Citizen's Charter

DirectorateofFoodandDrugsAdministration(FDA)

Government ofGoa

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Bambolim – 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 thepublic.
- To continue with the time tested tradition of sustaining Goa Food and Drugs Administration as one of the best FDA in theCountry.
- To pool into all sincere efforts to place FDA – Goa on the global map as one of the best regulatoryInstitution.

Values

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

Stakeholders Consulted

- Food BusinessOperators
- Pharmaceutical Manufacturers
- Wholesale and retail drugdealers
- Citizens

Main Acts & Rules Enforced

- Drugs & Cosmetics Act, 1940 and Rules1945
- 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/Regulations2011
- 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 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 licencegranted 4) Coveringletter
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 permissiongranted 4) Coveringletter
7.	Grant of Production & Sales Verification Certificate	1) Challan for the fees paid 2)Draft of Certificate 3) Productiondetails 4) List of equipment/ facilityprovided 5) Coveringletter
8.	Plan Approval of Manufacturing Facilities as per schedule M of Drugs and Cosmetics Rules	1) Coveringletter 2) Copy of the proposed plan layouts in duplicate 3) Write up on thefacility 4) List of charges proposed to be carried outin case of Revision of earlier approvedplan.
9.	Grant of Test Licence	1) Coveringletter 2) Challan for feespaid 3) Application in Form30 4) Drug profile for the productsapplied. 5) Date of clearance of drugs byDCG(I) 6) Additional informationdata
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 Retails Licences under the Drugs & Cosmetics Act and Rules)	1) Application in prescribedform 2) Coveringletter 3) Challan for feespaid. 4)Copy of regular Retail or wholesalelicence 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 FormA 2) Photo ID of theapplicant 3) 4Photographs 4) NOC/Trade licence from Panchayat/ Municipality 5) HealthNOC 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 willbe acknowledged instantly (with inwardno.) • Complaints received through email will be acknowledged within 24hrs. • Complaints received through post will be acknowledged within 5days • Public Grievance Portal
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; forreview;
Time for resolution complaint after escalation	Within 15 days from the date of escalation
Contact Details of Director and Public Grievances Officer (PGO)	PGO:- Smt. Shweta Dessai Designation: Deputy Director, DFDA Tel: 0832-2459226/30 Email:shweta.dessai@rediffmail.com 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. Coveringletter.
2. Application Form with nonjudicial stamp ofRs.2/-
   (i) For Non Biological Products*:-
   Form 24/24A/24B/24C/24D/24E/24F
   (ii) For BiologicalProducts*:-
   Form 27/27A/27B/27D
   (* Strike whichever is not Applicable)
3. Site MasterFile
4. Challan in original, indicating the licence feespaid.
5. Twocopiesoftheplandrawntoscalew.r.t.Manufacturingarea,Sectionwise),QualityControl (Sectionwise), Raw material store (including Thermolabile Raw Materials), Finished Product Store, Packing Material Store, Service areaetc.
6. List of Machinaries installed with make and Production capacity(Sectionwise).
7. List of Instruments/Equipments in Quality Control. (Sectionwise)Viz.
   (i) Instrumental & ChemicalAnalysis.
   (ii) MicrobiologicalAnalysis.
   (iii) Bacterial EndotoxinTest.
   (iv) ToxicityTest.
8. Names of the Competent Technical Staffin
   (i) Manufacturing,(Sectionwise).
   (ii) Quality Control,(Sectionwise).
   (iii) QualityAssurance
   Alongwith the relevant documents viz, Eductional Qualifications, Experience, approval, appointment letter and acceptance letter of the candidate etc.
9. N.O.C. from Pollution ControlBoard
10. ListofDirectors/Partnersofthefirmwithcompleteresidentialaddressasonthedateof application.
11. Power of Attorney in case applicant is other than thePartner/Director.
12. Certified copyof
    (i) Memorandum & Article of Association of Limited, Private Limitedcompany.
    (ii) Certified copy of PartnershipDeed.
13. Letter from Industrial Development Corpn. For allotment ofPlot.
14. Copy of the documents indicating ownership, rental, lease title of theplot.
15. ListofproductsintendedtobemanufacturedinTriplicatesectionwiseon theletterheadofthe firm.
16. Additional Information data form for each Productsapplied.
17. Draft Text of the Carton/Foil/Label of each of the productapplied.
18. Label text of the identical product available in themarket.

