GOVERNMENT OF REPUBLIC OF TRINIDAD AND TOBAGO

MINISTRY OF HEALTH
CHEMIST- FOOD AND DRUGS DIVISION

NEW DRUG SUBMISSION FORM

Guidelines:

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

1. (a) The New Drug Submission Forms 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 summary of 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. Five (5) samples of each drug be provided in its finished pharmaceutical form in which it is to be sold.

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

5. **REGISTRATION FEE:** $750.00 (T.T.) payable in advance.

   (Items1 (a) & (b) must be in duplicate).

   (Photocopies of this form are acceptable)

Checklist
To be completed by Applicant

TRINIDAD AND TOBAGO
MINISTRY OF HEALTH
CHEMISTRY/FOOD AND DRUGS DIVISION

SUMMARY OF REQUIREMENTS FOR NEW DRUG SUBMISSION

(1) Certificate in respect of Imported Drugs **Manufacture/Importer/Agent**

Name & Address

☐ Free Sale Certificate - Original

or

☐ Certificate of Pharmaceutical Product - Original

(2) Chemical Documentation **Name of Drug/Form/Strength**

(A) Finished Product

☐ Specifications
☐ Method of Analysis
☐ Certificate of Analysis - Original
☐ Stability Data
☐ Disintegration
☐ Dissolution Profile
☐ Five (5) Samples

(B) Active Ingredient(s)

☐ Specifications
☐ Method of Analysis
☐ Certificate of Analysis (each ingredient) - Original
☐ One (1) gram of each

(3) Pharmaceutical Documentation

(A) Pharmacodynamic data

☐ General Pharmacology
☐ Tests supporting efficacy

(B) Pharmacokinetic data

☐ Absorption
☐ Distribution
☐ Biotransformation/Metabolism
☐ Excretion
☐ Biological equivalence

(C) Pharmacotherapeutic data

- ☐ Therapeutic uses
- ☐ Clinical trials
- ☐ Therapeutic equivalence

(D) Toxicity data

- ☐ All types

N.B. Data: - Published and In-house.

(4) Manufacturing Details

- ☐ Manufacturing/Unit Composition Formula
- ☐ Brief Manufacturing Direction/Procedure
- ☐ Brief Manufacturing Controls
- ☐ Sampling and Testing Procedures
- ☐ GMP Certificate

(5) Packaging Materials (Containers and Closures)

- ☐ Description
- ☐ Composition
- ☐ Size and dimension requirements (guage, thickness, etc.) with target value and acceptable tolerances
- ☐ Colour
- ☐ Processes necessary to make the article acceptable to pharmaceutical production (e.g. coating, washing, sterility of surfaces, etc.)
- ☐ Samples

(6) Ink and Printing

- ☐ Colour of Ink
- ☐ Chemical Composition of Ink
- ☐ Description of Ink (colourfast, light resistant, rub resistant, reflectance, etc.)
- ☐ Other characteristics of Ink (odour, distribution, etc.)
- ☐ Printing - capacity to smear, smudge, scoff or be removed during normal handling of the package

(7) Package Insert

- ☐ Where applicable (Prescription Drugs)
- ☐ Standard Requirements

ALTERNATIVE/HERBAL MEDICINES IN TRINIDAD AND TOBAGO

The history of man has shown that multiple choices exist for protecting human health. Today's worldwide revival in the interest of natural products as preventative and therapeutic agents and the accompanying high demand for natural remedies have drawn the attention of the Ministry of Health in Trinidad and Tobago.

The Ministry has a responsibility to protect the health of the citizens. This requires the establishment of rules to govern the registration, importation, manufacture, storage, distribution, sale and use of herbal medicinal products. This is a special responsibility of the Chemistry/Food and Drugs Division in Port of Spain.

A Herbal Sub-Committee has been established by the Drug Advisory Committee to advise and assist the latter Committee on standards, schedules and conditions of sale for herbal medicinal preparations, and any other matters connected therewith.

The Drug Advisory Committee recommends to the Honourable Minister of Health, products for Approval.

The Herbal Sub-Committee consists of persons with interests and expertise in taxonomy, pharmacy, pharmacognosy, pharmacology, chemistry, conventional medicine and herbal medicine.

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. Nomemclature
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

During the last five (5) years approximately 13% of the approved medicines were of herbal origin.

Requirements for the label of a Herbal Medicine:

The label of a package of a Herbal Medicine shall carry -

(a) on the main panel of both the inner and the outer labels -

(i) the name (Proper or Common), dosage form and the standard, if any, under which the herbal medicine was manufactured;

(ii) a correct statement of the net contents in terms of weight, measure or number;

(b) on both the inner and outer labels -

(i) the name of the manufacturer or distributor of the herbal medicine;

(ii) the address of the manufacturer or distributor, except that where the immediate container contains five milliliters or less, this statement need not be made on the inner label;

(iii) in the case of a herbal medicine which consists of more than one ingredient, a quantitative list of the active ingredients;

- The Botanical Name of the plant(s) used and part(s) thereof, shall be declared.

