SOP No.	Revision	Issue date	Page 1 of .....
SOP-01-001	0	DD/MM/YYYY	
Effective date			Prepared by:
Standard Operating Procedure			Reviewed by:
			Authorized by:

NATIONAL MEDICICINE REGULATORY AUTHORITY (NMRA) PROCEDURES

STANDARD OPERATING PROCEDURE FOR ISSUING THE SAMPLE IMPORT LICENCE

NMRA	**Issuing Sample License**		Page 2 of …. No. …… Date. ……..
Prepared by: …… Date: ……	Reviewed by: …… Date: ……	Authorized by: …… Date: ……	Supersedes No.:. Date: ……
Title: SOP for Issuing Sample Licence Department: Registration and Licensing Division / Administrative Division Responsibility: Head of the Department			

1. Purpose:

Purpose of this document is to describe the procedure for issuing sample licences.

2. Scope:

This procedure applies for issuing sample licenses for drugs in order to facilitate import of samples to fulfill registration requirements or for testing purposes, in terms of NMRA Act and CDD regulations.

(Attached relevant sections)

3. Responsibility:

It is the responsibility of the Chief Pharmacist to ensure timely issuing of sample licence.

NMRA	**Issuing Sample License**		Page 3 of …. No. …… Date. ……..
Prepared by: …… Date: ……	Reviewed by: …… Date: ……	Authorized by: …… Date: ……	Supersedes No.:. Date: ……
Title: SOP for Issuing Sample Licence Department: Registration and Licensing Division / Administrative Division Responsibility: Head of the Department			

4. Procedure

4.1 Applicant submits the application [Annexure 1: Schedule V, Form C] to Health Management Assistant (1) along with a copy of a letter approving Company profile.

- In case of New Molecular Entity (NCE)/ Therapeutic Biological / Biotechnological products, a copy of the letter signed by the Secretary, Medicines Evaluation Committee (MEC) along with a copy of a letter approving Company profile.
- When the purpose of importation of samples of medicine is to carry out a clinical trial, a copy approval letter of the clinical trial issued by the NMRA must be submitted.

4.2 Health Management Assistant (1) checks **(**Annexure 2: Acceptance criteria**)** and forwards the date-stamped applications to the pharmacist (1).

4.3 Pharmacist (1) checks the application for above requirements, brand name and signatures minutes and, forwards to Health Management Assistant (1) for processing.

4.4 Health Management Assistant (1) issues Payment Letter (Annexure 4: Processing fee).

4.5 Applicant makes the payment to Bank of Ceylon, Regent Street Branch and receives paying receipt.

4.6 Applicant submits date stamped Yellow Receipt within 14 days to Health Management Assistant (1). If not, the application will be sent to Record room.

NMRA	**Issuing Sample License**		Page 4 of …. No. …… Date. ……..
Prepared by: …… Date: ……	Reviewed by: …… Date: ……	Authorized by: …… Date: ……	Supersedes No.:. Date: ……
Title: SOP for Issuing Sample Licence Department: Registration and Licensing Division / Administrative Division Responsibility: Head of the Department			

4.7 Health Management Assistant (1) cancels the yellow receipt, attach the license to be typed [Annexure 4; Schedule V, Form D] to the application and indicates the relevant license number & date in the yellow receipt.

4.8 Health Management Assistant (1) forwards the license along with the other documents to the typist for typing.

4.9 Typist submits the typed sample license with two copies to Health Management Assistant (2).

4.10 Health Management Assistant (2) submits typed license with two copies to pharmacist (2) for checking.

4.11 Pharmacist (2) signs in a copy of the license after checking and forwards to Health Management Assistant (2).

4.12 Health Management Assistant (2) minutes and forwards the license with two copies to D/MT& S for signature.

4.13 D/MT& S signs and forwards to Health Management Assistant (2).

Prepared by: …… Date: ……	Reviewed by: …… Date: ……	Authorized by: …… Date: ……	Supersedes No.:. Date: ……
Title: SOP for Issuing Sample Licence Department: Registration and Licensing Division / Administrative Division Responsibility: Head of the Department			

4.14 Health Management Assistant (2) issues the Sample Import Licence to applicant while attaching a copy to the dossier and sending the other copy to the data entry operator. The data entry operator enters the required data in the database and return to the Health Management Assistant (2) to bind the licenses separately.

