LICENCE UNDER DRUGS & COSMETICS ACT, 1940 & RULES THEREUNDER

(GRANT /RENEWAL OF RETAIL SALE DRUGS LICENCE (PHARMACY).

<table>
<tr><td>1</td><td>Name of licence</td><td colspan="3">Grant /Renewal of Retail Drugs Licence (Pharmacy)</td></tr>
<tr><td>2</td><td>Competent Authority</td><td colspan="3">Drugs Licensing Authority</td></tr>
<tr><td>3</td><td>Applicability Criteria</td><td colspan="3">Every Citizen can get appointment for firm licence on working day of office.</td></tr>
<tr><td>4</td><td>Stage</td><td colspan="3">Pre-Operation</td></tr>
<tr><td>5</td><td>Timeline</td><td colspan="3">30 Days</td></tr>
<tr><td>6</td><td>Document Required</td><td colspan="3">
<table>
<tr><th>Sr. No.</th><th>Documents</th><th>No. of copies</th></tr>
<tr><td>1</td><td>Covering letter</td><td>1 copy</td></tr>
<tr><td>2</td><td>Self Assesed check list of documents</td><td>1 copy</td></tr>
<tr><td>3</td><td>Form – 19.</td><td>1 copy</td></tr>
<tr><td>4</td><td>Copy of Ownership of premises/Agreement of leave & Licence/Lease Agreement./Rent receipt.</td><td>1 copy</td></tr>
<tr><td>5</td><td>Copy of Memorandum and Articles of Association.</td><td>1 copy</td></tr>
<tr><td>6</td><td>List of Directors</td><td>1 copy</td></tr>
<tr><td>7</td><td>Copy of Plan of Premises/Lay out of location.</td><td>1 copy</td></tr>
<tr><td>8</td><td>Certificates of Competent Person/ Super wiser in charge.
a) Copy of Offer of Appointment.
b) Copy of Consent/Acceptance Letter.
c) Copy of Experience Certificate.
d) Copy of Degree Certificate.
e) Copy of Marks Statement.
f) Affidavit of pharmacist.</td><td>1 copy</td></tr>
<tr><td>9</td><td>Copy of Power of attorney to sign the documents.</td><td>1 copy</td></tr>
<tr><td>10</td><td>Photo Identity proof</td><td>1 copy</td></tr>
</table>
</td></tr>
<tr><td>7</td><td>Procedure for Registration</td><td colspan="3">
<table>
<tr><td>Step -2</td><td>The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.</td></tr>
<tr><td>Step -3</td><td>The Drugs Inspector will examine the attached documents and will inspect the premises.</td></tr>
<tr><td>Step -4</td><td>The Drugs Inspector will convey to the applicant, if any deficiencies in documents and observation of inspection.</td></tr>
<tr><td>Step –5</td><td>After the compliance of observations the Drugs Inspector will forward the application to Drugs Licensing Authority.</td></tr>
<tr><td>Step – 6</td><td>After the Compliance the Drugs Licensing</td></tr>
</table>
</td></tr>
</table>

		Authority will grant the licence with his/her signature.
8	Fee & Mode of Payment	Rs. 3000/-
9	Application Form	**FORM 19** **[See Rule 59 (2)]** ***APPLICATION FOR GRANT OR RENEWAL OF A LICENCE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE DRUGS OTHER THANTHOSE SPECIFIED IN SCHEDULE X.*** 1)..... ..... hereby apply for licence to sell by wholesale/retail drugs specified in Schedule C and C(1) excluding those specified in Schedule X and/or drugs other then those specified in Schedules C and C(1) and X to the Drugs and Cosmetics Rules 1945 and also to operate a pharmacy on the premises situated at .... 2) The sale and dispensing of drugs will be made under the personal supervision of the qualified persons namely: - Name: - _____ Qualification: _____ Name: - _____ Qualification: _____ 3) Categories of drugs to be sold: 4) Particulars for special storage accommodation: 5) A fee of rupees _____ has been credited to the Government Account under the head of account: Dated: Signature:

ADMINISTRATION OF DAMAN & DIU (UT)
OFFICE OF THE DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE, DAMAN

ADDITIONAL INFORMATION TO BE SUPPLIED WITH THE APPLICATION IN

FORM - 19/19 A

1. Name of the Establishment:

2. Address House No. Road Vaddo Taluka Tel.No.

3. Category of the Establishment: Retailer and Wholesaler.

4. Name of the applicant Address Age Qualification

5. Whether the applicant is owner/ Partner/Secretary/Managing Director:

   (Attach the Power of attorney in case of Managing Director/Secretary)

6. Whether the Establishment is to be operated under Partnership/ Proprietorship/Pvt. Ltd. Co., Public Ltd. Co.

   In case of Partnership/Pvt. Ltd. Co. please furnish the following details:-

Name of the working partner/ Managing Director/Secretary	Age	Qualification	Experience in the line	Tel. No.

