UNION OF MYANMAR
Ministry of Health
Department of Health
Food and Drug Administration

A Guideline on Drug Registration Application

(revised in Jan. 2001)

UNION OF MYANMAR
Ministry of Health
Department of Health
Food and Drug Administration
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(Phone. 95 - 1 - 245332)

Initial application for Registration

1. An application for registration of drug must be submitted to the Department of Health, Food and Drug Administration in the original prescribed form (Form 1 Registration). Form (1) is available at one hundred kyats each at office of the Food and Drug Administration.

2. Separate registration has to be applied for pharmaceutical preparations of different strength or different dosage form. For parenteral preparations this requirement is applicable also to different pack size.

3. Form 1 must be filled out in type print. Enclosures submitted together with application form shall be marked with proper reference. **A form which is filled incompletely or improperly will not be accepted.**

4. Form (1) must also be accompanied with two sets of documents on complete information of drugs. (See Annex-I for type of documentation required). Documents have to be submitted in file in an order as listed in " Documents Required for Registration of Drugs". A list of documents submitted should be shown on the first sheet of the file.

5. **An application with incomplete documentation will not be accepted.**

6. (a) An application must be submitted in person by an authorised representative of owner of drug. * Any application made by mail or fascimile or means other than in person, will not be accepted. An authorised representative has to be a resident in Myanmar.

   (b) Should an authorisation for representation be granted to the local company, the representative shall be a company employee authorised to serve as a contact person.

7. Registration assessment fees must have been remitted to Myanmar Foreign

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* Product licence holder at country of origin

Trade Bank (MFTB) in favour of Drug Advisory Committee Account No. (91892) when submission of the application form is made.

8. (a) If it is an application for registration of drugs manufactured outside Myanmar. The Food and Drug Administration will issue " Approval for importation of Drug Samples" (Annex II) after receivingapplication. The drug samples as specified in the approval shall then be imported into the country. The holder of the approval shall comply not only with the conditions stipulated in the approval but also with the regulations of Commerce and Customs Department.

(b) As per Ministry of Health Notification 3/93 dated 5-8-93 paragraph 5, prior approval shall be obtained from Food and Drug Administration for importation of sample drug. For the importation of sample drug without prior approval of the FDA, the FDA will not issue approval certificate.

9. (a) The following kind of drug samples are normally required.
- Drug samples the quantity of which is sufficient for clinical trial on sixty patients. For certain rare diseases fewer numbers of samples may be acceptable.
- Samples for laboratory analysis
-Samples for retention.

(b) For the total numbers of sample drugs to be submitted, please refer to FDA circular 1/97 (a) " Required quantities of sample drugs for registration" (Annex III)

(c) All drug samples must be accompanied with their respective analytical report (the certificate of analysis). The name and designation of an official who signs the report must be stated. **The photocopy of report is not acceptable**.

10. The evaluation process for registration will be started only when all the requirements for registration application have been met; viz: (a) remittance of Registration Assessment Fees, (b) complete set of documents, (c) sufficient quantity of drug samples.

11. (a) When the drug is approved for registration, the applicant will be notified to remit 200 United States dollar as Registration Fees. The notification will be made only on the notice board of FDA.

b) **Failure to remit Registration Fees within 90 days from the date of intimation will constitute forgoing of an application by an applicant.** If so happens, neither the Registration Assessment Fees remitted nor registration documents and drug samples will be returned.

12. **Failure to make a follow-up of an application by an applicant for more than six months from the date of remittance of assessment fees, will be taken as forgoing of an application.**

13. The Registration Certificate (Form II) will be issued only when the acknowledgement of receipt of payments is submitted, issued by MFTB submitted.

14. The submitted dossiers are not reclaimable in case of rejection of application.

Updating Changes to Registered Drugs

1. Updating changes to registered drugs shall be made only with the approval of Food and Drug Administration.

2. For this purpose, the holder of Registration Certificate shall apply for Variation of Registration; to FDA, stating

   (a) reason for change.

   (b) relevant data or findings from studies on which is based the justification of change.

   (c) significant effect of changes to the specifications of drug.

3. The following shall be submitted together with the application:

   (a) The attestation by country's drug regulatory authority to approval of such changes. If the regulatory authority's attestation cannot be provided, explain the reason for it.

   (b) A photo copy of Registration Certificate of drug.

4. (a) When it is decided to approve of changes, US$ 100 fees will be levied on an applicant. The Drug Advisory Committee may waive this requirement if it believes that change is of benefit to public as regards quality, safety and efficacy of drugs.

