

SOP No. SOP-01-00....	Revision 0	Issue date DD/MM/YYYY	Page 1 of
Effective date		Prepared by:	
Standard Operating Procedure		Reviewed by:	
		Authorized by:	

**COSMETICS, DEVICES & DRUGS
REGULATORY AUTHORITY
PROCEDURES**

**STANDARD OPERATING PROCEDURE
FOR ISSUING VAT & DUTY WAIVERS**

Purpose:

Purpose of this document is to describe the procedure for issuing formulation approval letter.

Scope:

This procedure applies

Responsibility:

Procedure

- Step 1 Applicant submits the request letter (format champiAnnexure A) along with three copies of Performa Invoice, and valid registration certificate to the Health Management Assistant (1).
- Step 2 Applications are date-stamped (Copy of the application is signed and given to the applicant.) and checked by the Health Management Assistant (1) and sends it to the HMA (2) for checking.
- Step 3 Health Management Assistant (2) prepares the letter for Vat & Duty Waiver according to the standard format (Annexure B) and forwards to the pharmacist (1) for checking.
- Step 4 After checking, pharmacist (1) minute and forwards the file to Health Management Assistant (2).
- Step 5 Health Management Assistant (2) minute and forward to the pharmacist and then it is sent to the HMA(2) by the pharmacist(1).again it is sent to the HMA HMA sends it to the D/MT& S for signature. (4 copies)
- Step 6 D/MT& S signs and forwards to Health Management assistant (3).
- Step 5 Health Management Assistant (3) issues the letter to applicant.

Copies- office copies and other copies

ANNEXURE “A” RM for one item

MTS/E/C/CID/RM/05/10

Director General,
Department of Trade, Tariff & Investment Policy,
Ministry of Finance and Planning
The Secretariat, Colombo 01

**Request For Customs Import Duty Waiver on Raw Materials
For the Manufacture of Pharmaceuticals**

An application has been made to me by :

For the Customs Import Duty clearance of

Imported from :

On Pro-forma / Commercial Invoice number :

This is requested for the manufacturer of

Which is an approved pharmaceutical product in Sri Lanka

Hence I have No Objection in importing above pharmaceutical raw material in above stated quantity to manufacture the said pharmaceutical product.

I therefore, recommend the waiver of Customs Import Duty on this consignment of pharmaceutical raw materials.

.....
Dr.B.V.S.H.Beneragama

Director

Medical Technology & Supplies

120, Norris Canal Road, Colombo 10

Tel : 2698896, 2698897

Copy : 1. Director General of Health Services

2. The Controller of Imports & Exports

3. Director General of Customs

4. M/s - Please ensure that above pharmaceutical raw material is used to manufacture the stated product and cannot sale to private market.

RM for many items

Director General,
 Department of Trade, Tariff & Investment Policy,
 Ministry of Finance and Planning
 The Secretariat, Colombo 01

**Request For Customs Import Duty Waiver on Raw Materials
 For the Manufacture of Pharmaceuticals**

An application has been made to me by :

For the Customs Import Duty clearance of the following raw materials

<u>Items</u>	<u>Quantity</u>	<u>Proforma/Commercial Invoice No. & Date</u>
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2. These pharmaceutical raw materials are required for the manufacturer of approved pharmaceutical products in Sri Lanka

3. Hence I have No Objection in importing above pharmaceutical raw materials in above stated quantities to manufacture the said pharmaceutical products.

4. I therefore, recommend the waiver of Customs Import Duty on this consignment of pharmaceutical raw materials.

.....

Director
 Medical Technology & Supplies
 120, Norris Canal Road, Colombo 10
 Tel : 2698896, 2698897

- Copy :
1. Director General of Health Services
 2. The Controller of Imports & Exports
 3. Director General of Customs

4. M/s - Please ensure that above pharmaceutical raw material is used to manufacture the stated product and cannot sale to private market.