7. Name of the qualified person appointed.

Name	Address	Age	Qualification	Experience in the line	Tel. No.

8. In case of proprietorship or partnership, what was the business carried on by the applicant for the last three years.

9. Was the applicant over engaged himself or on behalf of firm in dealing with drugs? If so, please furnish the particulars.

Name of the Establishment	Category of the Establishment	Address	License No. & Date	Whether it is still in

10. Was the application over rejected or license previously suspended or cancelled or surrendered ? If so, the reasons thereof:

Name of the Establishment.	Category of the Establishment	Address	Licence No. Surrendered/ rejected/cancelled/ suspended.

11. Whether the applicant or Firm is already licenced to sell drugs If so, give details.

Name of Establishment	Address	Category of Establishment	Licence

12. Was the applicant or any person at present employed by him on this proposed premises over convicted and sentenced sentenced under Drugs & Cosmetics Act, 1940 or D.D.Act 1930, Poison Act, 1918 or Pharmacy Act, 1940. If so, give details:

Name of the person	Address	Whether he was employed

13. Whether the qualified person was empolyed during previous 5 years If so, give details:

Name of the Establishment	Address	Category	Reason for leaving

14. How many persons will be engaged on the counter for selling drugs ?

Qualification	Age

15. If the application is for wholesaler please furnish the name and address of the manufacturer which they will represent as sole distribution/Agent/ Importer.

Name of the manufacturer	Address

16. What are the classes of drugs proposed to be stocked?

17. In case of narcotics or poisonous whether separate cupboard with lock and key will be provided:

18. Besides drugs, whether the applicant wants to deal with any other commodities like milk powder, cosmetics, etc. If so, give details. Whether separate cupboard will be provided for this purpose.

19. Hours of business and working days:-

20. Whether the applicant is prepared to do the night duty voluntarily:-

21. Name of the trade or professional Association of which the applicant is a member and the date of commencement of membership:

22. Financial resources to run the Establishment. Furnish details.

23. Documents to be attached:
I) Blue print of the premises with Dimension.

II) Brief description of the building in respect of area, number of rooms, area of rooms, type of construction, type of flooring, ceiling, water connection, W.C.,lighting arrangements, painting, number of windows, doors, etc.,

24. Area and population of the village where the Establishment is to be set up:

25. Numbers of permanent Doctors residing: in the area:

Name	Address

26. Whether there is any hospital/ Nursing Home/P.C.H./R.M.C./ in the locality. If so, dive details:

27. Whether there is any licenced retail sale of drugs. If so, give details.

Name of the Establishment	Category

		Date: Signature :---------- Name_____ **ADDITIONAL INFORMATION IN SR.NO.23.** 1. Area: i) Plinth Area: _____ ii) Floor Area: _____ 2. Numbers of Room: _____ Total Rooms. _____ 3. Area of Rooms: 4. Type of Construction : _____ 5. Type of Flooring : _____ 6. Type of Ceiling : _____ 7. Water Connection : _____ 8. W.C. : _____ 9. Lightning Arrangement : _____ 10. Painting : _____ 11. Number of windows & Doors : _____ Date: Signature: _____ Name: _____ _____

ANNEXURE - 1

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI, DAMAN & DIU
DIRECTORATE OF MEDICAL & HEALTH SERVICES
PRIMARY HEALTH CENTRE
MOTI DAMAN-396 220

No.DCD/D&D/LA/2020-2021/ 12785 Dated: 14 /12/2020.

Read: Business Reforms Action Plan, 2020 issued by the Department for Promotion of Industry and Internal Trade & Industry, Government of India, New Delhi.

CIRCULAR

(A) FOR RETAIL DRUGS LICENCE (PHARMACY).

1) Fees: for the Grant of Retail Drugs Licence (Pharmacy) fees of Rs. 3,000/- (for licence under Form No. 19) or as prescribed under Drugs & Cosmetics Act, 1940 from time to time.

2) Procedure and list of documents to clear the application for Retail/Drugs Licence (Pharmacy).

