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

- Food Business Operators
- Pharmaceutical Manufacturers
- Wholesale and retail drug dealers
- Citizens

Main Acts & Rules Enforced

- Drugs & Cosmetics Act, 1940 and Rules there under
- Drugs & Magic Remedies (Objectionable Advertisements) Act,1954
- Drugs Price Control Order,2013
- Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules1987
- Food Safety and Standard Act, 2006 and Rules/Regulations made thereunder
- Goa Public Health (Amendment) Act,2005
- Cigarettes and other Tobacco Products Act (COTPA)

Services Provided

Sr. No.	Name of the Service	Service Standard	Service Indicator	Units
1.	Grant of fresh drugs/cosmetics manufacturing licence with maximum ten products	30 days from the receipt of completed application.	Time	Days
2.	Grant of licence for additional Pharmacopoeial products (maximum five products)/ cosmetics	14 days	Time	Days
3.	Grant of licence for additional products Patent & Proprietary Drugs (maximum ten 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 Rules	21 days	Time	Days
9.	Grant of Test Licence	7 days	Time	Days
10.	Grant of fresh loan licences with ten products	30 days	Time	Days
11.	Grant of licences for additional products under loan licence; Pharmacopoeial drugs (maximum ten products)	14 days	Time	Days
12.	Grant of licences for additional products under loan licence; patent & Proprietary drugs (maximum ten 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	Hours
18.	Issue of Permit for Narcotics Drugs for terminal cancer patients	2 hrs.	Time	Hours
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	Within 60 days	Time	Days
21.	Food Licence not involving inspection premises	Within 30 days	Time	Days
22.	Registration Certificate for food premises not involving inspection	Within 7 days	Time	Days
23.	Registration Certificate for food premises involving inspection	Within 30 days	Time	Days
24.	Registration Certificate for Temporary Premises	Within 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 ten products	As per Annexure I enclosed
2.	Grant of licence for additional products Pharmacopoeial Drugs (maximum ten products)/ cosmetics	As per Annexure II enclosed
3.	Grant of licence for additional productsPatent & Proprietary Drugs (maximum fiveproducts)	-- 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 Rules	1) Covering letter 2) E-Challan for the fees paid 3) Copy of the proposed plan layouts in duplicate 4) Write up on the facility 5) List of changes 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 Form30 4) Drug profile for the products applied. 5) Date of clearance of drugs by DCG(I) or its availability in any Official Pharmacopeia; or permission from DCG (I) under new Drugs & Clinical Trial Rules 6) Additional information data
10.	Grant of fresh loan licences with ten products	As per Annexure – III Enclosed
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 Retails 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	-- do --
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) NOC/Trade licence from Panchayat/ Municipality (As applicable) 4) Stall Allotment letter from the organizer

Complaint Handling Mechanism (CHM)

Where to lodge a complaint	• In person or post at the DFDA, Bambolim or Sub Office, Margao • Tel: 0832-2459226/30 ; 0832-2703766 • Email: off-dfda.goa@nic.in and south-dfda@goa.gov.in • Every Tuesday from 10.00 to 13.00 hrs Director and PGO will be available to receive and hear the public grievances. • Food Safety connect App. available on google play store
Acknowledgement of complaints	• Complaints received in person be acknowledged instantly • Complaints received through email will be acknowledged within 24hrs. • Complaints received through post will be acknowledged within 5days • Public Grievance Portal • Suo moto cognizance is taken via newspapers and social media platforms.
Time for resolution of complaint	• Within 30-60 days from the date of receipt of complaint. • Complaints on Food Safety Connect App. are attended within 30 days
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)	**Director, Food and Drugs Administration** Tel: 0832-2459226/30 Email: off-dfda.goa@nic.in PGO:- **Shri Venkatesh Sinari** Assistant Drugs controller 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 non-judiciary stamp of Rs. 2/-
   (i) For Non Biological Products*:-
   Form 24/24A/24B/24C/24D/24E/24F – as applicable.
   (ii) For Biological Products*:-
   Form 27/27A/27B/27D/27DA – as applicable.
   * (Strike whichever is not Applicable)
3. Site Master File.

4. E-Challan in original, indicating the licence fees paid.

5. Two Copies of the plan drawn to scale w.r.t. Manufacturing area (Section wise), Quality Control (Section wise), 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 (Section wise) – as applicable.

7. List of Instruments/Equipment's in Quality Control (Section wise) – as applicable.
   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 (Section wise).
   (ii) Quality Control (Section wise).
   (iii) Quality Assurance.
   Alongwith 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 – If applicable
10. Constitution details of the firm such as proprietorship details/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 Proprietor/Partner/Director.

12. Self attested copy of

    (i) Memorandum & Article of Association of Limited; if Private Limited Company/Limited Company.
    (ii) Self attested copy of Partnership Deed; if Partnership Firm.

(iii) Sole Proprietorship declaration in case of Proprietorship Firm.

13. Letter from Industrial Development Corporation for allotment of Plot – if in Industrial Estate.

14. Document towards the title of the premises such as Ownership, Rental Lease Deed.

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 product applied. (Specimen enclosed)

17. **Draft Text** of the Carton/Foil/Label of each of the Product applied.

18. **Clearance from** Drugs Controller General (India) in respect of **New Drug** as defined in New Drug Clinical Trial Rules 2019.

