



Citizen's Charter

Directorate of Food and Drugs Administration (FDA)

Government of Goa

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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

Sr. No.	Name of the Service	Service Standard	Service Indicator	Units
1.	Grant of fresh drugs/cosmetics manufacturing licence with maximum five products	30 days from the receipt of completed application.	Time	Days
2.	Grant of licence for additional products Generic Drugs (maximum five products)/ cosmetics	14 days	Time	Days
3.	Grant of licence for additional products Patent & Proprietary Drugs (maximum five products)	21 days	Time	Days
4.	Grant of Good Manufacturing Practices Certificate	7 days	Time	Days
5.	Grant of No Conviction Certificate	7 days	Time	Days
6.	Grant of Free Sale Certificate	7 days	Time	Days
7.	Grant of Production & Sales Verification Certificate	14 days	Time	Days
8.	Plan Approval of Manufacturing Facilities as per schedule M of Drugs and Cosmetics Rules	21 days	Time	Days
9.	Grant of Test Licence	14 days	Time	Days
10.	Grant of fresh loan licences with five products	30 days	Time	Days
11.	Grant of licences for additional products under loan licence; generic drugs (maximum five products)	14 days	Time	Days
12.	Grant of licences for additional products under loan licence; patent & Proprietary drugs (maximum five products)	21 days	Time	Days
13.	Grant of Drugs Retail licences	30 days	Time	Days

14.	Grant of Drugs Wholesale Licences	30 days	Time	Days
15.	Grant of Homeopathic Drugs Licences	30 days	Time	Days
16.	Grant of Narcotic Drugs & Psychotropic Substances Licences (Fresh Licence)	30 days	Time	Days
17.	Grant of Licence for stocking and sale of Narcotics Drugs & Psychotropic Substances (for those who are holding Wholesale or Retails Licences under the Drugs & Cosmetics Act and Rules)	14 days	Time	Days
18.	Issue of Permit for Narcotics Drugs for terminal cancer patients	2 hrs.	Time	Days
19.	Issue of Permit for Narcotics Drugs such as Pethidine Injections to Wholesalers, Retailers, Nursing Homes, Hospitals etc.	2 days	Time	Days
20.	Food Licence involving inspection of Premises	60 days	Time	Days
21.	Food Licence not involving inspection premises	60 days	Time	Days
22.	Registration Certificate for food premises not involving inspection	7 days	Time	Days
23.	Registration Certificate for food premises involving inspection	30 days	Time	Days
24.	Registration Certificate for Temporary Premises	3 days	Time	Days

List of documents required to be submitted

Sr. No.	Name of the Service	Documents required
1.	Grant of fresh drugs/cosmetics manufacturing licence with maximum five products	As per Annexure I enclosed
2.	Grant of licence for additional products Generic Drugs (maximum five products)/ cosmetics	As per Annexure II enclosed
3.	Grant of licence for additional products Patent & Proprietary Drugs (maximum five products)	-- do --
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) 6) Additional information data
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

12.	Grant of licences for additional products under loan licence; patent & Proprietary drugs (maximum five products)	As per Annexure II enclosed
13.	Grant of Drugs Retail licences	As per Annexure IV
14.	Grant of Drugs Wholesale Licences	-- do --
15.	Grant of Homeopathic Drugs Licences	-- do --
16.	Grant of Narcotic Drugs & Psychotropic Substances Licences (Fresh Licence)	As per Annexure V enclosed
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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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: jyotijs27@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

1. Covering letter.
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 Machineries 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 AssuranceAlongwith the relevant documents viz, Educational 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.

19. Clearance from Drugs Controller General (India), in respect of New Drug as defined under Rule 122-E of the Drugs & Cosmetics Rules 1945.
20. Write up on Water Purification System.
21. Write up on Air Handling Unit System.

Annexure – II (Service No. - 2)

List of documents for grant of additional Products

- 1) Covering letter
- 2) Chllan 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 alongwith 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.
12. House tax paid receipt.
13. NOC from Municipality/Panchayat
14. Certified copy of Qualification Certificate of the Registered Pharmacist/Competent Person.
15. Certified copy of Registration Certificate of the Registered Pharmacist.
16. Experience Certificate of the Registered Pharmacist/Competent Person.
17. Appointment letter of the Registered Pharmacist/Competent Person.
18. Acceptance 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.
21. Request for option letter.
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.
11. Copy of certificate obtained under Coop Act - 1861/Multi Safe Coop Act – 2002 in case of Cooperatives.
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.

Director
Directorate of Food & Drugs Administration,
Bambolim – Goa

