LICENCE UNDER DRUGS & COSMETICS ACT, 1940 & RULES THEREUNDER

(GRANT /RENEWAL OF DRUGS MANUFACTURING LICENCE)

<table>
<tr><td>1</td><td>Name of licence</td><td>Grant /Renewal of Drugs Manufacturing 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>Pre -Operation</td></tr>
<tr><td>5</td><td>Timeline</td><td>45 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>List of Directors with address</td><td>1 copy</td></tr>
<tr><td>4</td><td>Copy of Power of attorney to sign the documents.</td><td>1 copy</td></tr>
<tr><td>5</td><td>Copy of Plan approval</td><td>1 copy</td></tr>
<tr><td>6</td><td>Noc/Consent from SSI, Pollution.</td><td>1 copy</td></tr>
<tr><td>7</td><td>Copy of Memorandum of Articles</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 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.</td></tr>
<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>
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<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>
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<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>
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<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>8</td><td>Fee & Mode of Payment</td><td>Rs. 7500/- Each Form and 10 Free Products of Each Form.</td></tr>
<tr><td>9</td><td>Application Form</td><td>
F O R M 24
(See Rule 69)

APPLICATION FOR THE GRANT OF OR RENEWAL OF A LICENCE TO MANUFACTURE FOR SALE DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C AND C(1)
---

1. I/We_____ of _____ hereby apply for the grant / renewal of a licence to manufacture on the premises situated at _____ the following drugs being drugs other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945.

2. Name of drugs categorized according to Schedule M.

3. Names, Qualifications and experience of technical staff employed for manufacture and testing.

4. A fee of rupees _____ has been credited to Government under the head of account _____

Dated: Signature
</td></tr>
</table>

[FORM 27]

APPLICATION FOR GRANT OR RENEWAL OF A LICENCE TO MANUFACTURE FOR SALE [3][OR FOR DISTRIBUTION OF] DRUGS SPECIFIED IN SCHEDULES C AND C (1)[4] [EXCLUDING THOSE SPECIFICATION IN [5][PART XB AND] SCH. X]

---

1. I/We……..... hereby apply to the grant/renewal of a licence to manufacture on the premises situated at..... the under-mentioned drugs, being drugs specified in Schedules C and C (1), [1][excluding those specified in [2][Part XB and] sch. X] to the Drugs and Cosmetics Rules, 1945.

Name of drugs..... (each item to be separately specified)

2. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the above-mentioned drugs:

(a) Name(s) of staff responsible for test .....

(b) Name(s) of staff responsible for Manufacture ..... are ready for inspection / will be ready for inspection on

3. The premises and plan .....

4. A fee of rupees ..... and an inspection fee of rupees ..... has been credited to Government under the head of account .....

Date ..... *Signature .....*
Designation.....

Note - The application shall be accompanied by a plan of the premises.

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.

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<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>
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<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.