

The Drugs Registration Regulation, 2038(1981)

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Amending Regulation:

The Drugs Registration (First Amendment) Regulation, 2058(2001) 2058.5.18 (3 September 2001)

In exercise of the powers conferred by Section 40 of the Drugs Act, 2035(1978), His Majesty's Government has framed the following rules.

1. Short title and commencement:

- (1) These rules may be cited as the “Drugs Registration Regulation, 2038 (1981).”
- (2) This Regulation shall come into force in such area and on such date as His Majesty's Government may appoint by a notification in the Nepal Gazette.

2. Definitions:

Unless the subject or the context otherwise requires, in this Regulation:

- (a) “Act” means the Drugs Act, 2035(1978).
- (b) “Department” means the Department of Drugs Administration.

3. Recommendation letter to be obtained to establish drug industry:

- (1) If a person intends to obtain a recommendation letter to establish a drug industry pursuant to section 7 of the Act, such person shall make an application to the Department in the format as referred to in schedule-1.
- (2) If, on making necessary inquiry into the application after it is made pursuant to sub-rule (1), the Department thinks it reasonable to issue a recommendation letter to establish that drug industry, it shall issue the

recommendation letter to the applicant in the format as referred to in schedule-2 by collecting the fees as prescribed in schedule-14.¹

4. Product license to be obtained to manufacture drug:

- (1) A person who has already established a drug industry after having obtained the recommendation letter pursuant to sub-rule (2) of rule (3) or a person who has already established a drug industry prior to the commencement of this Act shall make an application to the Department in the format as referred to in schedule-3 to obtain the product license to manufacture the drug pursuant to section 8 of the Act.
- (2) After an application is made pursuant to sub-rule (1), the Department shall make necessary inquiry into the matter, register such drug in the registration book in the format as referred to in schedule-4 and issue the product license to the applicant in the format as referred to in schedule-5 by collecting the fees as prescribed in schedule-14.²

4A.³ Registration of drug prior to its sale and distribution:

- (1) For purposes of sub-section (1) of section 8A. of the Act, an industry having obtained the product license shall, prior to the sale and distribution of each drug manufactured by it, shall make an application to the Department setting out the following details, in the format as referred to in schedule-4A., for the registration of the sale and distribution of such drug:
 - (a) Product specification of the manufactured drug,
 - (b) Method of analysis of the manufactured drug and test report conducted by a laboratory specified by the Department,
 - (c) A sample of the manufactured drug, along with the label indicating its price,

¹ Inserted by the First Amendment.

² Amended by the First Amendment.

³ Inserted by the First Amendment.

- (d) Other matters specified by the Department.
- (2) If, on making necessary inquiry into the application received pursuant to sub-rule (1), the Department deems proper to sell and distribute the drug mentioned in the application, it shall register such drug and issue the drug sale and distribution registration certificate in the format as referred to in schedule-4B, by collecting the drug registration fees as prescribed in schedule-14 for each drug.
- (3) Each drug manufacturer who has obtained the product license pursuant to section 8 of the Act prior to the commencement of this Regulation shall register each drug manufacture by it pursuant to this rule within one year after the date of commencement of this Regulation and obtain the drug sale and distribution registration certificate.

4B. Registration prior to importation of drug:

- (1) For purposes of sub-section (2) of section 8A of the Act, a person who intends to import a drug shall make an application to the Department, setting out the following details of the drug which he intends to import, in the format as referred to in schedule-4C, for the drug import registration certificate:
 - (a) A certified copy of the certificate issued by an authentic body certifying that the manufacturer has followed good manufacturing practices,
 - (b) Product specification of the manufactured drug,
 - (c) Method of analysis of the manufactured drug and test report conducted by a laboratory specified by the Department,
 - (c) Pharmacopoeia standard,
 - (d) A sample of the manufactured drug,
 - (e) Other matters specified by the Department.

