Citizen’s Charter

Directorate of Food and Drugs Administration (FDA)

Government of Goa

Dhanwantari, Opp. The Shrine of Holy Cross, Bambolim – Goa.

Telephone: 0832-2459226; 2459230
Fax: 082-2459223
Email: off-dfdagoa@nic.in
Website: www.dfdagoa.gov.in

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Next Review: September, 2018
Our Vision

Directorate of Food and Drugs Administration is mandated to ensure the availability of safe food and drugs to the general public at large.

Our Mission

- To strive for excellence in health by ensuring the availability of safe food and safe effective and quality medicines to the public.
- To continue with the time tested tradition of sustaining Goa Food and Drugs Administration as one of the best FDA in the Country.
- To pool into all sincere efforts to place FDA – Goa on the global map as one of the best regulatory Institution.

Values

- Transparency
- Integrity
- Accountability
- Courtesy
- Responsiveness
- Professionalism
- Impartiality

Stakeholders Consulted

- Food Business Operators
- Pharmaceutical Manufacturers
- Wholesale and retail drug dealers
- Citizens
Main Acts & Rules Enforced

- Drugs & Cosmetics Act, 1940 and Rules 1945
- Drugs & Magic Remedies (Objectionable Advertisements ) Act, 1954
- Drugs Price Control Order, 2013
- Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules 1987
- Food Safety and Standard Act, 2006 and Rules/Regulations 2011
- Goa Public Health (Amendment) Act, 2005

Services Provided

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name of the Service</th>
<th>Service Standard</th>
<th>Service Indicator</th>
<th>Units</th>
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<tbody>
<tr>
<td>1.</td>
<td>Grant of fresh drugs/cosmetics manufacturing licence with maximum five products</td>
<td>30 days from the receipt of completed application.</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>2.</td>
<td>Grant of licence for additional products Generic Drugs (maximum five products)/cosmetics</td>
<td>14 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>3.</td>
<td>Grant of licence for additional products Patent &amp; Proprietary Drugs (maximum five products)</td>
<td>21 days</td>
<td>Time</td>
<td>Days</td>
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<tr>
<td>4.</td>
<td>Grant of Good Manufacturing Practices Certificate</td>
<td>7 days</td>
<td>Time</td>
<td>Days</td>
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<tr>
<td>5.</td>
<td>Grant of No Conviction Certificate</td>
<td>7 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>6.</td>
<td>Grant of Free Sale Certificate</td>
<td>7 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>7.</td>
<td>Grant of Production &amp; Sales Verification Certificate</td>
<td>14 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>8.</td>
<td>Plan Approval of Manufacturing Facilities as per schedule M of Drugs and Cosmetics Rules</td>
<td>21 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>9.</td>
<td>Grant of Test Licence</td>
<td>14 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>10.</td>
<td>Grant of fresh loan licences with five products</td>
<td>30 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>11.</td>
<td>Grant of licences for additional products under loan licence; generic drugs (maximum five products)</td>
<td>14 days</td>
<td>Time</td>
<td>Days</td>
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<tr>
<td>12.</td>
<td>Grant of licences for additional products under loan licence; patent &amp; Proprietary drugs (maximum five products)</td>
<td>21 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>13.</td>
<td>Grant of Drugs Retail licences</td>
<td>30 days</td>
<td>Time</td>
<td>Days</td>
</tr>
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<td></td>
<td>Description</td>
<td>Time</td>
<td>Type</td>
<td>Days</td>
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</tr>
<tr>
<td>14.</td>
<td>Grant of Drugs Wholesale Licences</td>
<td>30 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>15.</td>
<td>Grant of Homeopathic Drugs Licences</td>
<td>30 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>16.</td>
<td>Grant of Narcotic Drugs &amp; Psychotropic Substances Licences (Fresh Licence)</td>
<td>30 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>17.</td>
<td>Grant of Licence for stocking and sale of Narcotics Drugs &amp; Psychotropic Substances (for those who are holding Wholesale or Retails Licences under the Drugs &amp; Cosmetics Act and Rules)</td>
<td>14 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>18.</td>
<td>Issue of Permit for Narcotics Drugs for terminal cancer patients</td>
<td>2 hrs.</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>19.</td>
<td>Issue of Permit for Narcotics Drugs such as Pethidine Injections to Wholesalers, Retailers, Nursing Homes, Hospitals etc.</td>
<td>2 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>20.</td>
<td>Food Licence involving inspection of Premises</td>
<td>60 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>21.</td>
<td>Food Licence not involving inspection premises</td>
<td>60 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>22.</td>
<td>Registration Certificate for food premises not involving inspection</td>
<td>7 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>23.</td>
<td>Registration Certificate for food premises involving inspection</td>
<td>30 days</td>
<td>Time</td>
<td>Days</td>
</tr>
<tr>
<td>24.</td>
<td>Registration Certificate for Temporary Premises</td>
<td>3 days</td>
<td>Time</td>
<td>Days</td>
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## List of documents required to be submitted