   (b) An original Registration Certificate must then be submitted to make approved amendments on the certificate.

Renewal of Registration

1. Application for renewal of registration shall be submitted 90 days before the validity of the registration terminates. Failure to adhere to the 90 days requirement may result in disruption of continued validity of registration.
2. Application shall be submitted in the same manner as prescribed for application for registration of drug.
3. The drug samples for clinical trial are normally not required. However if the situation warrants the repeat-clinical trial, the samples will be asked. The samples for laboratory analysis and for retention are still required. Please refer to FDA circular 1/97 b" Required quantities of sample drug for analysis and retention ". (Annex IV)
4. The documentary requirement is the same as that of an initial application (See Type of documents required for registration Annex I). Information provided, however, has to be updated. New findings which had not been submitted in an initial application have to be submitted too.
5. Registration Assessment fees must have been remitted to the Drug Advisory Committee Account No. 91892 at the time of application of renewal of registration. When the renewal of registration is approved of, two hundred United States dollar must be remitted as Registration Fees.
6. Upon approval of renewing, new Registration Number will be designated, which shall make the old Registration Number void.
7. Failure to apply for renewal of registration shall result in invalidation of registration with effect from the date of expiry of the certificate.

Fees levied

1.	Registration Assessment Fees	100 US$	+ Fees (in Kyats) for
2.	Registration Fees	200 US$	laboratory analysis
3.	Variation of Registration	100 US$	

Note: (1) & (2) are levied either for fresh registration or renewal of registration.

Registration of Active Pharmaceutical Raw Materials

1. Documentary requirements

A. Administrative Documents

1. A certificate of product issued by the regulatory authority of its own country that the product is authorised to be sold in country of origin.
2. (a) Properly endorsed photocopy of valid manufacturing licence.
   (b) GMP certificate of manufacturing plant.
3. A letter of authorisation for legal representation of manufacturer (owner of product) in Myanmar.
4. A business registration certificate of local representatives.

B. Pharmaceutical Documents

1. Generic name
2. Chemical name
3. Empirical & Structural Chemical formula
4. Pharmacopoeia to which the product conforms.
5. Pharmaceutical specifications (including physical characteristics, solubility, identification, loss on drying, sulphated, ash, heavy metal, purity , assay, etc.)
6. Method of analysis
7. Manufacturing process
8. Quality Assurance System (including control of starting material, in-process control, finished raw material control, packaging control, etc.).
9. Certificate of analysis.
10. Stability test report of at least three different batches.
11. Recommended Shelf-life.
12. Recommended Storage conditions.
13. Packaging specifications.

2.

Fees		Amounts
(a)	Assessment fees	US$ 100 + Fees in Kyats for laboratory analysis
(b)	Registration fees	US$ 200
(c)	Variation fees	US$ 100

3. Application shall be made in the same manner as prescribed for registration application of finished product.

4. A sample (20 gm) has to be submitted together with the dossier. The sample must be packed & labelled properly. An approval of FDA for importation of sample raw material is also required.

(Annex-I)

Type of documents required for registration of drugs

I. Administrative Documents

1. A letter of authorisation of legal representative of owner of drug issued to an applicant.

   Note: (i) Owner of drug shall inform FDA of any changes of person(s) representing him in Myanmar. Any consequences arising out of failure to inform so, shall be the responsibility of owner of drug.

   (ii) For continued representation, the applicant shall submit from time to time, as required by the validity of authorisation, a renewed letter of authorisation from owner of drug.

2. A company profile (For company whose products have not been registered before in Myanmar).
3. The certificate of Pharmaceutical Products in a format adopted by WHO for Certification Scheme on the quality of Pharmaceutical Products moving in International Commerce.* (See Annex-V).
4. GMP certificate and properly endorsed photocopy of manufacturing licence.
5. Proforma statement (See Annex-VI).
6. Completely filled "Summary Drug Information Sheet" (See Annex-VII)

II. Pharmaceutical Documents

1. Name of Drug (brand name, generic name).
2. Formula and composition with necessary reference to its justification (where applicable).
3. The pharmacopoeia** to which active substances and excipients conform. If it is a New Chemical Entity, the relevant references must be provided.
4. Data on physical and chemical properties, structural and empirical formula of active substances and excipients (where applicable).

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* (a) An original certificate must be submitted. Stick always to the updated format.
(b) If valid period is not stated on the certificate, the certificate shall not be older than one year at time of submission.