- (2) Notwithstanding anything contained in sub-rule (1), in making an application to import any *Ayurvedic*, homeopathic and other traditional drug, the following details shall be attached with it:
 - (a) Details mentioned in the book or literature,
 - (b) Product specification of the manufactured drug,
 - (c) Recommendation of the concerned body in the case of a patented drug,
 - (d) A sample of the manufactured drug, and
 - (e) Other matters specified by the Department.
- (3) If, on making necessary inquiry into the application received pursuant to sub-rule (1), the Department deems proper to import the drug mentioned in the application, it shall register such drug in the format as referred to in schedule-4D and issue the certificate in the format as referred to in schedule-4E by collecting the drug registration fees as prescribed in schedule-14 for each drug.
- (4) Notwithstanding anything contained in sub-rules (1) and (2), the Department may, on recommendation of the drug advisory committee, issue the import recommendation letter for importing the following drug in the following circumstance:
 - (a) In the case of a life saving drug, on the basis of the concerned doctor,
 - (b) Where a drug is imported as a grant to a governmental or non-governmental body or organization,
 - (c) Where a governmental body imports a drug as per the international bidding system.

5.⁴ Recommendation letter to be obtained for exportation or importation of drug:

⁴ Amended by the First Amendment.

- (1) For purposes of section 9 of the Act, a person who intends to import or export a drug shall make an application to the Department in the format as referred to in schedule-6.
- (2) If, on making necessary inquiry into the application received pursuant to sub-rule (1), the Department deems proper to import or export the drug mentioned in the application, it shall issue the recommendation letter in the format as referred to in schedule-7 by collecting the drug import and export fees as prescribed in schedule-14.

6. To obtain certificate of registration of name, and shop or firm selling and distributing drug:

- (1) If a person intends to obtain a certificate after having his name and shop or firm pursuant to section 10 of the Act, such person shall make an application to the Department in the format as referred to in schedule-8.
- (2) If, on making necessary inquiry into the application after it is made pursuant to sub-rule (1), the Department thinks it reasonable to issue such certificate, it shall register the name of the person and shop or firm selling and distributing the drug in the registration book in the format specified by it and issue the certificate to the applicant in the format as referred to in schedule-9, by collecting the fees as prescribed in schedule-14.⁵

7. To obtain license to make publicity or advertisement of drug:

- (1) If a person intends to obtain a license to make publicity or advertisement of a drug pursuant to sub-section (2) of section 19 of the Act, such person shall make an application to the Department in the format as referred to in schedule-10.
- (2) If, on making necessary inquiry into the application after it is made pursuant to sub-rule (1), the Department deems proper to publicize or

⁵ Inserted by the First Amendment.

advertise the drug mentioned in the application, it shall issue the drug publicity or advertisement license in the format as referred to in schedule-11 by collecting the drug publicity or advertisement fees as prescribed in schedule-14 for each drug to be publicized or advertised, subject to section 19 of the Act.

8. License to be obtained for clinical trial of new drug:

- (1) If a person intends to carry out a clinical trial of any new drug pursuant to section 31 of the Act, such person shall make an application to the Department in the format as referred to in schedule-12.
- (2) If, on making necessary inquiry into the application after it is made pursuant to sub-rule (1), the Department deems proper to issue the license to carry out the clinical trial of that new drug, it shall issue the license in the format as referred to in schedule-13, by collecting the fees as prescribed in schedule-14.⁶

9. Renewal fees:

The renewal fees as referred to in schedule-14 shall be chargeable for the renewal, pursuant to sub-section (2) of section 11 of the Act, of any license, certificate and recommendation letter issued pursuant to this Regulation.