- the common or vernacular name of plant(s) used may be declared.

(iv) dosage regimen and adequate directions for use in the English Language;

(v) the expiry date;

(vi) directions as to the type of storage necessary to maintain the potency, efficacy, safety or properties of the herbal medicine;

(vii) a declaration of any warnings or contraindications, if applicable;

(viii) the declaration;

CAUTION: "Keep out of the reach of children".
"If pregnant or breast feeding ask a health care professional before use".

(c) on any panel, including the panel at the bottom of the package –

(i) the batch or lot number; and

(ii) any registration number, if applicable.

For Official Use

Receiving No:
Control No:
DAN No:

To be filled out by Applicant upon presentation of New Drug Submission/Supplemental Submission

(1) Name of Drug/Form/Strength :……

(2) Name and Address of Manufacturer or :……..

Distributor:…….

(3) Phone Number (if local manufacturer):…….

(4) Country of Origin:……..

(5) Name & Address of Importer:……

……

(6) Phone Number:……

(7) List of ingredients (Active Only)

NAME	QUANTITY	NAME	QUANTITY

(8) Claims/Indications:……

……

……

……

……

TRINIDAD AND TOBAGO

NEW DRUG SUBMISSION FORM

Second Schedule, Division 3, Food and Drugs Act Chap 30:01

To: The Chief Chemist/Director of Food and Drugs, #115 Frederick Street, Port of Spain, Trinidad.

We hereby make the New Drug Submission for .....
and attach the following information IN DUPLICATE:

(a) a description of the New Drug, its proper name and trade name; [ ]
(b) a statement of all ingredients, route of administration, dosage, claims to be made, contra-indication and side-effects (if known), and description of pharmaceutical form in which it is to be sold; [ ]
(c) details of tests applied to control potency, purity and safety of new drugs; [ ]
(d) labels and samples of the new drug in the finished pharmaceutical form; (Note 1) [ ]
(e) samples of the components - active ingredient(s); [ ]
(f) certificates as specified in (g) to (j) in para. 3 (f) (i)-(v) Div.3, of the Second Schedule of the Food and Drugs Regulations; [ ]

Canada	[ ]	United Kingdom	[ ]
F.D.A., U.S.A.	[ ]	Australia	[ ]

(g) certificates from State or City authorities in the United States respecting the sale and conditions of sale in the United States; [ ]

(h) certificates in English Language recognised as having adequate experience and facilities for assessing the safety of new drugs by the Ministries of Health in

Belgium	[ ]	Netherlands	[ ]	Denmark	[ ]
France	[ ]	Sweden	[ ]		

(i) certificates (with English translation) from other authorities in ..... (2);
(j) detailed reports of animal test [ ] and/or clinical trials [ ] to establish the safety of the new drug (Note 2).

We undertake to inform you of any change made in the conditions of use, labelling, pharmaceutical form, dosage, or strength, purity, quality of the drug which makes them significantly different to those given in this submission, (para. 5 of this Division of the Regulations).

We also undertake to inform you of any report of unexpected side-effects, injury, toxicity, or sensitivity reaction associated with the use of this New Drug in any way (para. 9 of this Division of the Regulations).

....
Date Importers/Manufacturers Agent in Trinidad and Tobago

NEW DRUG SUBMISSION FORM

(TYPE OR FILL IN BLOCK LETTERS)

TRADE NAME .....

FORM .....….

INGREDIENTS:

(SEE NOTES)

	QUANTITY OR %		QUANTITY OR %
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

CLAIMS, INDICATIONS

KNOWN CONTRA INDICATIONS SIDE-EFFECTS

DOSAGE

MANUFACTURER (Complete Name & Address)	NAME: ADDRESS:
IMPORTER/AGENT (Complete Name & Address)	NAME: ADDRESS: PHONE:

Notes: The pharmaceutical form (tablet, capsule, cream, elixir, injection etc.,) must be indicated. Different strengths in the same form (e.g. 1.5 and 10 mg tablets) must be treated separately.

Active ingredients must be listed before inactive ingredients. Quantities should be given in appropriate units, or in percentages (for creams, liquids), or in amounts per ml or per ampoule.

FOR OFFICIAL USE ONLY

CONDITION OF SALE:

1. FREE SALE
2. THIRD SCHEDULE
3. CONTROLLED
4. DEFERRED

COMMENTS: