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