10. Issuance of duplicate copy:

- (1) If any recommendation letter, product license, license or certificate issued pursuant to this Regulation is lost or otherwise destroyed, the concerned person who intends to obtain a duplicate copy thereof shall make an application, with a stamp of one rupee being affixed thereto, and setting out the details of such loss or destroy, to the Department.
- (2) After an application as referred to in sub-rule (1) is made, the Department may issue a certified duplicate copy of such

⁶ Inserted by the First Amendment.

recommendation letter, product license, license or certificate to the applicant, by collecting the fees as referred to in schedule-14.⁷

11. Observance of codes:

A person who has obtained a recommendation letter, product license, license and certificate pursuant to this Regulation shall, while doing, or causing to be done, any act as referred to in such recommendation letter, product license, license or certificate, observe the codes issued by the Department in respect of such act.

12. Power of His Majesty's Government to alter schedule:

His Majesty's Government may, by a notification published in the Nepal Gazette, make necessary alteration on the schedules.

⁷ Inserted by the First Amendment.

Schedule-1

(Relating to sub-rule (1) of rule 3)

Application for recommendation letter of establishment of drug industry

The Administrator,
Department of Drugs Administration.

Subject: Request for recommendation letter for establishment of drug industry.

Dear sir,

Whereas, I/we intend to establish the following drug industry;

Now, therefore, I/we make this application, affixing a stamp of one rupee hereto, and setting out the following details, to obtain a recommendation letter for the same.

1. Proposed drug industry's:
 - (a) Name:
 - (b) Place where it is established: (Also mention the name and ward number of the District and Municipality or Village Development Committee)
 - (c) Estimated capital and source of that capital:
 - (d) Where a preliminary study report carried out on the establishment is attached or not:
 - (e) Whether a sketch and map of the plan also showing the area where the industry is to be established is attached or not:

SN	Of the drug to be manufactured by the proposed industry				Remarks
	Name	System (set out whether it is Allopathic, Homeopathic, Ayurvedic, Unani etc)	Group or sub-group	Composition (set out whether it is a tablet, injection, capsule etc.)	

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3. For the manufacturing of drug by proposed industry:

- (a) Description of required raw materials and source thereof:
- (b) Whether a machine is required or not, if so required, possible details thereof:
- (c) Of the required house or building:
 - (1) Whether sketch and map is attached or not:
 - (2) What will be its composition:
 - (3) Whether outside environment will be polluted, neat and clean or otherwise, mention it:
 - (4) Whether the air can pass through the room or not:
Mention why and for what reasons such room has to be so built that the air can or cannot so pass through it:
 - (5) Whether the sun or light can enter the room or not:
Mention why and for what reasons such room has to be so built that the sun or light can or cannot so enter it:

Applicant's:

Signature:

Name, surname:

Address:

Date:

Schedule-2
(Relating to sub-rule (2) of rule 3)
His Majesty's Government
Ministry of Health
Department of Drugs Administration

Recommendation letter for establishment of drug industry

This recommendation letter is hereby issued, setting out the following matters, for the establishment of the following drug industry, subject to the Drugs Act, 2035 (1978) and the Drugs Registration Regulation, 2038 (1981).

1. Of the drug industry recommended for establishment:
 - (a) Name:
 - (b) Place where it is established:
 - (c) Estimated capital:
2. Of the drug that can be manufactured by the drug industry after having obtained the product license:

Of the drug				Remarks
Name	System	Group or sub-group	Composition	

3. Recommendation letter receiving person's:
 - (a) Name and surname:
 - (b) Address:
4. Validity period of recommendation letter:

Signature of the recommendation letter receiving person:

Date:

Recommendation letter issuing officer's:

Signature:

Name and surname:

Designation:

Date:

(The matters to be written on the reverse side of this recommendation letter)

Renewal of the recommendation letter

Recommendation letter				Department's seal	Remarks
Validity extension period		Renewing officer's signature, and date	Renewal fees		
From	To				

Schedule-3
(Relating to sub-rule (1) of rule 4)
Application for product license

The Administrator,
 Department of Drugs Administration.

Dear sir,

Whereas, in order to manufacture the following drugs by the following drug industry already established after having obtained the following recommendation letter and license, I/we intend to obtain the product license by having the drugs registered;

Now, therefore, I/we have made this application, affixing a stamp of one rupee hereto, to obtain the product license. The duplicate copies of the recommendation letter and license are attached herewith.

