Government of the Republic of Trinidad and Tobago
Ministry of Health
CHEMISTRY, FOOD AND DRUGS DIVISION
#4-6 Queen's Park East, Port of Spain 101002

NEW DRUG REGISTRATION DETAILED REQUIREMENTS

Updated September 2025

Instructions:

In order to expedite the processing of your New Drug Submissions, please ensure/provide the following in duplicate: -

1.(a) The New Drug Submission Forms (Form A, B and C) are filled out properly.
As much information as possible must be filled out on the forms provided.

DO NOT PUT - "SEE DOSSIER"

You may use a blank sheet of paper if more space is required and attach to the form.

(b) All relevant technical data such as - clinical studies, product description, product formulation/specification, methods of analysis, certificate of analysis must be provided to support each new Drug Submission. (See detailed requirements attached).

2. Each drug is properly certified - original "Free Sale Certificate"/ "Certificate of Pharmaceutical Product" (CPP) is required from the relevant Health Authorities.

3. A minimum of five (5) samples of each drug be provided in its finished pharmaceutical form in which it is to be sold.

4. Sample(s) (1 gram) of the active ingredient(s) be provided.

5. Submission must be presented in four separate sections (dossiers) clearly labeled using the following format:

Dossiers - Administrative
Chemical
Pharmaceutical
Other

Please ensure the proper name or trade name is stated on the cover page of each dossier.

1. Administrative Documentation

- See Section 1 of Detailed Requirements for New Drug Submission (NDS).
- Completed Application Form.

2. Chemical Documentation

- See Section 2 of Detailed Requirements for New Drug Submission.

3. Pharmaceutical Documentation
- include non-clinical data and clinical data including Comparative Studies (where applicable)
-See Section 3 of Detailed Requirements for New Drug Submission.

4. Other - See Section 4 - 7 of Detailed Requirements for New Drug Submission.
Dossiers must be submitted in Duplicate.

6. REGISTRATION FEE: $750.00 (T.T.) or $ 100.00 (T.T.) payable in advance.

(1) Administrative Documentation

1.1 Completed Application Forms A, B and C

1.2 Receipt

Proof of payment totaling a cost of $750 or $100 paid at the Ministry of Health or any District Revenue Office must accompany each new drug submission or supplemental drug submission respectively. Receipts cannot be used for more than one product. Please present the original receipt for verification and a copy with your submission.

1.3 Certificate of Pharmaceutical Product - Original, Apostille and Attested

OR

Certificate of Free Sale Issued by the Drug Regulatory Authority of the Manufacturing Country or Exporting Country - Original, Apostille and Attested

(2) Chemical Documentation

(A) Finished Product

2.A.1 Specifications

(a) Provide a complete description of the quality indexes or specifications (physical, chemical, and microbiological) and acceptable limits in table format, independently of the methods of analysis and quality reference (reference pharmacopeia or manufacturer);
(b) Justify any omission of the quality indexes established in the reference Pharmacopoeias for the product whose registration is being requested;
(c) All solid forms of controlled or modified release (tablets, capsules, ovules) require time-release testing.

2.A.2 Method of Analysis

(a) Provide information on the methods of analysis used for quality control:

- A specific monograph, when from a reference pharmacopeia;
- A complete description of the method of analysis, when from the manufacturer.

2.A.3 Certificate of Analysis of the Finished Product- Original

(a) Include a certificate with evidence of the quality specifications issued by the manufacturer of the finished product. In the case of initial production of products in development, it is acceptable that the tests were conducted in pilot batches.

2.A.4 Stability Data (Zone IV) – Long-Term and Accelerated Stability Studies

Submit the stability study, including the following study protocol:
(a) Quality specifications and methods of analysis;
(b) Detailed description of the container closing system used with the product being

evaluated;
(c) Storage conditions (temperature, light sensitivity and relative humidity in the environment);
(d) Results from at least three lots of the finished product (using preferably different lots of the Active Pharmaceutical Ingredient);
(e) Conclusions and proposed expiration date and storage conditions;
(f) The professional responsible for the study should sign off on the stability studies;
(g) When the dosage form of the medicine is accompanied by a solvent or diluents, include stability studies on the diluted, dissolved or dispersed product, as applicable, in the conditions under which it's to be utilized;
(h) If more than one vehicle is used for its preparation, submit data from the stability studies conducted for each of them;
(j) If a product is packaged in two or more container closing systems, present the stability studies for each of them.
(i) If a product is packaged in two or more volumes, stability studies have to be presented according to international regulations in force.
(j) It is required the submission of accelerated studies and long term (shelf-life or shelf-life only).