** For preparations being listed in either B.P, USP or Eu. Phr., they must conform to BP, USP or Eu. Phr. standards. In exception, for preparations not being listed in above pharmacopoeias, the standards of the pharmacopoeia other than BP, USP or Eu. Phr. may be accepted.

5. Analytical methods for active substances and excipients. The pharmacopoeia to which they conform.

6. Quality Control of Raw Material.

   (a) Standard control procedure (control on supplier, accept/reject system, quarantine/release system, sampling procedure, test parameters and testing methods reporting and record keeping system etc.)

   (b) Raw material specifications.

   (c) Specimen Q.C. Report on raw material.

   (d) Attestation to above particulars by a responsible person not lower than Q.C. Manager. Signature, name and designation should be printed on the attestation.

7. Manufacturing process.

8. Standard procedure for In-process Quality Control.

   (a) Accept/reject system.

   (b) Sampling procedure.

   (c) Test parameters and testing methods.

   (d) Reporting and record keeping system.

   (e) Specimen in-process Q.C. Report.

   (f) Attestation to above particulars by a responsible person not lower than Q.C. Manager. Signature, name and designation should be printed on the attestation.

9. Finished Product.

   (a) Specifications, including detailed description of physical characteristics.

   (b) Detailed composition of capsule shell, tablet coating.

   (c) Disintegration and dissolution profile.

   (d) Analytical methods and its parameters tested; the pharmacopoeia to which it conforms.

   (e) A sample copy of certificate of analysis.

   (f) Stability test report (testing method, test parameters, testing condition including temperatures, humidity, type of packing)

(i) Testing condition which is similar to climatic condition of tropical countries is preferred.

(ii) Test done on drugs in its original packing(s) for which the application is made, is required.

(iii) Test reports on at least three different batches have to be submitted.

(g) Recommended shelf life and storage condition citing relevant data for making such claim.

10. Packaging

The following are required to be submitted for all types of packaging that are applied for registration. Lack of any of them in the submitted dossier would result in non-consideration for approval of respective packagings.

(a) type of package, its shape, size, color.

(b) nature of packaging material.

(c) pack size.

(d) specimen package.

(e) specimen label.

(f) specimen package insert.

(g) quality control procedure on label and packaging, and its specimen Q.C. report.

III. Pharmacological & Clinical Documents*

1. Data on basic pharmacological and microbiological studies.

(a) Toxicity data

(b) Teratogenicity data

(c) Mutagenicity data

(d) Data on efficacy and general pharmacology.

(e) Data on pharmacokinetics.

2. Data on Clinical Studies.

(a) Phase 1, Phase II, Phase III and IV where applicable

(b) Clinical Pharmacokinetics.

(c) Bio-availability.

(d) Drug interactions.

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* For common established me-too drugs, the pharmacological and clinical data may be left out, unless there are new findings on them.

ကျန်းမာရေးဝန်ကြီးဌာန
Ministry of Health
ကျန်းမာရေးဦးစီးဌာန
Department of Health
အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာန
Food and Drug Adminstration

ထောက်ခံချက်အမှတ် ————————
Approval No.

သက်ဆိုင်ရာသို့
To whom it may concern

အောက်ဖော်ပြပါပုဂ္ဂိုလ်သည် ဖော်ပြပါဆေးဝါးများအား မြန်မာနိုင်ငံတွင် မှတ်ပုံတင်ရန် လျှောက်ထားလာပါသဖြင့် လိုအပ်သော စမ်းသပ်မှုများဆောင်ရွက်ရန် ကျွာသက်တွင် ဖော်ပြထားသည့်ဆေးဝါးနမူနာများကို မြန်မာနိုင်ငံအတွင်းသို့ တစ်ကြိမ် တင်သွင်းခြင်းအား ထောက်ခံလိုက်သည်။

In order to carry out necessary tests on drugs which have been applied for registeration in Myanmar, approval is hereby granted to under mentioned person to import **one** consignment of drug samples as specified in the attached schedule overleaf.

တင်သွင်းသူ့အမည် .....
Name of Person
နိုင်ငံသားစီစစ်ရေးကဒ်ပြားအမှတ် .....
NRC. No .
လိပ်စာ .....
Address
လုပ်ငန်းအမည် .....
Name of Business
တင်ပို့သူအမည် .....
Name of Consignor
လိပ်စာ .....
Address
ခွင့်ပြုသည့်နေ့ .....
Date of Approval
ခွင့်ပြုသည့်ကာလ .....
Valid up to

ခါတ်ပုံ

လက်မှတ် .....
Signature .....
ခွင့်ပြုသူအမည်.....
Name .....
ရာထူး .....
Designatior, ...