Step -1

The Applicant can apply for the grant of **Retail/Drugs Licence (Pharmacy)** with the following documents and necessary application fee.

List of Documents.

Sr. No.	Documents	No. of copies
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Form – 19.	1 copy
4	Copy of Ownership of premises/Agreement of leave & Licence/Lease Agreement./Rent receipt.	1 copy
5	Copy of Memorandum and Articles of Association.	1 copy
6	List of Directors	1 copy
7	Copy of Plan of Premises/Lay out of location.	1 copy
8	Certificates of Competent Person/ Super wiser in charge. a) Copy of Offer of Appointment. b) Copy of Consent/Acceptance Letter. c) Copy of Experience Certificate. d) Copy of Degree Certificate. e) Copy of Marks Statement. f) Affidavit of pharmacist.	1 copy

	9	Copy of Power of attorney to sign the documents.	1 copy
	10	Photo Identity proof	1 copy
Step -2	The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.		
Step -3	The Drugs Inspector will examine the attached documents and will inspect the premises.		
Step -4	The Drugs Inspector will convey to the applicant, if any deficiencies in documents and observation of inspection.		
Step –5	After the compliance of observations the Drugs Inspector will forward the application to Drugs Licensing Authority.		
Step – 6	After the Compliance the Drugs Licensing Authority will grant the licence with his/her signature.		

(B) FOR WHOLESALE DRUGS LICENCE.

1) Fees: for the Grant of Wholesale Drugs Licence fees of Rs. 3,000/- (for licence under Form No. 19) or as prescribed under the Drugs & Cosmetics Act, 1940 from time to time.
2) Procedure and list of documents to clear the application for Wholesale Drugs Licence.

Step -1

The Applicant can apply for the grant of **Wholesale Drugs Licence** with the following documents and necessary application fee.

List of Documents.

Sr. No.	Documents	No. of copies
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Form – 19.	1 copy
4	Copy of Ownership of premises/Agreement of leave & Licence/Lease Agreement./Rent receipt.	1 copy
5	Copy of Memorandum and Articles of Association.	1 copy
6	List of Directors	1 copy
7	Copy of Plan of Premises/Lay out of location.	1 copy
8	Certificates of Competent Person/ Super wiser in charge. e) Copy of Offer of Appointment. f) Copy of Consent/Acceptance Letter. g) Copy of Experience Certificate. h) Copy of Degree Certificate. e) Copy of Marks Statement. f) Affidavit of pharmacist.	1 copy
9	Copy of Power of attorney to sign the documents.	1 copy
10	Photo Identity proof	1 copy

Step -2	The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.
Step -3	The Drugs Inspector will examine the attached documents and will inspect the premises.
Step -4	The Drugs Inspector will convey to the applicant, if any deficiencies in documents and observation of inspection.
Step –5	After the compliance of observations the Drugs Inspector will forward the application to Drugs Licensing Authority.
Step – 6	After the Compliance the Drugs Licensing Authority will grant the licence with his/her signature.

(C) FOR DRUGS MANUFACTURING LICENCE.

1) Fees: for the Grant of Drugs Manufacturing Licence fees of Rs. 15,000/- (for licence under Form No. 24 & Form No. 27) or as prescribed under Drugs & Cosmetics Act, 1940 from time to time.
2) Procedure and list of documents to clear the application for Granting of Drugs Manufacturing Licence.

Step -1 — The Applicant will apply for the approval of Plant Lay-out along with the following documents before the grant of fresh manufacturing licence.

List of Documents.

Sr. No.	Documents	No. of copies
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	List of Directors with address	1 copy
4	Copy of Power of attorney to sign the documents.	1 copy
5	Copy of Plan approval	1 copy
6	Noc/Consent from SSI, Pollution.	1 copy
7	Copy of Memorandum of Articles	1 copy

Step -2	The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.
Step -3	The Drugs Inspector will examine the attached documents and study the plant lay-out as per the guidelines of Schedule –M of the Drugs & Cosmetics Rules, 1945. And if any deficiency in documents or any observations then will convey to the applicant for necessary rectification.

