

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

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

**STANDARD OPERATING PROCEDURE FOR
ISSUING PERSONAL USER LICENCE**

Purpose:

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

Scope:

This procedure applies

Responsibility:

Procedure

- Step 1 Applicant submits the **application [Annexure ... Schedule ..., Form ..., Regulation]** to Pharmacist (1) along with the request letter (from the patient or the guardian) and the prescription written by a qualified medical practitioner.
- Step 2 **Applications** are date-stamped, checked by the pharmacist (1). After checking, the pharmacist signs (**minute**) and forwards to Health Management Assistant (1) for processing. **Receiving officer (?) checks the brand name.**
- Step 3 Health Management Assistant (1) issues Payment Letter.
- Step 4 Applicant makes the payment to the **shroff counter** of the Ministry of Health. The applicant receives a yellow receipt from the shroff.
- Step 5 **Applicant submits date stamped Yellow Receipt within 14 days to Health Management Assistant (1).** If not, the application will be sent to Record room.
- Step 6 Health Management Assistant (1) cancels the yellow receipt, attach the licence to be typed [Annexure 4; Schedule V, Form D, Regulation 25(2)] to the application and indicates the relevant licence number & date in the yellow receipt.
- Step 7 Health Management Assistant (1) forwards the licence along with the other documents to the typist for typing.
- Step 8 Typist submits the typed sample licence with two copies to Health Management Assistant (1).
- Step 9 Health Management Assistant (1) submits typed licence with two copies to pharmacist (2) for checking.
- Step 10 Pharmacist (2) signs in a copy of the licence after checking and forwards to Health Management Assistant (1).

- Step 11 Health Management Assistant (1) minute and forward the licence with two copies to D/MT& S for signature.
- Step 12 D/MT& S signs and forwards to Health Management Assistant (2).
- Step 13 Health Management Assistant (2) issues the Sample Import Licence to applicant.
- Personal user licences are issued only for the unregistered drugs.
 - The quantity is limited to 100 doses.

ANNEXURE “.....”

SCHEDULE V

Form E

Regulation 29

APPLICATION FOR LICENCE TO IMPORT DRUGS FOR PERSONAL USE

I of hereby apply for a licence to import the drug(s) specified below solely for my personal use.

I attach a prescription from a registered medical practitioner in regard to the need for the said drug(s).

Name of drug(s) and quantity :.....

Date :.....

Signed :.....

Name :.....

Address :.....

ANNEXURE "....."

SCHEDULE V

LICENCE TO IMPORT DRUGS FOR PERSONAL USE

Licence Number :

..... of is hereby licensed to import the following drug (s) in the quantities specified.

Drug(s)

Quantity

This licence is subject to the conditions prescribed in regulation 29 of the Drugs Regulations made under Cosmetics, Devices and Drugs Act No.27 of 1980 as amended by Act, No.38 of 1984 and shall be in force for a period of one year from the date of issue unless it is earlier suspended or cancelled.

Date of Issue :.....

.....
Authority.