ဆက်သွယ်ရန်လိပ်စာ ပူးတွဲတွင်ကြည့်ပါ
See conditions attached

ထောက်ခံသည့်ဆေးဝါး

Approved Drugs

စဉ် Sr. No	ဆေးဝါးအမည် (အမှတ်တံဆိပ်အမည်/မျိုးရိုးအမည်) Name of Drug (trade name/generic name)	ဆေးဝါးပုံသဏ္ဌာန်/ ပါဝင်မှုပမာဏ Dosage forms/ Strength	ထုပ်ပိုးပုံ Packing & Presentation	ရေတွက်ပုံ A/U	ခထောက်ခံသည့်ပမာဏ Approved Amount	ထုပ်လုပ်စက်ရုံ/နိုင်ငံ Name of Manufacturer/ Country

(အကောက်ခွန်ဌာနမှ ဖြည့်စွက်ရန်)

ထုတ်ပေးသူလက်မှတ် .....

ထုတ်ပေးသူအမည် .....

ထုတ်ပေးသူရာထူး/ဌာန .....

စည်းကမ်းချက်များ
Conditions

၁။ ဤတင်သွင်းခြင်းထောက်ခံချက်(မူရင်း)သာ တရားဝင်ဖြစ်သည်။ မည်သည့်ပုံစံမျိုးဖြင့်ဖြစ်စေ၊ မိတ္တူသည် တရားဝင်ထောက်ခံချက် မဟုတ်

This approval shall be official only with use of original Approval Certificate. Copy in any from shall be void.

၂။ ဤဆေးဝါးနမူနာ တင်သွင်းခြင်းထောက်ခံချက်သည် တစ်ကြိမ် တင်သွင်းခြင်းကို ထောက်ခံခြင်း ဖြစ်ပြီး ဖော်ပြထားသော သတ်မှတ်ကာလအတွင်းတွင်သာ အကျိုးသက်ရောက်စေရမည်။

This approval shall be applicable for **only one consignment** and shall be invalidated from the date stated on it.

၃။ ဤတင်သွင်းခြင်းထောက်ခံချက်သည်လက်မှတ်တွင် ဖော်ပြထားသည့်ပုဂ္ဂိုလ်အာ ခွင့်ပြုခြင်းသာ ဖြစ်ပြီး အခြားတစ်ဦး တစ်ယောက်အား လွှဲပြောင်းခြင်း မပြုရ။

The approval is granted to a person as stated in the permit. This permit is not transferable to another person.

၄။ အသုံးမပြုသည့် တင်သွင်းခြင်း ထောက်ခံစာအား တင်သွင်းခွင့် သက်တမ်းကုန်သည့်နေ့မှစ၍ (၂)ရက် အတွင်း အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာနသို့ ပြန်လည်အပ်နှံရမည်။

The unused approval must be returned to the Food & Drug Administration within two days from date of expiry of the approval.

၅။ တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲပေးပါ ဖော်ပြထားသော အချက်အလက်များအား ပြင်ဆင်ခြင်း၊ ဖျောက်ဖျက်ခြင်း မပြုလုပ်ရ။

No Change or deletion shall be made to any expression of the approval and of the attached schedule.

၆။ ဤတင်သွင်းခြင်းထောက်ခံစာအရ တင်သွင်းခဲ့သော ဆေးဝါးနမူနာများနှင့် တင်သွင်းခွင့်ထောက်ခံစာအား အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာနသို့ ဆိုက်ရောက်ရာ ဌာနမှ ထုတ်ယူပြီးသည့်နေ့မှစ၍ (၂)ရက် အတွင်းပေးပို့ရမည်။

The imported drug samples and the approval must be submitted to the Food & Drug Administration within two days from the date of clearance from port of entry.

၇။ ပေးပို့သည့် ဆေးဝါးနမူနာသည် တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲပေးပါ သတ်မှတ်ချက်များအတိုင်း ဖြစ်စေရမည်။ ကွဲလွဲချက်များဖြစ်ပေါ်ပါက တင်သွင်းခွင့်ရှိသူမှ လုံးဝ တာဝန်ယူရမည်။

Submitted drug samples must be totally in compliance with specifications stated in the schedule. The holder of the approval shall bear the responsibilities of any discrepancies.