<table>
<tr><td>Step -4</td><td>After the compliance of observations of Drugs Inspector, the application will be forwarded to the Drugs Licensing Authority for approval.</td></tr>
<tr><td>Step - 5</td><td>The Drugs Licensing Authority after the compliance will issue /approve the Plant Lay-out with his/her signature.</td></tr>
<tr><td>Step – 6</td><td>After the approval of Plant Lay-out the applicant with following documents and necessary application fee will apply for the grant/renewal of Drugs Manufacturing Licence.
<table>
<tr><th>Sr. No.</th><th>Documents</th><th>No. of copies</th></tr>
<tr><td>1</td><td>Covering letter alongwith payment of application fee.</td><td>1 copy</td></tr>
<tr><td>2</td><td>Self Assesed check list of documents</td><td>1 copy</td></tr>
<tr><td>3</td><td>Form 24 & 27 (Maximum 10 Products should apply under each form)</td><td>1 copy</td></tr>
<tr><td>4</td><td>Product List.</td><td>2 copies</td></tr>
<tr><td>5</td><td>List of Excipients.</td><td>1 copy</td></tr>
<tr><td>6</td><td>Similar Product.</td><td>1 copy</td></tr>
<tr><td>7</td><td>Draft Label.</td><td>1 copy</td></tr>
<tr><td>8</td><td>Method of Analysis.</td><td>1 copy</td></tr>
<tr><td>9</td><td>Additional Information Form.</td><td>1 copy</td></tr>
<tr><td>10</td><td>Copy of Memorandum of Articles</td><td>1 copy</td></tr>
<tr><td>11</td><td>List of Directors with address</td><td>1 copy</td></tr>
<tr><td>12</td><td>Copy of Power of attorney to sign the documents.</td><td>1 copy</td></tr>
<tr><td>13</td><td>Copy of Plan approval</td><td>1 copy</td></tr>
<tr><td>14</td><td>Noc/Consent from SSI, Pollution.</td><td>1 copy</td></tr>
</table></td></tr>
<tr><td>Step - 7</td><td>The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.</td></tr>
<tr><td>Step - 8</td><td>The Drugs Inspector will Scrutiny the application and will inspect factory premises.</td></tr>
<tr><td>Step – 9</td><td>The Drugs Inspector will convey to the applicant, if any deficiencies in documents and observation of inspection.</td></tr>
<tr><td>Step –10</td><td>After the compliance of observations the Drugs Inspector will forward the application to Drugs Licensing Authority.</td></tr>
<tr><td>Step -11</td><td>After the Compliance the Drugs Licensing Authority will grant the licence with his/her signature.</td></tr>
</table>

(Dr. A. Muthumma)
Secretary (Health)
DNH, Daman & Diu.

ANNEXURE -3

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI, DAMAN & DIU
DIRECTORATE OF MEDICAL & HEALTH SERVICES
PRIMARY HEALTH CENTRE
MOTI DAMAN-396 220

No.DCD/D&D/LA/2020-2021/ 12787 Dated: 14 /12/2020.

Read: Business Reforms Action Plan, 2020 issued by the Department for Promotion of Industry and Internal Trade & Industry, Government of India, New Delhi.

CIRCULAR

(A) FOR RETAIL & WHOLESALE DRUGS LICENCE.

As per the provisions of Drugs & Cosmetics (Tenth Amendment) Rules, 2017 vide notification No. G.S.R. 1337 (E) dated 27th October, 2017, the rule 63 of said rules, that deals with renewal of retail and wholesale licence, is substituted as follow.

Rule – 63. Duration of licence: A licence issued in Forms 20, 20A, 20B, 20BB, 20F, 20G, 21, 21A, 21B or Form 21BB shall remain valid, if licensee deposits as licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(B) FOR DRUGS MANUFACTURING LICENCE (UNDER FORM 25 & OTHERS).

As per the provisions of Drugs & Cosmetics (Tenth Amendment) Rules, 2017 vide notification No. G.S.R. 1337 (E) dated 27th October, 2017, the rule 72 of said rules, that deals with renewal of drug manufacturing licence, is substituted as follow.

Rule -72. Duration of licence : A licence issued in Form 25, Form 25B and Form 25F shall remain valid if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(C) FOR DRUGS MANUFACTURING LICENCE (UNDER FORM 28 & OTHERS).

As per the provisions of Drugs & Cosmetics (Eleventh Amendment) Rules, 2019 vide notification No. G.S.R. 499 (E) dated 17th July, 2019, rule the 77 of said rules that deals with the renewal of Drugs manufacturing licence is substituted as follow.

Rule -77. Duration of licence: A licence issued in Form 28, Form 28B and Form 28D shall remain valid, if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless it is suspended or cancelled by the licensing authority.

(Dr. A. Muthumma)
Secretary (Health)
DNH, Daman & Diu.