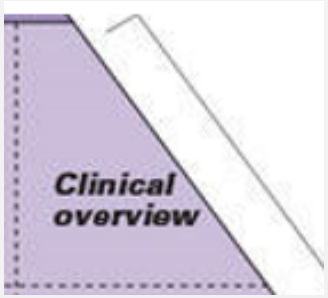
2.4 NON CLINICAL OVERVIEW

module 2 ج.ت

- Integrated and critical assessment of the pharmacologic , pharmacokinetic and toxicological evaluation of the pharmaceutical product.
- Addressed the interpretation data, the clinical relevance of the findings and the implications of nonclinical findings for the safe use of the pharmaceutical product.

2.5 CLINICAL OVERVIEW

- **Summary and analysis of the clinical data**
- **Provide a brief overview of the clinical findings**, including **important limitations** (e.g., lack of comparisons with an especially relevant active comparator, or absence of information or some patient populations, on pertinent endpoints, or on use in combination therapy).
- **Analyse the benefits and risks of the medicinal product in its intended use** based upon the conclusions of the relevant clinical
- **Address particular efficacy or safety issues** encountered in development, and how they have been evaluated and resolved.
- **Explore unresolved issues**, explain why they should not be considered as barriers to approval, and describe plans to resolve them.
- **Explain the basis for important or unusual aspects** of the prescribing information



Non – clinical & Clinical Summaries

- 2.6 Non-Clinical Summaries

- Summary of pharmacokinetic, pharmacological and toxicology studies – in-vivo/in-vitro, species, route and duration
- Appropriate age and gender related effects

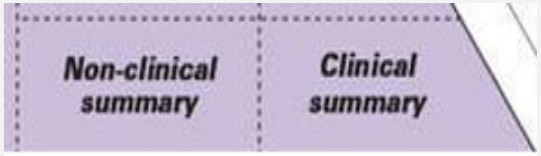
- 2.7 Clinical Summaries

* Biopharmaceutical study
* analytical clinical

- This section is intended to provide a **detailed, factual summarization of all of the clinical information** in the CTD.

This includes:

- information provided in **clinical study reports**;
- information obtained from **any meta-analyses or other cross-study analyses** for which full reports have been included in Module 5; and
- **post-marketing data for products** that have been marketed in other regions



ORGANIZATION OF CTD

Module 3. Quality

- Information on Quality should be presented in the structured format described in Guideline M4Q.

رح نحكي هون عن **body of data**. ونحكي عن شغلتين
- **quality of products**
- **quality of drug substances**

عنا حاليا اشي اسمه **electronic submission** وهاد نوعين نوع زي الي عملته الدكتوره انها حطته على **drive** وبعدين لما خلصت مسكت **folder** الرئيسي وحطه على **CD** وسلمه ولكنه مش. ال **electronic** الي يغطى ب **eCTD** ف لما نروح على **ICH** ونشوف **spacefication for submission** ل **electronic guidance** رح نشوفهم حاطين تسميه الملفات وتسميه **sub species** وكيف لازم تكون بلغه البرمجه. مثلا **32s2** لما تشوفه الصي. لانيه تكون عارفه **manufacturers and route for** يكون زي البصمه **drug substances**

طريقة تصنيع active ingredient

ORGANIZATION OF CTD
MODULE 3 : QUALITY

electronic submission صاد الرقمية

3.2.S DRUG SUBSTANCE (NAME, MANUFACTURER).

- 3.2.S.1 General Information
- 3.2.S.1.1 Nomenclature
- 3.2.S.1.2 Structure
- 3.2.S.1.3 General Properties
- 3.2.S.2 Manufacture
- 3.2.S.2.1 Manufacturer(s)
- 3.2.S.2.2 Description of Manufacturing Process and Process Controls
- 3.2.S.2.3 Control of Materials
- 3.2.S.2.4 Controls of Critical Steps and Intermediates
- 3.2.S.2.5 Process Validation and/or Evaluation
- 3.2.S.2.6 Manufacturing Process Development
- 3.2.S.3 Characterisation
- 3.2.S.3.1 Elucidation of Structure and other Characteristics
- 3.2.S.3.2 Impurities

لما نجي نعمل **development** بدنا نختار مثلا **iboprofen** هل نروح نختار من شركه وحده طبعا لا(نفرض شركه سكرت يكون في غيرها احتياط) لازم نجيب على الاقل من **3** شركات ونسجل بالملف عنا **3sublayer** مش إجباري الشغله يعني ممكن شركه استخدمت **method** استخدم فيها اسيتون وممن **method** ثانيه استخدم فيها بنزين مع مركب ثاني وهاي الفكره لذلك لازم نجيب الدواء من شركات الها نفس **route of synthesis** حتى ما تتغلب **stable or impurity**

ORGANIZATION OF CTD
MODULE 3 : QUALITY

3.2.S DRUG SUBSTANCE (NAME, MANUFACTURER).
3.2.S.4 Control of Drug Substance
3.2.S.4`.1 Specification
3.2.S.4.2 Analytical Procedures
3.2.S.4.3 Validation of Analytical Procedures
3.2.S.4.4 Batch Analyses
3.2.S.4.5 Justification of Specification
3.2.S.5 Reference Standards or Materials
3.2.S.6 Container Closure System
3.2.S.7 Stability
3.2.S.7.1 Stability Summary and Conclusions
3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment
3.2.S.7.3 Stability Data