2.A.5 Disintegration

(a) Monograph or Method of Analysis
(b) Test parameters;
(c) Test medium;
(d) Specification.

2.A.6 Dissolution Profile

(a) Monograph or Method of Analysis;
(b) Test parameters i.e. type and volume of dissolution medium, rotation rate,
(c) temperature of solution and time.
(d) Preparation of dissolution medium, preparation of sample and standard solution
(e) (if any), etc.
(f) Type and method of analysis (HPLC, UV, etc.) and test procedures. For example, if HPLC method is used, test method has to include the preparation of mobile phase, brand and type of column used, run time, detector used (UV, RI, etc.), injection volume, system suitability test and other parameters.
(g) Typical chromatograms/UV spectrum for sample & standard solution, system suitability etc.
(i) Complete formula for calculation. For example, 'slow release' products calculation must include quantity of active substance in the medium volume which has been taken out for analysis.

2.A.7 Physical Samples

- Four (4) Samples (correspondent Certificate of Analysis)

(3) Active Ingredient(s) Documentation

(B) Active Ingredients

3.B.1 Specifications

a) Provide a complete description of quality indexes or specifications (physical, chemical and microbiological) and acceptable limits, with the quality reference (reference pharmacopeia or from the manufacturer);
b) If the reference is from the manufacturer, include any impurities resulting from the synthesis, their identification and the rationale justifying acceptable limits.

3.B.2 Method of Analysis

a) A specific monograph, when from a reference pharmacopeia;
b) A complete description of the method of analysis, when from the manufacturer.

3.B.3 Certificate of Analysis for Each Active Ingredient - Original

a) Include a certificate of analysis from the original manufacturer for each active ingredient, with verification of its respective quality specifications, with correspondence to the lots used in the product to be registered.

3.B.4 Good Manufacturing Practice Certificates for Active Ingredient(s) Manufacturer Only

(a) GMP Certificate, Certificate of Compliance or ISO Certification issued to the manufacturer of the raw materials by a Recognized Regulatory Body is required.
(b) A statement that the facilities are regularly inspected and found to conform with current Good Manufacturing Practices (GMP) shall also be included.

3.B.5 Sample of Active Ingredient(s) for Laboratory Testing

(a) One (1) gram of each ingredient (correspondent Certificate of Analysis)

(4) Pharmaceutical Documentation - (Data: - Published and In-house)

4.1 Pharmacodynamic data

4.2 Pharmacokinetic data

4.3 Pharmacotherapeutic data

4.4 Toxicity data

4.5 Immunogenicity Data (if applicable)

4.6 Comparative Studies (if applicable)

4.7 Adverse Event Reports (Within the last five years with summary Report)

4.8 Risk Management Plan

4.9 Periodic Safety Update Records/Public Assessment Reports (PSUR/PAR) (most recent with summary reports) (Optional)

4.10 Pharmacovigilance Plan/Post-Marketing Surveillance Plan (Optional)

(5) Manufacturing Documentation

5.1 Manufacturing/Unit Composition Formula

(a) Include a description of its qualitative and quantitative composition, by dosage unit and percent (weight or volume), detailing each component, Active Pharmaceutical Ingredient(s), preservatives, stabilizers and excipients.

5.2 Brief Manufacturing Direction/Procedure

(a) A description of the manufacturing process that includes all steps or stages up to completion of the finished product, along with its packaging and labeling;
(b) A flow chart of this process that includes the stages of formulation, fill, lyophilisation (if applicable), labeling and packaging, indicating the points at which material input occurs and indicating intermediate steps, critical points, and controls in this process;
(c) In cases where more than one manufacturer is involved in the process, the flow chart should include the step(s) in which each of them participates;
(d) Information on process validation;
(e) Reprocesses, with justification and duly validated, whenever applicable.