၈။ အထက်ပါ စည်းကမ်းချက်များအား လိုက်နာရန် ပျက်ကွက်ပါက တည်ဆဲဥပဒေများအရ အရေးယူခြင်း ခံရမည်။

Failure to comply with above mentioned conditions, is liable to actions in accordance with existing rules and regulation laws.

၉။ ဤတင်သွင်းခြင်းထောက်ခံစာကိုင်ဆောင်သူသည် မှတ်ပုံတင်လျှောက်ထားရန်အတွက် ဆေးဝါးများ တင်သွင်းရာတွင် တည်ဆဲအကောက်ခွန်စည်းမျဉ်းစည်းကမ်းလုပ်ထုံးလုပ်နည်းများကို လိုက်နာရမည်။

In importing sample drugs, holder of the approval shall comply with existing rules and regulations of Commerce and Customs department.

Steps to be taken in Submitting dossier and sample drugs for Registration

The following are the steps which if an applicant follows strictly will take him straight to the finishing line.

Steps	Applicant	Steps	FDA
1.	A thorough study of a booklet " A Guideline on Submission of Application for Drug Registration".		
2.	Getting Form (1), a prescribed form for application. (Separate Forms (1) are to be used for application of different kind of drugs and dosage forms). Form (1) is available at General Affairs Section.		
3.	Entering list of drugs , wished to be applied for registration, in register book at Drug Control Section (1).		
4.	Getting a letter of intimation from FDA to remit required assessment fees. Remitting required payment to account No. 91892 at Myanmar Foreign Trade Bank. Payment made either by cash or FEC or by telegraphic transfer usually helps avoid unwanted delay in obtaining credit advice issued by MFTB for the payment.	1.	Issuing letter of intimation for remittance of assessment fees. (Drug Control Section 1 DCS 1).
5.	Submission of Sample drugs. a) Getting FDA approval for importation of sample drugs. a.1. The following shall be submitted to Drug Control section I. when ask for approval • one original and two photocopies of Credit Advice issued by MFTB upon remittance of assessment fees + a letter, in a format prescribed by FDA, informing FDA that payment for the drugs has been made.	2.	Checking the documents; returning an original copy after checking. (DCS 1)

Steps	Applicant	Steps	FDA
	• list of sample drugs to be imported, specifying name of drug (trade name, generic name), dosage form, presentations, contents of each unit dose, pack size (accounting unit), quantities. (For the convenience sake, a form has been prepared by FDA, which just needs to be filled out). • for the sample drugs which are already at port, in addition to above, airway bill, signed invoice, & packing list of sample drugs. a.2. For the sample drugs which are shipped prior to step 4, (formal application of registration) approval of importation will not be issued. a.3. Compliance with Commerce and Custom department's regulations on import is absolutely necessary.	3.	Issuing an approval for importation of sample drugs (DCS 1)
	b) Submission of sample drugs within two days from the date of clearance from port of entry. b.1. The submitted samples must be accompanied with an original approval issued by FDA, photocopied airway bill, signed invoice and packing list of sample drugs.	4.	Accepting the sample drugs; issuing the receipt of sample drugs.
6.	Submission of Form (1) and registration dossier at drug control section (1) for checking against check-list. Getting the result of checking the same day. a) Retreating non-conforming dossier, correcting defects and getting back to step 6. b) For conforming dossiers getting an acknowledgement of receipt of Form (1) and registration dossier from Drug Control Section (1).	5.	Checking against check-list for documentary requirements for drug registration. a) Returning non-conforming dossier b) Accepting conforming dossier b.1. Issuing acknowledgement of receipt of Form (1) and registration dossier. b.2. Designating application number and date for future reference.

Steps	Applicant	Steps	FDA
		6.	Previewing of documents a) Proceeding to further stages of evaluation if the information provided is adequate. b) Asking further information if the information provided is inadequate. Proceeding to further stages of evaluation when the information asked for arrives.
7.	Getting an intimation (within 21 days from step 6(b)) to provide further information, if it is needed. a) Submitting further information at Dispatch Section.		
8.	Enquiring about approval approximately 3 months after step 6 for common, established drugs, approximately 6 months for less common drugs but not new chemical entity and approximately 12 months for new chemical entity (NEC).		
9.	For approved drugs: a) Getting letter of intimation from General Affairs Section (GAS), to remit registration fees at MFTB. b) Remitting registration fees within 90 days from the date of intimation (to avoid unwanted delay, remittance in Cash, FEC or by TT is advisable)	7.	Issuing letter of intimation to remit registration fees for those which are approved. (General Affairs Section, GAS)
10.	For rejected drugs.	8.	Issuing letter of intimation for rejected products. (GAS)
11.	Submission of Credit Advice issued by MFTB upon remittance of registration fees. One original and two photocopies of credit advice have to be submitted in a forwarding letter in FDA prescribed format, at General Affairs Section.	9.	Accepting and acknowledging the receipt of Credit Advice.