If the importer receives the Sample Import License, he is entitled to submit the dossier of such product for registration before expiry of the sample license.

Annexure -1

59. (1) Any person who intends to manufacture or import any medicine shall make an application for the registration of that medicine in the prescribed form to the Authority.

Application for Registration of a medicine.

(2) The application shall be accompanied by the prescribed particulars, the samples of the medicine and the prescribed fee.

Annexure - 2

Form C — Regulation 24(1)

SCHEDULE V

APPLICATION FOR A LICENCE TO IMPORT A LIMITED QUANTITY OF ANY DRUG(S) FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS OR CLINICAL TRIAL

I/We ..... of ..... hereby apply for a licence to import from M/s. ..... of ..... the drug(s) specified below for the purpose of test, examination, distribution as samples, analysis or clinical trial.

Name(s) of drug(s) and dosage forms :

1. .....
2. .....
3. .....

Signed :.....

Address :.....

Date :.....

Designation of applicant :.....

Annexure -3

Form D — Regulation 25(2)

SCHEDULE V

LICENCE TO IMPORT DRUGS FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS OR CLINICAL TRIALS

Licence Number :

M/s. ..... of .....

..... is/are hereby licensed to import from .....

the drug(s) specified below for the purpose of test, examination, distribution as samples, analysis or clinical trial.

This licence is subject to the conditions prescribed in regulation 26 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act, No. 38 of 1984.

The Licence shall be valid for the importation of one batch of drugs only and be valid for one year from the date of issue.

Name(s) of Drug(s) with quantities which may be imported :

1. .....
2. .....
3. .....

.....

Date of issue :..... Authority.

Annexure 4

Acceptance Criteria of the application for Sample Licence

NATIONAL MEDICINES REGULATORY AUTHORITY
SRI LANKA.
120, Norris Canal Road, Colombo 10, Sri Lanka.
Telephone: +94 011 2698896/7 Fax: +94 011 2689704

EVALUATION REPORT ON PHARMACEUTICAL MANUFACTURING FACILITY

Application No			
Name of the Manufacturer			
Site Address			
Address, Head Office			
Local Agent	.		
Categories of Products			
Evaluator's (External / Internal) Comments:			
Decision	Pending (awaiting additional data)	Evaluated by:	
Recommendation of CP evaluation committee	…… 1. 2. 3.		

Use for Payment
Please deposit Rs. …… (which is equivalent to USD400/USD200/USD100 + 15% VAT & 10% stamp duty) to the Account of National Medicines Regulatory Authority – **BOC A/C No. 78088835**, Regent Street Branch.
Please submit the cash receipt (Form Gen.172) to CEO/NMRA (Act. No 5 of 2015) No.120, Norris Canal Road, Colombo 10, for processing of certificate, **within 14 days** of receipt of this evaluation report

Chief Executive Officer, National Medicines Regulatory Authority

……
CEO
National Medicines Regulatory Authority

Annexure 5

දුරකථන
தொலைபேசி
Telephone
0112698896/7
0112695173

ෆැක්ස්
Fax
0112689704

විද්‍යුත් තැපෑල
மின்னஞ்சல்
e-mail
nmra@health.gov.lk

වෙබ් අඩවිය
இணையத்தளம்
Website

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය
எனது இல
My No.
NMRA/SCOCT /CTM/ 002/2017

ඔබේ අංකය
உமது இல
Your No.

දිනය
திகதி
Date
10/01/2018

National Medicines Regulatory Authority, No: 120, Norris Canal Road, Colombo 10.

Dr. ……,
Coordinating Principal Investigator,

Dear Dr. ……,

Re: (Title of the Trial)

We thank you for submitting the above trial application for the review of Subcommittee on Clinical Trials (SCOCT) of the National Medicine Regulatory Authority (NMRA).