1. Serial number of the recommendation letter of that Department and date thereof:
2. Date of license obtained from-----Department:
3. Drug industry:
 - (a) Name:
 - (b) Place of establishment:

(Also mention the name and ward number of the district, Municipality and Village Development Committee.)

Drug to be manufactured										
SN	Name	System	Group or sub-group	Composition	Type or kind	Color	Weight per unit	Active ingredient		Disease to be cured from consumption
								Name	Quantity	

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5. Whether the required materials related with the manufacture of drugs are available in an adequate quantity or not:

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-4
(Relating to sub-rule (2) of rule 4-----⁸)
Registration book

The following drug has been registered as follows for its manufacture,⁹ subject to the Drugs Act, 2035(1978) and the Drugs Registration Regulation, 2038(1981).

Registration number	Of the drug										
	Name	System	Group or sub-group	Composition	Type or kind	Color	Active ingredient		Disease to be cured from its consumption	Name manufacturing company; and country	Registering officer's signature; and date
							Name	Quantity			

⁸ Deleted by the First Amendment.

⁹ Inserted by the First Amendment.

Schedule-4A¹⁰

(Relating to sub-rule (1) of rule 4)

Application for drug sale and distribution registration certificate

The Administrator,
Department of Drugs Administration.

Dear sir,

Whereas, the drug as referred to in the product license, bearing number-----, issued by that Department is appropriate for sale and distribution;

Now, therefore, I/we have made this application, setting out the following details and affixing a stamp of five rupees hereto, to obtain the sale registration certificate, pursuant to sub-rule (2) of rule 4A. of the Drugs Registration Regulation, 2038(1981).

1. Drug of which sale registration certificate is intended to be obtained:
 - (a) Name:
 - (b) System:
 - (c) Group or sub-group:
 - (d) Composition:
 - (e) Active ingredient and quantity (per unit):
 - (f) Expiry date:
 - (g) Pharmacopoeia standard:
 - (h) Retail price:
 - (i) Laboratory having conducted analysis and test, and the analysis and test report issued by that laboratory and date thereof:
2. Other details:

¹⁰ Inserted by the First Amendment.

- (a) Whether the product specification setting down the size, color, measurement or weight, taste and flavor of drug, method of packing and details mentioned in its label is attached or not:
- (b) Whether the method of analyzing and testing the drug is attached or not:
- (c) Whether the label, cartoon and sample of drug is attached or not:

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-4B¹¹
(Relating to sub-rule (2) of rule 4A.)
His Majesty's Government
Ministry of Health
Department of Drugs Administration
Drug sale and distribution registration certificate

Sale and distribution registration certificate number:

Sir,

The sale and distribution registration certificate has been issued for the following drug, pursuant to sub-section (1) of section 8A of the Drugs Act, 2035(1978) and sub-rule (2) of rule 4A of the Drugs Registration Regulation, 2038(1981).

1. Of the drug:
 - (a) Name:
 - (b) System:
 - (c) Group and sub-group:
 - (d) Composition:
 - (e) Active ingredient and quantity (per unit):
 - (f) Expiry date:
2. Product specification (certified copy is attached):
3. Fees received for the sale registration certificate: Rs.---
4. Validity period of certificate:

Certificate receiver's:

Name and surname:

Address:

Signature:

Date:

¹¹ Inserted by the First Amendment.

Certificate issuing officer's:

Signature:

Name and surname:

Designation:

Date:

Note bene:

Prior approval has to be obtained from the Department if any alteration is to be made in the product specification and label submitted to the department and in the above-mentioned details:

Amendment to the certificate

Date	Details of amendment

Renewal

Period of extension of validity		Fees	Officer's signature	Remarks
From	To			

Schedule-4C¹²

(Relating to sub-rule (1) of rule 4B)

Application for drug import registration certificate

The Administrator,
Department of Drugs Administration.