ORGANIZATION OF CTD
MODULE 3 : QUALITY

3.2.P DRUG PRODUCT (NAME, DOSAGE FORM)
3.2.P.1 Description and Composition of the Drug Product
3.2.P.2 Pharmaceutical Development
3.2.P.2.1 Components of the Drug Product
3.2.P.2.1.1 Drug Substance
3.2.P.2.1.2 Excipients
3.2.P.2.2 Drug Product
3.2.P.2.2.1 Formulation Development
3.2.P.2.2.2 Overages
3.2.P.2.2.3 Physicochemical and Biological Properties
3.2.P.2.3 Manufacturing Process Development
3.2.P.2.4 Container Closure System
3.2.P.2.5 Microbiological Attributes
3.2.P.2.6 Compatibility

هاد **active ingredients** كيف اجانا بشو
كيف نشتريه هل هو **sterile** هل بده **light**
protection.... هاد المهم

ORGANIZATION OF CTD
MODULE 3 : QUALITY

3.2.P DRUG PRODUCT (NAME, DOSAGE FORM)
3.2.P.3 Manufacture
3.2.P.3.1 Manufacturer(s)
3.2.P.3.2 Batch Formula
3.2.P.3.3 Description of Manufacturing Process and Process Controls
3.2.P.3.4 Controls of Critical Steps and Intermediates
3.2.P.3.5 Process Validation and/or Evaluation
3.2.P.4 Control of Excipients
3.2.P.4.1 Specifications
3.2.P.4.2 Analytical Procedures
3.2.P.4.3 Validation of Analytical Procedures
3.2.P.4.4 Justification of Specifications
3.2.P.4.5 Excipients of Human or Animal Origin
3.2.P.4.6 Novel Excipients

هون نحكي عن الدواء مثلا عن الايبوبروفين
انه يتكون من **lactose, microcrystallin cellulose**.....
الخ بالتفصيل يكون وشو سبب استخدامهم انه **filler, binder**

ORGANIZATION OF CTD
MODULE 3 : QUALITY

3.2.P DRUG PRODUCT (NAME, DOSAGE FORM)
3.2.P.5 Control of Drug Product
3.2.P.5.1 Specification(s)
3.2.P.5.2 Analytical Procedures
3.2.P.5.3 Validation of Analytical Procedures
3.2.P.5.4 Batch Analyses
3.2.P.5.5 Characterisation of Impurities
3.2.P.5.6 Justification of Specification(s)
3.2.P.6 Reference Standards or Materials
3.2.P.7 Container Closure System
3.2.P.8 Stability
3.2.P.8.1 Stability Summary and Conclusion
3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment
3.2.P.8.3 Stability Data

في عنا فيها اشي اسمه **pharmaceuticals**
developed وهي كيف طريقه التصنيع شو
manufacturing ليش مثل قررنا نعمل
ال **compression** وهل هو **directly** او
granulation بالتفاصيل شو نعمل بكل وحده
من حيث الخط توزين المكونات والسرعه
(refrance of standard)

هون نحكي عن شكل العلبه،
ابعادها ، شو مكتوب عليها.
اذا**tablet** هل محطوط
بعلبه هل عليها قطنه او لا
هل فيها سيليكا الي تمتص
الرطوبه او لا

ORGANIZATION OF CTD
MODULE 3 : QUALITY

3.2.P DRUG PRODUCT (NAME, DOSAGE FORM)
3.2.P.5 Control of Drug Product
3.2.P.5.1 Specification(s)
3.2.P.5.2 Analytical Procedures
3.2.P.5.3 Validation of Analytical Procedures
3.2.P.5.4 Batch Analyses
3.2.P.5.5 Characterisation of Impurities
3.2.P.5.6 Justification of Specification(s)
3.2.P.6 Reference Standards or Materials
3.2.P.7 Container Closure System
3.2.P.8 Stability
3.2.P.8.1 Stability Summary and Conclusion
3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment
3.2.P.8.3 Stability Data

ORGANIZATION OF CTD
MODULE 4 : NON-CLINICAL STUDY REPORTS

- Module 4 describes the format and organisation of the nonclinical (pharmaco-toxicological) data relevant to the application.

- ❑ 4.2 STUDY REPORTS → يحتوي على
- ❑ 4.2.1 Pharmacology *
- ❑ 4.2.2 Pharmacokinetics *
- ❑ 4.2.3 Toxicology *
- ❑ 4.3 literature references *

ORGANIZATION OF CTD
MODULE 5 : CLINICAL STUDY REPORTS

- Module 5 describes the format and organisation of the **clinical data relevant to the application**.
  - 5.3.1 Reports of Biopharmaceutical Studies
  - 5.3.2 Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials
  - 5.3.3 Reports of Human Pharmacokinetic (PK) Studies
  - 5.3.4 Reports of Human Pharmacodynamic (PD) Studies
  - 5.3.5 Reports of Efficacy and Safety Studies
  - 5.3.6 Reports of Post-Marketing Experience
  - 5.3.7 Case Report Forms and Individual Patient Listings
  - 5.4 literature references

ELECTRONIC SUBMISSION

CTD dossier in bookrack

Reviewer's desk