The conduct of above study under the supervision of the following investigators mentioned in your applicationis here by approved.

1.
2.
3.
4.

The following documents submitted by you were reviewed:

Document	Version and Date
1. Application forma and undertaking by the principal investigator	
2. Clinical Trial Protocol	
3. Investigator's Brochure	
4. Curriculum Vitae of the Investigators	
5. Participant information sheet and consent form in English	
6. Participant information sheet and consent form in Sinhala	
7. Participant information sheet and consent form in Tamil	
8. Ethical approval	

Please note that you are expected to follow the requirements given below, for this study:

- Do not implement any deviation from, or change to, the protocol approved by this committee, without prior written approval of this committee. (Deviations/changes to the approved protocol may be implemented without prior approval of this committee only when necessary

Annexure – 6

Document Submission form to get Initial Decision

for New Molecular Entity/ Therapeutic Biological/ Biotechnological Products

from Medicines Evaluation Committee (MEC)

For office use only.

1. Reference Number: .....
2. Date of submission: .....

---

3. Name of the local agent: .....
4. Name of the Manufacturer: .....
5. Actual Manufacturing site address: .....
   .....
   .....
6. Product Name- Generic: .....

   Product Name- Brand: .....
7. Dosage form: .....
8. Strength: .....
9. Indication: .....
10. Following documents should be annexed:
    a) Registration status in County of origin (Copy of COPP). ☐
    b) Registration status in NMRA reference countries (Copies of registration certificates). ☐
    c) Documentary evidence for post marketing details in country of origin (minimum for 2 years). ☐
    d) Periodic safety update report. ☐
    e) Public assesment report from a reference country where it is registered. ☐
    f) Product Information Leaflet. ☐
11. Total Number of pages: .....
12. Checked by: .....(Pharmacist/P-Code)

For MEC use only.

MEC decision:

Accept	Decline

Signature:

(Secretary/MEC)

Annexure - 7

Document Submission form to get Initial Decision

for New Molecular Entity/ Therapeutic Biological/ Biotechnological Products

from Medicines Evaluation Committee (MEC)

For office use only.

1. Reference Number: .....
2. Date of submission: .....

---

3. Name of the local agent: .....
4. Name of the Manufacturer: .....
5. Actual Manufacturing site address: .....
   .....
   .....
6. Product Name- Generic: .....

   Product Name- Brand: .....
7. Dosage form: .....
8. Strength: .....
9. Indication: .....
10. Following documents should be annexed:
    a) Registration status in County of origin (Copy of COPP). ☐
    b) Registration status in NMRA reference countries (Copies of registration certificates). ☐
    c) Documentary evidence for post marketing details in country of origin (minimum for 2 years). ☐
    d) Periodic safety update report. ☐
    e) Public assesment report from a reference country where it is registered. ☐
    f) Product Information Leaflet. ☐
11. Total Number of pages: .....
12. Checked by: .....(Pharmacist/P-Code)

For MEC use only.

MEC decision:

Accept	Decline

Signature:

(Secretary/MEC)

Annexure -8

SCHEDULE *(Continued)*

(xi) Fee for sample import license for clinical trials.- (USD) 100.00

(xii) Fee for advertisement

Advertisement	Fee (USD)
Processing fee for Advertisement (All categories)	1,000.00

*(Separate applications should be submitted for each advertisement).

(v) Fees for License

Types of Licenses	Fee (USD)
Sample Import License	100.00
Import License	100.00
Manufacturing License	100.00
Amendment of License	100.00

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015.

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under paragraph (u) of Subsection (2) of Section 142 read together with Sections 59 and 63 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE,
Minister of Health, Nutrition and Indigenous Medicine.

Colombo,
13th of June, 2017.

REGULATIONS

1. These regulations may be cited as the Registration and Licensing of Medicines (fees) Regulations, No. 02 of 2017 and shall come into operation from 14.06.2017.

2. Applications for registration and licensing of a medicine under sections 59 and 63 of the National Medicines Regulatory Authority Act, No. 5 of 2015 shall be accompanied by the processing fees, and any other relevant fees subsequently as set out in the Schedule hereto.