Dear sir,

I/we have made this application, setting out the following details and affixing a stamp of five rupees hereto, to obtain the drug import registration certificate, pursuant to sub-section (2) of section 8A. of the Drugs Act, 2035(1978) and sub-rule (1) of rule 4B of the Drugs Registration Regulation, 2038 (1981).

1. Drug of which import registration certificate is intended to be obtained:
 - (a) Name:
 - (b) System:
 - (c) Group and sub-group:
 - (d) Composition:
 - (e) Active ingredient and quantity (per unit):
 - (f) Expiry date:
 - (g) Pharmacopoeia standard:
 - (h) Retail price:
 - (i) Laboratory having conducted analysis and test, and the analysis and test report issued by that laboratory and date thereof:
2. Other details:
 - (a) Whether the product specification setting down the size, color, measurement or weight, taste and flavor of drug, method of packing and details mentioned in its label is attached or not:

¹² Inserted by the First Amendment.

- (b) Whether the method of analyzing and testing the drug is attached or not:
- (c) Whether the label, cartoon and sample of drug are attached or not:

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-4D¹³

(Relating to sub-rule (3) of rule 4B)

Registration book

The following drug has been registered as follows for its import, subject to the Drugs Act, 2035(1978) and the Drugs Registration Regulation, 2038(1981).

Registration number	Of the drug											
	Name	System	Group and sub-group	Composition	Type or kind	Color	Active ingredient		Disease to be cured from consumption	Name of manufacturing company; and country	Registering officer's signature; and date	Remarks
							Name	Quantity				

¹³ Inserted by the First Amendment.

Schedule-4E¹⁴

(Relating to sub-rule (3) of rule 4B.)

His Majesty's Government

Ministry of Health

Department of Drugs Administration

Drug import registration certificate

Import registration certificate number:

Sir,

The drug import registration certificate has been issued, setting out the following details, pursuant to sub-section (2) of section 8A of the Drugs Act, 2035(1978) and sub-rule (3) of rule 4B. of the Drugs Registration Regulation, 2038(1981).

1. Of the drug:
 - (a) Name:
 - (b) System:
 - (c) Group and sub-group:
 - (d) Composition:
 - (e) Active ingredient and quantity (per unit):
 - (f) Expiry date:
2. Manufacturer's:
 - (a) Name:
 - (b) Address and country:
3. Fees received for the import registration certificate: Rs.---
4. Validity period of certificate:

Import registration certificate obtainer's:

Name and surname:

¹⁴ Inserted by the First Amendment.

Address:

Import registration certificate receiver's:

Signature:

Name and surname:

Address:

Date:

Certificate issuing officer's:

Signature:

Name and surname:

Designation:

Date:

Note bene:

Prior approval has to be obtained from the Department if any alteration is to be made in the product specification and label submitted to the department and in the above-mentioned details:

Amendment to the certificate

Date	Details of amendment

Renewal

Period of extension of validity		Fees	Officer's signature	Remarks
From	To			

Schedule-5
(Relating to sub-rules (2) and (3) of rule 4)
His Majesty's Government
Ministry of Health
Department of Drugs Administration

Serial number:

Product license

This product license is hereby issued setting out the following matters, allowing the-----industry already established in -----, based on the following recommendation letter and the license, subject to the Drugs Act, 2035(1978) and the Drugs Registration Regulation, 2038(1981).

1. Serial number of the recommendation letter of this Department and date thereof:
2. Date of license obtained from-----Department:
3. Drug industry:
 - (a) Name:
 - (b) Place of establishment:

(Also mention the name and ward number of the district, Municipality and Village Development Committee.)