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<td>1.</td>
<td>Grant of fresh drugs/cosmetics manufacturing licence with maximum five products</td>
<td>As per Annexure I enclosed</td>
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<tr>
<td>2.</td>
<td>Grant of license for additional products Generic Drugs (maximum five products)/ cosmetics</td>
<td>As per Annexure II enclosed</td>
</tr>
<tr>
<td>3.</td>
<td>Grant of licence for additional products Patent &amp; Proprietary Drugs (maximum five products)</td>
<td>-- do --</td>
</tr>
</tbody>
</table>
| 4.      | Grant of Good Manufacturing Practices Certificate                                     | 1) Challan for the fees paid
                                                | 2) Draft of Certificate
                                                | 3) Copy of manufacturing licence granted
                                                | 4) Covering letter                                                                         |
| 5.      | Grant of No Conviction Certificate                                                   | 1) Challan for the fees paid
                                                | 2) Draft of Certificate
                                                | 3) Covering letter                                                                         |
| 6.      | Grant of Free Sale Certificate                                                       | 1) Challan for the fees paid
                                                | 2) Draft of Certificate
                                                | 3) Copy of permission granted
                                                | 4) Covering letter                                                                         |
| 7.      | Grant of Production & Sales Verification Certificate                                 | 1) Challan for the fees paid
                                                | 2) Draft of Certificate
                                                | 3) Production details
                                                | 4) List of equipment/ facility provided
                                                | 5) Covering letter                                                                         |
| 8.      | Plan Approval of Manufacturing Facilities as per schedule M of Drugs and Cosmetics Rules | 1) Covering letter
                                                | 2) Copy of the proposed plan layouts in duplicate
                                                | 3) Write up on the facility
                                                | 4) List of charges proposed to be carried out in case of Revision of earlier approved plan |
| 9.      | Grant of Test Licence                                                                | 1) Covering letter
                                                | 2) Challan for fees paid
                                                | 3) Application in Form 30
                                                | 4) Drug profile for the products applied.
                                                | 5) Date of clearance of drugs by DCG(I)
<pre><code>                                            | 6) Additional information data                                                             |
</code></pre>
<p>| 10.     | Grant of fresh loan licences with five products                                      | Annexure - III                                                                     |
| 11.     | Grant of licences for additional products under loan licence; generic drugs (maximum five products) | As per Annexure II enclosed                                                        |</p>
<table>
<thead>
<tr>
<th>No.</th>
<th>Grant of licences for additional products under loan licence; patent &amp; Proprietary drugs (maximum five products)</th>
<th>As per Annexure II enclosed</th>
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<tr>
<td>13</td>
<td>Grant of Drugs Retail licences</td>
<td>As per Annexure IV</td>
</tr>
<tr>
<td>14</td>
<td>Grant of Drugs Wholesale Licences</td>
<td>-- do --</td>
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<td>Grant of Narcotic Drugs &amp; Psychotropic Substances Licences (Fresh Licence)</td>
<td>As per Annexure V enclosed</td>
</tr>
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| 17  | Grant of Licence for stocking and sale of Narcotics Drugs & Psychotropic Substances (for those who are holding Wholesale or Retail Licences under the Drugs & Cosmetics Act and Rules) | 1) Application in prescribed form  
2) Covering letter  
3) Challan for fees paid.  
4) Copy of regular Retail or wholesale licence obtained |
| 18  | Issue of Permit for Narcotics Drugs for terminal cancer patients                                  | Original prescription from RMP |
| 19  | Issue of Permit for Narcotics Drugs such as Pethidine Injections to Wholesalers, Retailers, Nursing Homes, Hospitals etc. | Application in prescribed form |
| 20  | Food Licence involving inspection of Premises                                                    | As per Annexure VI enclosed |
| 21  | Food Licence not involving inspection premises                                                  | -- do -- |
| 22  | Registration Certificate for food premises not involving inspection                             | As per Annexure VII enclosed |
| 23  | Registration Certificate for food premises involving inspection                                 | -- do -- |
| 24  | Registration Certificate for Temporary Premises                                                  | 1) Application in Form A  
2) Photo ID of the applicant  
3) 4 Photographs  
4) NOC/Trade licence from Panchayat/ Municipality  
5) Health NOC  
6) Stall Allotment letter |
**Complaint Handling Mechanism (CHM)**