Director General,
 Department of Trade, Tariff & Investment Policy,

Ministry of Finance and Planning
The Secretariat, Colombo 01

**Request For Customs Import Duty Waiver on Packaging Materials
For the Manufacture of Pharmaceuticals**

An application has been made to me by :

For the Customs Import Duty clearance of
Imported from :

On Pro-forma / Commercial Invoice number :

This is requested for the manufacturer of

Which is an approved pharmaceutical product in Sri Lanka

Hence I have No Objection in importing above pharmaceutical Packaging material in above stated quantity to manufacture the said pharmaceutical product. I therefore, recommend the waiver of Customs Import Duty on this consignment of pharmaceutical packaging materials.

This letter is issued in par with the recommendation made by the treasury on exemption of Customs Import Duty for Pharmaceutical packaging material by the treasury letter No. RPO 01/2008 dated 07.11.2008.

.....
Dr.B.V.S.H.Beneragama
Director
Medical Technology & Supplies
120, Norris Canal Road, Colombo 10
Tel : 2698896, 2698897

- Copy :
1. Director General of Health Services
 2. The Controller of Imports & Exports
 3. Director General of Customs
 4. M/s - Please ensure that above pharmaceutical packaging material is used to manufacture the stated product and cannot sale to private market.

MTS/E/C/CID/PM/07/10

Director General,
Department of Trade, Tariff & Investment Policy,
Ministry of Finance and Planning
The Secretariat, Colombo 01

**Request For Customs Import Duty Waiver on Packaging Materials
For the Manufacture of Pharmaceuticals**

An application has been made to me by :

For the Customs Import Duty clearance of the following packaging materials

<u>Items</u>	<u>Quantity</u>	<u>Proforma/Commercial Invoice No. & Date</u>
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2. These pharmaceutical packaging materials are required for the manufacturer of approved pharmaceutical products in Sri Lanka

3. Hence I have No Objection in importing above pharmaceutical packaging materials in above stated quantities to manufacture the said pharmaceutical products.

4. I therefore, recommend the waiver of Customs Import Duty on this consignment of pharmaceutical packaging materials.

This letter is issued in par with the recommendation made by the treasury on exemption of Customs Import Duty for Pharmaceutical packaging materials by the treasury letter No. RPO 01/2008 dated 07.11.2008.

.....
Director
Medical Technology & Supplies
120, Norris Canal Road, Colombo 10
Tel : 2698896, 2698897

Copy : 1. Director General of Health Services
2. The Controller of Imports & Exports
3. Director General of Customs
4. M/s - Please ensure that above pharmaceutical packaging materials is used to manufacture the stated product and cannot sale to private market.

MTS/E/C/CID/RM/05/10

RM for new products

Director General,
Department of Trade, Tariff & Investment Policy,
Ministry of Finance and Planning
The Secretariat, Colombo 01

**Request For Customs Import Duty Waiver on Raw Materials
For the Manufacture of Pharmaceuticals**

An application has been made to me by :

For the Customs Import Duty clearance of the following raw materials

<u>Items</u>	<u>Quantity</u>	<u>Proforma/Commercial Invoice No. & Date</u>
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2. These pharmaceutical raw materials are required formulate new products for registration in Sri Lanka.
3. Hence I have No Objection in importing above pharmaceutical raw materials in above stated quantities to manufacture the said pharmaceutical products for registration purpose.
4. I therefore, recommend the waiver of Customs Import Duty on this consignment of pharmaceutical raw materials.

.....
Dr.B.V.S.H.Beneragama
Director
Medical Technology & Supplies
120, Norris Canal Road, Colombo 10
Tel : 2698896, 2698897

Copy : 1. Director General of Health Services
2. The Controller of Imports & Exports
3. Director General of Customs

4. M/s - Please ensure that above pharmaceutical raw material is used to manufacture the stated product and cannot sale to private market.

****format(Anexture for sample preparation)