Drug licensed for manufacture										
S N	Registratio n number; name	Syst e m	Grou p or sub- group	Compositio n	Typ e or kind	Colo r	Weight and measuremen t per unit	Active ingredient		Remark s
								Nam e	Quantit y	

4. Product license obtainer's:

(a) Name and surname:

(b) Address:

5. Fees received for the issuance of product license: Rs.---

6. Validity period of product license:

Product license receiver's:

Signature:

Date:

Product license issuing officer's:

Signature:

Name and surname:

Designation:

Date:

(The matters to be written on the reverse side of this product license)

Renewal of the product license

Product license				Department's seal	Remarks
Validity extension period		Renewing officer's signature, and date	Renewal fees		
From	To				

Schedule-6

(Relating to sub-rule (1) of rule 5)

Application for drug export/import recommendation letter

The Administrator,
Department of Drugs Administration.

Dear sir,

Whereas, I/we intend to obtain a recommendation letter to export/import the following drug;

Now, therefore, I/we have made this application, setting out the following matters and affixing a stamp of one rupee hereto, to obtain the recommendation letter.

Drug to be exported/ imported								
SN	Name	System	Group or sub-group	Standard	Composition	Active ingredient		Name of manufacturing company, and country
						Name	Quantity	

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-7
(Relating to sub-rule (2) of rule 5)
His Majesty's Government
Ministry of Health
Department of Drugs Administration

Drug export/import recommendation letter

This recommendation letter is hereby issued, setting out the following matters, to export/import the following drug, subject to the Drugs Act, 2035(1978) and the Drugs Registration Regulation, 2038(1981).

1.

Drug recommended to be exported/ imported								
S N	Registr ation numbe r; name	Syste m	Group or sub- group	Standard	Compositi on	Active ingredient's		Name of manufacturing company, and country
						Name	Quantity	

2. Recommendation letter obtainer's:
 - (a) Name and surname:
 - (b) Address:
3. Validity period of recommendation letter:
4. Recommendation letter receiver's:

Signature:

Date:

Recommendation letter issuing officer's:

Signature:

Name and surname:

Designation:

Date:

(The matters to be written on the reverse side of this recommendation letter.)

Renewal of the recommendation letter

Recommendation letter				Department's seal	Remarks
Validity period		Renewing officer's signature, and date	Renewal fees		
From	To				

Schedule-8
(Relating to sub-rule (1) of rule 6)
Application for certificate

The Administrator,
Department of Drugs Administration.

Dear sir,

Whereas, I/we intend to have registered my/our name and the name of the following shop or firm and obtain a certificate for the sale and distribution of the following drug;

Now, therefore, I/we have made this application, setting out the following matters and affixing a stamp of one rupee hereto, to obtain the certificate.

1. The drug selling and distributing pharmacist or entrepreneur and other person's:

	Name and surname	Address	Qualifications		Whether certified copy of qualifications is attached or not	Remarks
			Qualifications	Experiences		

2. Of the shop or firm selling and distributing the drug:

- (a) Name and address:

- (b) Estimated capital:

(c) Name, surname and address of the owner:

3.

SN	Of the drug to be sold and distributed						Remarks
	System	Group or sub-group	Composition	Manufacturing company and country	Storage		
					Method	Means	

4. Mode of sale and distribution of the drug: retail/wholesale

5. Whether a certified copy of the document issued by the manufacturer of the drug to be sold and distributed, guaranteeing that such drug is safe for the people, efficacious and of quality standard, is attached or not. If it is not attached, mention that by when it can be submitted.

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-9
(Relating to sub-rule (2) of rule 6)
His Majesty's Government
Ministry of Health
Department of Drugs Administration

Serial number:

Certificate

1. This certificate is hereby issued, setting out the following matters, allowing the following person, shop or firm to sell and distribute the following drug, subject to the Drugs Act, 2035(1978) and the Drugs Regulation, 2038(1981).
 Of the pharmacist or entrepreneur and other person allowed to sell and distribute the drug:

	Name and surname	Address	Qualifications		Whether certified copy of qualifications is attached or not	Remarks
			Qualifications	Experiences		

2. Of the shop or firm allowed to sell and distribute the drug:
 - (d) Name and address:
 - (e) Estimated capital:
 - (f) Name, surname and address of the owner:

3.