| Where to lodge a complaint | - In person or post at the DFDA; Bambolim  
|                           |   - Tel: 0832-2459226/30  
|                           |   - Email: off-dfda.goa@nic.in  
|                           |   - Every Tuesday from 10.00 to 13.00 hrs Director and PGO will be available to receive and hear the public grievances. |
| Acknowledgement of complaints | - Complaints received in person/telephone will be acknowledged instantly (with inward no.)  
|                           |   - Complaints received through email will be acknowledged within 24 hrs.  
|                           |   - Complaints received through post will be acknowledged within 5 days |
| Time for resolution of complaint | Within 30-60 days from the date of receipt of complaint. |
| Escalation of complaints | In case the complaint is not resolved in 30 days time or the resolution is not to the satisfaction of the complainant, the same can be escalated to Director, FDA; for review; |
| Time for resolution complaint after escalation | Within 15 days from the date of escalation |
| Contact Details of Director and Public Grievances Officer (PGO) | PGO:- Jyoti Sardesai  
|                           |   Designation: Deputy Director, DFDA  
|                           |   Tel: 0832-2459226/30  
|                           |   Email:jyotij27@yahoo.co.in  
|                           | Director, Food and Drugs Administration  
|                           | Tel: 0832-2459226/30  
|                           | Email: off-dfda.goa@nic.in |
Annexure – I (Service No. – 1)

List of documents for the grant of licence for Manufacturing Pharmaceutical Products

2. Application Form with nonjudicial stamp of Rs.2/-
   (i) For Non Biological Products *:-
       Form 24/24A/24B/24C/24D/24E/24F
   (ii) For Biological Products*:-
       Form 27/27A/27B/27D
       (* Strike whichever is not Applicable)
3. Site Master File
4. Challan in original, indicating the licence fees paid.
5. Two copies of the plan drawn to scale w.r.t. Manufacturing area, Sectionwise), Quality Control
   (Sectionwise), Raw material store (including Thermolabile Raw Materials), Finished Product
   Store, Packing Material Store, Service area etc.
6. List of Machinaries installed with make and Production capacity (Sectionwise).
7. List of Instruments/Equipments in Quality Control. (Sectionwise) Viz.
   (i) Instrumental & Chemical Analysis.
   (ii) Microbiological Analysis.
   (iii) Bacterial Endotoxin Test.
   (iv) Toxicity Test.
8. Names of the Competent Technical Staff in
   (i) Manufacturing, (Sectionwise).
   (ii) Quality Control, (Sectionwise).
   (iii) Quality Assurance
       Alongwith the relevant documents viz, Eduactional Qualifications, Experience, approval,
       appointment letter and acceptance letter of the candidate etc.
9. N.O.C. from Pollution Control Board
10. List of Directors/Partners of the firm with complete residential address as on the date of
    application.
11. Power of Attorney in case applicant is other than the Partner/Director.
12. Certified copy of
   (i) Memorandum & Article of Association of Limited, Private Limited company.
   (ii) Certified copy of Partnership Deed.
13. Letter from Industrial Development Corpn. For allotment of Plot.
14. Copy of the documents indicating ownership, rental, lease title of the plot.
15. List of products intended to be manufactured in Triplicate section wise on the letter head of the
    firm.
16. Additional Information data form for each Products applied.
17. Draft Text of the Carton/Foil/Label of each of the product applied.
18. Label text of the identical product available in the market.
20. Write up on Water Purification System.
21. Write up on Air Handling Unit System.
List of documents for grant of additional Products

1) Covering letter
2) Chilan for fees paid
3) Additional Information data
4) List of products
5) Draft of label text
6) Analytical specifications and method of analysis for API & FP
7) List of excipients
8) Documentary evidence for being not a new Drug or NOC from DCGCI
Annexure – III (Service No. – 10)

Grant of fresh loan licence for drugs manufacturing

1) Covering letter
2) Challan for fees paid
3) Application Form
4) List of products for which licence is required
5) Additional information data
6) Constitution of the firm and related documents
7) Certified copy of Power of Attorney (POA) in case the applicant is POA holder
8) Copy of request letter from the applicant firm to the loanee firm
9) Consent letter from the loanee firm
10) Undertaking regarding maintaining of separate stock register and proper records of drugs manufacture by the loanee firm.
11) Draft text of label of the products.
12) Analytical specifications and MOA of the API and FP
13) Documentary evidence that the product applied for is not a new drug or premises/NOC from DCGCI
14) List of excipients
15) List of approved Technical Staff of the loanee firm for manufacturing and testing.
Annexure – IV (Service No. 13, 14, 15)