Steps	Applicant	Steps	FDA
12.	Getting Registration Certificate one week after step 10.	10.	Issuing Registration Certificate one week after receiving Credit Advice. (GAS) The Registration Certificate will be handed only to an authorised representative of owner of drug. If it is a local company a person shall be an employee of the company (contact person) whose specimen signatures have been provided to FDA by a company.

Annex III

DEPARTMENT OF HEALTH
FOOD & DRUG AMINISRATION
Circular No. 1/97 a
Required quantities of sample drugs for initial registration

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Suspension/ Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/ Bot.)
1.	Anti-bacterial	2500	100	750	350	100
2.	Anti-fungal	2000		750		100
3.	Anti-viral	2000				
4.	Anti-malarial	2000		650		
5.	Anti-tuberculous	3000		750		
6.	Anti-amoebic	2000	100	600	350	
7.	Anthelmintic					
	(a) Single dose	150 doses	100			
	(b) Multiple does	500 doses	100			
8.	Anti-inflammatory Drugs (Non-steroidol)	2000	100	400		100
9.	Anti-depressant	3000		600		
10.	Anti-psychotic	3000		600		
11.	Anti-convulsant	2000	100	350		
12.	Anti-parkinsonism	4000				
13.	Anxiolytic	2000		400		
14.	Anti-diabetic	2000		250		
15.	Anti-thyroid	5000				
16.	Anti-emetic	2000	100	450		
17.	Anti-diarrhoeal	2000				
18.	Antispasmodic	2000		450		
19.	Antacid	2000	100			
20.	Anti-ulcer	2000	100	450		
21.	Anti-asthmatic	2000	100	600		
22.	Antitussive	2000	100			
23.	Antihistamine	2000	100	350		100
24.	Mucolytic	2000	100			
25.	Anti-anginal	2000		350		
26.	Anti-hypertensive	2000		450		
27.	Anti-arrhythmic	2000		450		
28.	Beta adenergic blockers	2000		350		
29.	Calcium Antagonnist	2000		350		
30.	Diuretic	2000		200		
31.	Anti-hyperlipidaemic	4000				
32.	Anti-haemorrhoidal	2000				
33.*	Anti-neoplastic					

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Suspension/ Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/ Bot.)
34.	Anti-migraine	2000				
35.*	Anaesthetics					
36.	Amino Acids	2000			100(LVP) 350(SVP)	
37.	Antianaemic	2000		450		
38.	Cold Remedy	2000	100			
39.	Contraceptive	200 cycles				
40.	Corticosteroids	3000		350		100
41.	Intravenous Replacement Fluids				100(LVP) 350(SVP)	
42.	Plasma Expander				100	
43.	I/V Glucose (10%, 25%, 50%)			350		
44.	Multivitamin	2000	100	350		
45.	Nootropics	3000		450		
46.	(a) Oral Rehydration Salt tablets	700				
	(b) Oral Rahydration Salt Powder	200 Sachets (one litre pack) 400 Sachet (less than one litre pack)				
47.	Uricosurics	2000				
48*	Vaccines					100
49.	Dematologicals					100
50.	Eye /Ear Drops					

LVP = Large Volume Parenteral, (500 ml & above)

SVP = Small Volume Parenteral. (less than 500 ml)

Note: (1) For those with (*)markings and for controlled medicine please check with FDA for exact number

(2) All the submitted sample drugs must have a minimum of two years' shelf - life

(3) In case of large sized packs(e.g. 500's, 1000's litre pack or jar) the required amounts are 7 bottles or boxes for 500 sized packs 1 litre packs or 1 kg jars & 5 bottles or boxes for 1000 sized packs and packs which are more than 1 litre or 1 kg sizes.

(4) If more than one type of packagings or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remainings have to be submitted in a minimum of four unit-pack each if it is a small sized pack and two unit-pack each if it is a large sized pack.