SN	Of the drug allowed to be sold and distributed						Remarks
	System	Group or sub-group	Composition	Manufacturing company and country	Storage		
					Method	Means	

4. Mode of allowed sale and distribution of the drug: retail/wholesale

5. Whether, prior to the sale and distribution of any drug as referred to in number 3, a certified copy of the document issued by the manufacturer of that drug, guaranteeing that such drug is safe for the people, efficacious and of quality standard, has been submitted or not.

6. Certificate obtainer's:

(a) Name and surname:

(b) Address:

Certificate receiver's:

Signature:

Date:

Certificate issuing officer's:

Signature:

Name and surname:

Designation:

Date:

Note bene: Any person who sells and distributes the drug pursuant to this certificate shall not be entitled to sell and distribute such drug without submitting to the Department a certified copy of the document which that person has obtained from the manufacturer of the drug guaranteeing that such drug is safe for the people, efficacious and of quality standard.

(The matters to be written on the reverse side of this certificate.)

Renewal of the certificate

Certificate				Department's seal	Remarks
Validity period		Renewing officer's signature, and date	Renewal fees		
From	To				

Schedule-10

(Relating to sub-rule (1) of rule 7)

Application for license to have publicity and advertisement of drug

The Administrator,
Department of Drugs Administration.

Dear sir,

Whereas, I/we intend to publicize or advertise the following drug;

Now, therefore, I/we have made this application, setting out the following matters and affixing a stamp of one rupee hereto, to obtain the license for the same.

1. SN	Of the drug to be publicized or advertised									
	Name	System	Group or sub-group	Composition	Type or kind	Active ingredient's		Name of manufacturing company, and country	Disease to be cured by consumption	Remark
						Name	Quantity			

2. Means of publicity or advertisement of drug:

(a) In which language:

(b) By which means: (poster, motion picture, newspapers, mobile demonstration etc.)-----

3. Description relating to the words or symbols to be used for publicity and advertisement of drug:

4. Area where the drug is publicized or advertised:

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-11
(Relating to sub-rules (2) and (3) of rule 7)
His Majesty's Government
Ministry of Health
Department of Drugs Administration

License for publicity and advertisement of drug

This license is hereby issued, setting out the following matters, allowing the following person to publicize and advertise the following drug, subject to the Drugs Act, 2035(1978) and the Drugs Regulation, 2038(1981).

1. Of the drug licensed for publication or advertisement										
SN	Name	System	Group or sub-group	Composition	Type or kind	Active ingredient's		Name of manufacturing company, and country	Disease to be cured by consumption	Remark
						Name	Quantity			

2. Allowed for publicity and advertisement of drug:
 - (a) Means:
 - (b) Words or symbols:
 - (c) Area:
3. Licensee's:
 - (a) Name and surname:
 - (b) Address:
 - (c) Occupation:

4. Fees received for the issuance of license: Rs.

5. Validity period of the license:

License receiver's:

Signature:

Date:

License issuing officer's:

Signature:

Name and surname:

Designation:

Date:

(The matters to be written on the reverse side of this license.)

Renewal of the license

Certificate				Department's seal	Remarks
Validity period		Renewing officer's signature, and date	Renewal fees		
From	To				

Schedule-12

(Relating to sub-rule (1) of rule 8)

Application for license to conduct clinical trial

The Administrator,
Department of Drugs Administration.

Dear sir,

Whereas, I/we intend to conduct the clinical trial of the following drug;
Now, therefore, I/we have made this application, setting out the following matters
and affixing a stamp of one rupee hereto, to obtain the license for the same.

