LICENCE UNDER DRUGS & COSMETICS ACT, 1940 & RULES THEREUNDER

(GRANT/RENEWAL OF WHOLESALE DRUGS LICENCE).

<table>
<tr><td>1</td><td>Name of licence</td><td>Grant /Renewal of Wholesale Drugs Licence</td></tr>
<tr><td>2</td><td>Competent Authority</td><td>Drugs Licensing Authority</td></tr>
<tr><td>3</td><td>Applicability Criteria</td><td>Every Citizen can get appointment for firm licence on working day of office.</td></tr>
<tr><td>4</td><td>Stage</td><td>Operation</td></tr>
<tr><td>5</td><td>Timeline</td><td>30 Days</td></tr>
<tr><td>6</td><td>Document Required</td><td>
<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>
<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>
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</table>
</td></tr>
</table>

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:
		G. P. Bvc – (0) – 574 – 20,000 – 9 – 76. ***D. C. O. – 1145 – 21 – 483/H, Dated 2 – 4 – 56 [Spl. D. C. A. 7E]*** *ADDITIONAL INFORMATION TO BE SUPPLIED WITH THE APPLICATION IN FORM 19 OR 19-A.* ***1. Name of all the partners or Directors proprietors, etc. and full residential address of each –*** ***(1) ……*** ***……*** ***(2) ……*** ***……*** ***(3) ……*** ***……***

(4) ……
……

2. *What are the educational–qualification of –*

(a) The applicant or / and
(b) Person in-charge of the premises for which licence is applied for

3. *What are the businesses carried on by the applicant within last three years ?*

4. *Has the applicant ever engaged himself or on behalf of any other person in selling drugs any time prior to this application ? If so the dates together with necessary documentary evidence may be supplied.*

5. *What other business is carried out by the applicant at present.*

6. *Is the application for fresh licence or renewal ?*

7. *Year in which licence was first granted.*

8. *Particulars of licences granted under Drugs Rules :* *Lic. No.* *Form* *Date of issue*

9. *Was the application ever rejected or licence previously cancelled or suspended or surrendered ? If so, for what reason.*

10. *Was the applicant ever warned for selling goods which were not of standard quality ?*

11. *Was the applicant or any person at present employed by him on these premises ever convicted and sentenced under :*

a) Drugs and Cosmetics Act. 1940 ……..
b) Dangerous Drugs Act. 1930 ……
c) Bombay Prohibition Act. 1949 ……..
d) Bombay Drugs (Control) Act. 1952 ……
e) The Poisons Act. 1919 ……
f) The Pharmacy Act. 1948 ……..

12. *a) Poison Rules …….* *Licence No…….*
Date of issue ……

b) Dangerous Drugs Rules…. *……..* *Licence No…….*
Date of issue ……

13. *Sales of Intoxicants Taxation Act…* *Licence No…….*
Date of issue…….

14. *Spirituous Medicinal Preparation Rules Licence No……*
Date of issue ……

15. *Sales Tax Registration No.* *Date of Registration*
CST DA / CST /
LST DA /

16. *Shops and establishment Act……..* *Licence No.*

17. *Has the applicant ever imported spirituous Medicinal or Toilet preparations from other States ? If so, a statement of the names of the names of the manufacturers. Spirituous preparation, their quantities and dates on which*

			imported during last year should be given in separate sheet or paper duly signed and dated by the applicant.
			and or
			Had the applicant ever dealt in Spirituous Medicinal or Toilet preparations manufactured by manufacturers within this state ?
		18.	***Is the applicant an agent or distributors of any drug manufacturing concern ? If so, the area of distribution and date of appointment should be stated with full particulars.***
		19.	***Is the firm of company a: -***
			a) Restaurant ? …….. ***b) Grocer ? ……..*** ***c) Panbidi shop ? ……..*** ***d) General Merchant ? ……..*** ***e) Medical store ? ……..*** ***f) Dispensing Chemist ? ……..*** ***g) Distribution Agent ? ……..*** ***h) Commission Agent ? ……..*** ***i) Importer ? ……..***
		20.	***The applicant has in all one room for storage and sale of drugs. The floor area in square feet of each room must be given with a sketch.***
			The applicant is a legal tenant or a licensee there of necessary documentary evidence should be enclosed.
		21.	***The applicant does / does not stock or sell drugs at any other premises nor has the office except at the premises for which this application is applied for.***
			Or ***The address of other premises are :***
		22.	***What class of drugs are stocked. Sold or distributed :***
			a. Poisons ***b. Injections*** ***c. Oral Vitamin Products*** ***d. Household Remedies*** ***e. Tinctures and Other spirituous preparations.*** ***f. Ayurvedic Medicines***
		23.	***The applicant deals in the following class of commodities only besides drugs on these premises, viz.***
			1. ***2.*** ***3.*** ***4.*** ***5.*** ***6.*** ***7.***
		24.	***The applicant was / was not dealing in spirits wine / country liquor prior to introduction of prohibition in Bombay.***
		25.	***The applicant will deal / will not deal in any spirituous medicinal or toilet preparation, which are liable to be***

		misused for other than **bonafied** ***medicinal purpose.*** ***26. Hours of business and working days.*** ***27. Name of the trade or professional Association of which applicant is a member and the date of commencement of membership.*** ***I certify that all the above information is true and understand that my application is liable to be rejected summarily or the licence is liable to be cancelled forth with if the above information is proved to be false in any particular.*** ***Date :*** ***Signature of applicant :***

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.