DEPARTMENT OF HEALTH
FOOD & DRUG AMINISRATION
Circular No. 1/97 b
Required quantities of sample drugs for renewal

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Suspension/ Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/ Bot.)
1.	Anti-bacterial	500	20	50	20	15
2.	Anti-fungal	500	20	50		15
3.	Anti-viral	500	20	50		15
4.	Anti-malarial	500		50		
5.	Anti-tuberculous	500		50		
6.	Anti-amoebic	500	20	50	20	
7.	Anthelmintic					
	(a) Single dose	50	20			
	(b) Multiple does	50	20			
8.	Anti-inflammatory Drugs (Non-steroidol)	500	20	50		15
9.	Anti-depressant	500	20	50		
10.	Anti-psychotic	500	20	50		
11.	Anti-convulsant	500	20	50		
12.	Anti-parkinsonism	500	20	50		
13.	Anxiolytic	500	20	50		
14.	Anti-diabetic	500		50		
15.	Anti-thyroid	500				
16.	Anti-emetic	500	20	50		
17.	Anti-diarrhoeal	500	20			
18.	Antispasmodic	500	20	50		
19.	Antacid	500	20			
20.	Anti-ulcer	500	20	50		
21.	Anti-asthmatic	500	20	50		
22.	Antitussive	500	20			
23.	Antihistamine	500	20	50		
24.	Mucolytic	500	20			
25.	Anti-anginal	500		50		
26.	Anti-hypertensive	500		50		
27.	Anti-arrhythmic	500		50		
28.	Beta adenergic blocke	500		50		
29.	Calcium Antagonnist	500		50		
30.	Diuretic	500		50		
31.	Anti-hyperlipidaemic	500				
32.	Anti-haemorrhoidal	500				
33.*	Anti-neoplastic					

	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Suspension/ Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/ Bot.)
34.	Anti-migraine	500	20	50		
35.*	Anaesthetics					
36.	Amino Acids	500			10(LVP) 50(SVP)	
37.	Antianaemic	500	20	50		
38.	Cold Remedy	500	20			
39.	Contraceptive	50 cycles				
40.	Corticosteroids	500		50		
41.	Intravenous Replacement Fluids				10(LVP) 50(SVP)	
42.	Multivitamin	500	20	50		
43.	Nootropics	500	20	50		
44.	(a) Oral Rehydration Salt tablets	100				
	(b) Oral Rahydration Salt Powder	30 Sachets (1L pack) 50 Sachets (< 1L pack)				
45.	Uricosurics	500				
46*	Vaccines					
47.	Dematologicals					15
48.	Eye /Ear Drops					15

LVP = Large Volume Parenteral, (500 ml & above)

SVP = Small Volume Parenteral. (less than 500 ml)

Note: (1) For those with (*)markings and for controlled medicine please check with FDA for exact number

(2) All the submitted sample drugs must have a minimum of two years' shelf - life

(3) In case of large sized packs(e.g. 500's, 1000's litre pack or jar) the required amounts are 3 bottles or boxes for 500 sized packs 1 litre packs or 1 kg jars & 2 bottles or boxes for 1000 sized packs and packs which are more than 1 litre or 1 kg sizes.

(4) If more than one type of packagings or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remainings have to be submitted in a minimum of four unit-pack each if it is a small sized pack and two unit-pack each if it is a large sized pack.

Certificate of Pharmaceutical Product[1]

(conforms to WHO revised format TRS No: 863, 1996)

Certificate No. .....

Exporting Country: .....
Importing Country: .....

1. Names (if applicable) and dosage form:
1.1 Active Ingredient[2](s) and amount(s) per unit dose[3] (complete qualitative composition including excipients, see attached)[4]. SEE ATTACHMENTS
1.2 Is this product **licensed** to be placed on the market for use in the exporting country[5]? YES - See Block A NO - See Block B[6]
1.3 Is this product actually on the market in the exporting country? YES

A		B				
2A.1	Number of product-lincense[7] and date of issue:	2B.1	Applicant for certificate (name and address):			
2A.2	Product-license holder: (name and address)	2B.2	Status of Applicant:			
2A.3	Status of product-license holder:	2B.3	Why is authorization lacking	not required	not requested	under consideration / refused
2A.3.1	For categories b & c the name and address of the manufacturer producing the dosage form an	2A.3.1 or 2B.2.1 Mfr:				
2A.4	Is an approved summary basis appended[8]? Yes / No					
2A.5	Is the attached product information complete and consonant with the license[10]? Yes / No					
2A.6	Applicant for certificate if different from the license holder (name and address)[11]	Remarks[12]:				

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes / No / not applicable
3.1 Periodicity of routine inspection (years):
3.2 Has the manufacture of this type of dosage form been inspected: Yes / No
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization[14]. Yes / No / not applicable[13]
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product Yes / No

Validity of certificate .....
(months / year)

Name of authorized person .....
Signature .....
Stamp & date .....