1. Of the new drug of which clinical trial is to be conducted:

Name	System	Group or sub-group	Composition	Type or kind	Active ingredient's		Remarks
					Name	Quantity	

2. Of the disease to be suffered by a patient or person on whom clinical trial is conducted:

(a) Name:

(b) Method of diagnosis:

3. Of the consumption of the new drug to be administered in the course of clinical trial:

- (a) Method:
 - (b) Mode:
 - (c) Dosage (daily):
 - (d) Period:
4. Mode of clinical trial:--
5. Place where clinical trial is or intended to be conducted:
- (a) Name and address of hospital:
 - (b) Name and address of other doctor:
6. Of the person on whom clinical trial is intended to be conducted:
- (a) Name and surname:
 - (b) Address:
 - (c) Occupation:
 - (d) Qualifications:
7. Mention whether the following details of the new drug are attached or not:
- (a) Toxicological report:
 - (b) Quality control method:
 - (c) Other necessary matters:

Applicant's:

Signature:

Name and surname:

Address:

Date:

Schedule-13
(Relating to sub-rule (2) of rule 8)
His Majesty's Government
Ministry of Health
Department of Drugs Administration

License for clinical trial

This license is hereby issued, setting out the following matters, allowing the following person to conduct clinical trial of the following new drug, subject to the Drugs Act, 2035(1978) and the Drugs Regulation, 2038(1981).

1. Of the new drug licensed for clinical trial:

Name	System	Group or sub-group	Composition	Type or kind	Active ingredient's		Remarks
					Name	Quantity	

2. Of the disease licensed for clinical trial:

- (a) Name:
- (b) Method of diagnosis:

4. Of the consumption of the new drug to be administered in the course of clinical trial:

- (a) Method:
- (b) Mode:
- (c) Dosage (daily):
- (d) Period:

4. Mode of clinical trial:
5. Place where clinical trial is to be conducted:
6. Of the person allowed to conduct clinical trial:
 - (a) Name, surname and address:
 - (b) Occupation:
 - (c) Qualifications:
7. Validity period of license:
 License receiver's:
 Signature:
 Date:

License issuing officer's:

Signature:

Name and surname:

Designation:

Date:

(The matters to be written on the reverse side of this license.)

Renewal of the license

Certificate				Department's seal	Remarks
Validity period		Renewing officer's signature, and date	Renewal fees		
From	extension To				

Schedule-14

(Relating to sub-rule (2) of rule 3, sub-rule (2) of rule 4, sub-rule (2) of rule 4A, sub-rule (3) of rule 4B, sub-rue (2) of rule 5, sub-rule (2) of rule 6, sub-rule (2) of rule 7, sub-rule (2) of rule 8, rule 9, and sub-rule (2) of rule 10)

Fees			
SN	Description	Initial fees Rs.	Renewal fees Rs.
1.	For the recommendation letter for the establishment of an industry pursuant to sub-rule (2) of rule 3	200/-	-
2.	For the product license pursuant to sub-rule (2) of rule 4	200/-	50/-
3.	For the sale and distribution registration certificate pursuant to sub-rule (2) of rule 4A.	100/-	50/-
4.	For the import registration certificate pursuant to sub-rule (2) of rule 4B	200/-	100/-
5.	For the export/import recommendation letter pursuant to sub-rule (2) of rule 5	200/-	100/-
6.	For the shop registration certificate pursuant to sub-rule (2) of rule 6:		
	(a) Capital not exceeding fifty thousand rupees	200/-	100/-
	(b) Capital from fifty thousand one rupees to one hundred thousand rupees	500/-	250/-
	(c) Capital from one hundred thousand one rupees to five hundred thousand rupees	1000/-	500/-
	(d) Capital exceeding five hundred thousand one rupees	2000/-	1000/-
7.	For the publicity and advertisement license pursuant to sub-rule (2) of rule 7:		
	(a) For the license for publicity and advertisement through television	5000/-	2500/-

	(b) For the license for publicity and advertisement through printing or other media	2000/-	1000/-
8.	For the clinical trial license pursuant to sub-rule (2) of rule 8	5000/-	-
9.	For duplicate copies of license, certificate and recommendation letter pursuant to sub-rule (2) of rule 10 (a) For the first time (b) For the second time or each time more than that	50/- 100/-	- -