19. Write up on Water Purification System.

20. Write up on Air Handling Unit System.

21. Details a per Annexure II attached (Sr. No. 6 to 12)

Annexure – II (Service No. - 2)

List of documents for grant of additional Products

1) Covering letter
2) e-Challan for fees paid
3) Additional Information data(Specimen enclosed)
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 Permission from CDSCO as per New Drugs and Clinical Trials Rules 2019
9) BA/BE study data in case of class II and class IV BCS class drugs
10) Stability data long term and Accelerated data for minimum six months.
11) Export NOC in case of new drugs/unapproved drugs/banned drugs for export purpose only.
12) Copy of the official monograph in case of Pharmacopoeial drug.

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 as per the format (Annexure VII) enclosed
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) Documentaryevidencethattheproductappliedforisnotanewdrugorpremises/permissionfrom DCG(I)
14) List of excipients
15) List of approved Technical Staff of the loanee firm for manufacturing and testing.
16) Copy of wholesale licence held at Goa
17) Consent letter from loanee firm to manufacture the drugs for applicant
18) BA/BE study data
19) Stability data

Annexure – IV (Service No. 13, 14, 15)

Documents to be submitted alongwith the application for grant of Retail/Wholesale Licence.

1. Covering letter
2. Application in respective **Form- 19, 19B,19C**dully filled and signed.
3. Additional information data form dully filled and signed.
4. Re 1/- Court fee stamp to be fixed on each application.
5. Self-declaration form regarding sale of drugs in presence of whole time Registered Pharmacist/Competent Person only.
6. Undertaking form duly filled & signed by the RP.
7. e - Challan receipt for **Rs. 3000**/-, alongwith the details mentioned on the list attached, **(additional fees Rs. 250/- for homoeopathic licence and Rs. 500/- for schedule X licence if requested)**

Head of Accounts:::: Demand No.53
0210 Medical and Public Health, 04 Public Health, 104 Fees and Fines, 01 Fines.
For payment of fees follow URL https://egov.goa.nic.in/echallanpg/mainpage.aspx

8. Blue print plan of the premises drawn to scale.
9. Site plan of the premises on a blue print.
10. Certified copy of Lease Deed
11. Ownership documents (**if owned**).
12. Certified copy of Partnership Deed (**if in partnership firm**)
13. Description of the premises, with area and height of the premises and other details.
14. Occupancy Certificate (attested)**(only incase of new construction)**
15. House tax paid receipt.(attested)
16. NOC from the Municipality/Panchayat.(attested)
17. Certified copy of Qualification certificates of Registered Pharmacist/Competent Person,
18. Certified copy of Registration Certificate of the Registered Pharmacist issued by GSPC
19. Experience certificates of the Registered Pharmacist/Competent Person.
20. Resignation/Relieving letter of the Registered Pharmacist/Competent Person from the previous employer
21. Appointment letter issued to the Registered Pharmacist/Competent Person
22. Acceptance letter by the Registered Pharmacist/Competent Person.
23. Bio-data of the applicant mentioning the details of DOB, experience and details of Occupation for previous five years.
24. Request for option letter (incase of retail sale)
25. Certified copy of power of attorney of applicant **if applicable**.
26. Copy of Invoice of refrigerator &digital display thermometer
27. ID card copy of Proprietor/Partners/Directors/Registered Pharmacists/competent persons **(PAN CARD, ADHAR CARD (RP, CP),**
28. AADHAR CARD COPY OF **RP/CP**

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, 22, 23)

A) Documents for issue of Registration Certificate:-

1) Photo of Applicant
2) Government issued Photo ID such as Aadhar Card, Pan Card, Voter ID etc. (any of the above document)
3) Proof of Address of Business Activity (if address is other than as mentioned in Photo ID Card)

*except for slaughter houses and meat processing unit, NOC from local body will be the additional document as mandated under the Act.

B) For Grant of License:-

a) General Documents

1) Latest passport size photograph of the Applicant
2) Identification proof like Voter ID Card, Aadhar Card (any of the above document)
3) Proof of possession of premise such as ownership document/license agreement/electricity bills etc. (any of the above document)
4) Partnership deed/self-declaration of proprietorship/Memorandum and articles of association etc.; as applicable, in case of company Form IX : Nomination of person as per clause 2.5.1 of FSS Rules, 2008 (nomination not applicable in case of proprietor)

b) List of additional specific documents related to specific type of food business activity.

Food Services such as Hotels/Restaurants, Food Vending Establishments, Club/Canteen or any other prepared food establishments	PWD Water bill. In case of other source ,Water potability test report
Transporters	1. List of Vehicle Registration Certificates
Manufacturer/Processor	1. Blueprint/layout plan of the processing unit showing the dimensions in meters/square meters and operation-wise area allocation and Production unit photographs 2. PWD water bill. Incase of other source of water potable report **(Not applicable if water is not being used as ingredient)**
Dairy Processing	Source or procurement plan for milk
eat Processing	Source of raw material NOC from Municipal Corporation/ Panchayat
Slaughter House	NOC from Municipal Corporation/Panchayat
Relabellers and Repackers	NOC from Manufacturers Repackers shall upload NOC from Manufacturers as a separate documents in Other Document Section.

Nutraceuticals	Product Specification (ingredients as per applicable Schedule) of each product mentioning the purity criteria adopted for ingredients of Nutraceutical and health supplement products as per the prescribed format
Packaged Drinking Water	BIS Certificate

STRUCTURAL ORGANIZATIONAL CHART OF THE DIRECTORATE OF FOOD AND DRUGS ADMINISTRATION