5.3 Brief Manufacturing Controls

(a) Description of controls at critical steps or stages and key intermediate products;

5.4 Sampling and Testing Procedures

(a) A document describing the process of collecting and testing incoming materials and the finished product to monitor and verify the effectiveness of control measures put in place to prevent, eliminate or reduce any hazards that present a risk of contamination.

5.4.1 Batch Release Certificate

(a) Certification of the finished product batch that signifies the batch compliance with the Good Manufacturing Practice and the requirements of the Marketing Authorization Holder.

5.5 Good Manufacturing Practice (GMP) Certificate(s) for the Finished Product

(a) GMP Certificate Issued by the Drug Regulatory Authority of the Manufacturing Country.
(b) The certificate shall be issued by the regulatory agency on pharmaceuticals from the country of origin of the drug product.
(c) A statement that the manufacturer is duly registered with the regulatory authority shall be included.

(d) A statement that the facilities are regularly inspected and found to conform with current Good Manufacturing Practices (GMP) shall also be included.

5.6 Packaging Materials (Containers and Closures)

(a) Description
(b) Composition
(c) Size and dimension requirements (gauge, thickness, etc.) with target value and acceptable tolerances
(d) Colour
(e) Processes necessary to make the article acceptable to pharmaceutical production (e.g. coating, washing, sterility of surfaces, etc.)
(f) Samples

5.7 Ink and Printing

(a) Colour of Ink
(b) Chemical Composition of Ink
(c) Description of Ink (colour fast, light resistant, rub resistant, reflectance, etc.)
(d) Other characteristics of Ink (odour, distribution, etc.)
(e) Printing - capacity to smear, smudge, scoff or be removed during normal handling of the package
(f) Safety of Ink Used e.g. food grade

5.8 Artworks in Duplicate

Soft copy of the primary and secondary label of the finished product.
All claims made on the label must be accompanied with documentation to substantiate them. E.g. NON-GMO, Gluten free, etc.
The artwork must have:

(a) Proper Name/Standard/Trade Name
(b) Common Name (Optional)
(c) Lot/ Batch Number
(d) Expiry Date
(e) The Name and Address of the Manufacturer or Distributor
(f) Net Content
(g) Warning and Precautions
(h) Direction of Use (if applicable)
(i) Special Storage Conditions

5.9 Package Insert/Patient Information Leaflet (if applicable)

Text for the package insert, should contain at least information indicated below.
a) International Non-proprietary Name (INN) and Anatomical Therapeutic Chemical Classification (ATC);
b) Brand name;
c) Dosage Form;
d) Concentration;
e) Contents/volume;

f) Number of doses per container (for multi-doses packaging), when applicable;
g) Composition;
h) Declaration of excipients;
i) Route of administration;
j) Indications (resulting from clinical trials that assess the medicine's efficacy);
k) Instructions for use;
l) Posology/dosage;
m) Maximum dose in 24 hours, for over-the-counter (OTC) products;
n) Precautions;
o) Warnings;
p) Adverse reactions;
q) Contraindications;
r) Interactions;
s) Overdose (risk and information on how to manage risk);
t) Use during pregnancy and breast-feeding;
u) The importance of monitoring patient use and where to report possible problems with the medicine;

ALTERNATIVE/HERBAL MEDICINES IN TRINIDAD AND TOBAGO

Assessment for product registration

Any drug, if unknown by name, form, properties and actions would cause complications. So too, would a known drug if badly administered. To ensure that safe and efficacious herbal drugs reach the consumer, the following are considered by the Sub-Committee in the assessment of each herb and herbal medicinal product:

1. Nomenclature
2. Part of plant used
3. Historical Aspects
4. Habitat
5. Botanical Description
6. Pharmcognosy
7. Phytochemistry
8. Properties
9. Pharmacology
10. Clinical Aspects
11. Safety
12. Indication
13. Formulation
14. Dosage

There are two options for submissions:

1. **The preferred method is the hard copy of the administrate file (please attach hard copies of labels) and flash drive.**

2. **The dossiers can be supplied in hard copy.**