Annex - VI

PROFORMA STATEMENT

SN	TRADE NAME	GENERIC NAME OR FORMULA	INDICATION	REMARKS

PACKING
LIFE
FOB PRICE
MANUFACTURER

Annex-VII

Department of Health
Food and Drug Administration
Summary Drug Information

Name	Address	Phone/ Fax
Applicant *		
Owner of Drug		
Manufacturer		

For Official Use
Date of application:
Application No:
Assessment Fees:
Registration Certificate No:
Date of issue:
Date of expiry:
Sales Category:
Variation:

Brand Name
Non Proprietary Name
Dosage Form
Strength
Therapeutic Category
Presentation** (type of packing, pack size)

Composition (including excipients & coloring substances)

Indications:

Dosage:

* An authorised representative of owner of drug in Myanmar

* All types of packagings that are applied for registration have to be stated.

DRUG SAMPLE	
Batch No.	Type of Packing
Manufacture Date	
Exp. Date	Presentation (Pack Size)
Certificate of Analysis	Submitted Quality

Finished Product Specifications	
Physical Specifications (colour, shape, size, weight, hardness, disintegration etc.)	Chemical & Microbiological specifications

Packaging Specifications (primary packaging, secondary packaging)

shelf life & recommended storage conditions

*Submission for consideration	*Approval/ Rejection

*For official Use

· Food & Drug Administration

Division of Drug Control

Drug Registration Section

PRODUCT INFORMATION CHECK LIST

Name of Drug.....

Owner of Drug.....
Manufacturer.....
Applicant Name &.....

(I) Administrative Documents

(1) Letter of authorization.	(1)
(2) Company Profile.	(2)
(3) Certificate of Pharmaceutical Product.	(3)
(4) G.M.P. Certificate.	(4)
(5) Manufacturing Licence.	(5)
(6) Proforma Statement.	(6)
(7) Summary Drug Information Sheet.	(7)

Remarks on administrative documents.....

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(II) Pharmaceuticals Documents

(1) Name of Drug, its composition and physical chemical	(1)
(2) Properties of active substances and excipients. Analytical method for active substances and excipients.	(2)
(3) Standard control procedure on raw materials .	(3)
(4) Raw Material specifications.	(4)
(5) Specimen Q.C. report on raw materials.	(5)
(6) Manufacturing process.	(6)
(7) Standard procedure for in-process quality control.	(7)
(8) Specimen in-process Q.C. report.	(8)
(9) Finish Product specifications.	(9)
(10)Disintegration and dissolution profile.	(10)
(11)Analytical method for finished product.	(11)
(12)A sample copy of certificate of analysis.	(12)
(13)Stability test report.	(13)
(14)Packaging specifications.	(14)
(15)Specimen package, label & package insert.	(15)
(16)Q.C. procedure & report on label and packaging.	(16)

Remarks on Pharmaceuticals documents.....

.....

.....

(III) Pharmacological Documents

(1) Data on basic pharmacological and microbiological studie	
(a) Toxicity data.	(a)
(b) Teratogenicity data.	(b)
(c) Mutagenicty.	(c)
(d) Data on efficacy and general pharmacology.	(d)
(e) Data on pharmacokinetics.	(e)
(2) Data on clinical studies	
(a) Phase I, II, Phase III, IV.	(a)
(b) Clinical Pharmacokinetics.	(b)
~~(c) Bio –availability.~~ Not Require	(c)
(d) Drug interaction.	(d)

Remarks on Pharmacological documents.....

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4. Details of quanlitative composition are preferred, but their provision is subject to the agreement of the product-licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Sections 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and / or labels a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.

9. This refers to the document, prepared by some national regulatory authorities that summarizes the technical basis on which the product has been licensed.

10. This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

11. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.

12. Please indicate the reason that the applicant has provided for not requesting registration:
   (a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country of export;
   (b) the product has been reformulated with a view to improving its stability under tropical condition
   (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   (e) any other reason, please specify.

13. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

14. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations 9WHO Technical Report Series, No. 822, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

15. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufactu of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.