Documents to be submitted along with the application for grant of Retail/Wholesale Licence.
1. Covering letter mentioning the complete details of documents submitted.
2. Application in respective Form (19, 19-B).
3. Additional information data form duly filled and signed.
4. Rs.1/- Court fee stamp to be fixed on each application.
5. Challan for Rs.3000/- (Rs.250/- additional to be paid if homoeopathic licence is also requested).
   Head of Accounts
   0210 – Medical and Public Health,
   04 – Public Health, 104 – Fees and Fines,
   01 - Fines
6. Blue print plan of the premises drawn to scale.
7. Site plan of the premises on a blue print.
8. Certified copy of Lease deed (if rented) Ownership documents (if owned).
9. Certified copy of Partnership deed, (if partnership firm)
10. Description of the premises.
11. Occupancy certificate.
13. NOC from Municipality/Panchayat
15. Certified copy of Registration Certificate of the Registered Pharmacist.
17. Appointment letter of the Registered Pharmacist/Competent Person.
19. Affidavit regarding sale of drugs in presence of whole time Registered Pharmacist/Competent Person only.
20. Biodata of the applicant mentioning the details of age, experience and details of occupation for previous five years.
22. Certified copy of power of attorney of applicant if applicable.

Note:-
1. Carpet area required for wholesale/retail premises is 15 sq. mt.
2. Applicant should obtain inspection book from this Directorate by paying the necessary fees of Rs.50/- on grant of licence at the time of issuance of licences.

Annexure – V (Service No. 16)

Grant of NDPS licence

1) Application in the prescribed form

2) Copy of challan for fees paid
3) Constitution of the firm.

4) Copy of Regular manufacturing licence in case of manufacturing firm.

5) Copy of qualification and Registration Certificate as RMP of the Doctor in-charge of the clinic; Nursing home, Hospital

6) Plan of the premises

7) Power of Attorney (POA) of the person in case the applicant is POA holder.
Annexure – VI (Service No. 20, 21)

Grant of Food Licence

1. Form – B duly complied by the proprietor/partner or the authorized signatory along with one passport size photograph of Proprietor/Managing Partner.
2. Blue print/layout plan of the processing unit showing the dimension in metres/square metres and operation – wise area allocation.
3. List of Directors with full address and contact details.
4. Name and List of Equipments and Machinery along with the number, installed capacity and horse power used.
5. Photo ID and address proof issued by Government authority of Proprietor/Partner/Director(s) Authorized Signatory (voter’s card/driving license/passport).
6. List of food category desired to be manufactured. (In case of Manufacturers).
7. Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, collection of samples, packing & dispatch.
8. Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognized/public health laboratory to confirm the portability indicating the name of authorized representative of Lab who collected the sample and date of collecting sample.
9. Proof of possession of premises. (Sale deed/Rent agreement/Electricity bill, etc.)
10. Partnership Deed/Affidavit/ Memorandum & Article of Association towards the constitution of the firm.
12. NOC from Manufacturer in case of Re-labellers.
13. Food Safety Management System plan or certificate if any.
14. Source of milk or procurement plan of milk including location of milk collection centres etc. in case of Milk and Milk Products processing unit.
15. Source of raw material for meat and meat processing plants.
16. Pesticide residues reports of water to be used as ingredients in case of units manufacturing Packaged drinking water packaged Mineral water and/or carbonated water from a recognized public health laboratory indicating the name of authorized representative of Lab who collected the sample and date of collecting sample, including source of raw waste and treatment plan.
17. Recall plan wherever applicable with details on whom the product is distributed.
18. NOCs from Municipality or local body and from State Pollution Control Board except in case of notified industrial area.
19. NOC from Health Department.
20. Copy existing license issued under Prevention of Food Adulteration Act, & Rules.
Annexure – VII (Service No.22, 23)

LIST OF DOCUMENTS TO BE SUBMITTED FOR THE GRANT OF REGISTRATION CERTIFICATE

1. Covering letter
2. Application in Form A
3. Plan of the Premises showing layout and area therein
4. Attested true copy of lease deed/sale deed/Proof of ownership
5. Memorandum of Articles of Association in case of company alongwith the list of Directors and Addresses
6. Attested true copy of Partnership Deed: In case of partnership firm alongwith list of partners and address
7. Attested true copy of Municipality/Panchayat NOC
8. Attested copy of Power of Attorney if given: to Manager or any other person in-charge
9. Additional two photographs of the Proprietor/Managing Partner of the Firm/Managing Director of the Company
10. No objection Certificate from the Directorate of Health Services in case of Hotels/Restaurant/Manufacture/re-packers etc.
11. Original Prevention of Food adulteration Food License
12. Proof of ID (attested copy of ration card/driving license/election I.D. Card/Passport)
13. Proof of Annual Turn Over in case of Existing premises

Fees to be paid in cash at the time of submitting the application.