19. ClearancefromDrugsControllerGeneral(India),inrespectofNewDrugasdefinedunderRule 122-E of the Drugs & Cosmetics Rules1945.
20. Write up on Water PurificationSystem.
21. Write up on Air Handling UnitSystem.

Annexure – II (Service No. - 2)

List of documents for grant of additional Products

1) Coveringletter

2) Challan for feespaid

3) Additional Informationdata

4) List ofproducts

5) Draft of labeltext

6) Analytical specifications and method of analysis for API &FP

7) List ofexcipients

8) Documentary evidence for being not a new Drug or NOC fromDCGCI

Annexure – III (Service No. – 10)

Grant of fresh loan licence for drugs manufacturing

1) Coveringletter
2) Challan for feespaid
3) ApplicationForm
4) List of products for which licence isrequired
5) Additional informationdata
6) Constitution of the firm and relateddocuments
7) Certified copy of Power of Attorney (POA) in case the applicant is POAholder
8) Copy of request letter from the applicant firm to the loaneefirm
9) Consent letter from the loaneefirm
10) Undertakingregardingmaintainingofseparatestock registerandproperrecordsofdrugs manufacture by the loaneefirm.
11) Draft text of label of theproducts.
12) Analytical specifications and MOA of the API andFP
13) Documentaryevidencethattheproductappliedforisnotanewdrugorpremises/NOCfrom DCGCI
14) List ofexcipients
15) List of approved Technical Staff of the loanee firm for manufacturing andtesting.

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 documentssubmitted.
2. Application in respective Form (19,19-B).
3. Additional information data form duly filled andsigned.
4. Rs.1/- Court fee stamp to be fixed on eachapplication.
5. ChallanforRs.3000/-(Rs.250/-additionaltobepaidifhomoeopathiclicenceis also requested). Head ofAccounts
   0210 – Medical and Public Health,
   04 – Public Health, 104 – Fees and Fines,
   01 - Fines
6. Blue print plan of the premises drawn toscale.
7. Site plan of the premises on a blueprint.
8. Certified copy of Lease deed (if rented) Ownership documents (ifowned).
9. Certified copy of Partnership deed, (if partnershipfirm)
10. Description of thepremises.
11. Occupancycertificate.
12. House tax paidreceipt.
13. NOC from Municipality/Panchayat
14. Certified copy of Qualification Certificate of the Registered Pharmacist/CompetentPerson.
15. Certified copy of Registration Certificate of the RegisteredPharmacist.
16. Experience Certificate of the Registered Pharmacist/CompetentPerson.
17. Appointment letter of the Registered Pharmacist/CompetentPerson.
18. Acceptance letter of the Registered Pharmacist/CompetentPerson.
19. AffidavitregardingsaleofdrugsinpresenceofwholetimeRegisteredPharmacist/Competent Personony.
20. Biodataofthe applicantmentioningthedetailsofage,experienceanddetailsofoccupationfor previous fiveyears.
21. Request for optionletter.
22. Certified copy of power of attorney of applicant ifapplicable.

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 prescribedform

2) Copy of challan for feespaid

3) Constitution of thefirm.

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

5) CopyofqualificationandRegistrationCertificateasRMPoftheDoctorin-chargeoftheclinic;Nursing home,Hospital

6) Plan of thepremises

7) Power of Attorney (POA) of the person in case the applicant is POAholder.

Annexure – VI (Service No. 20, 21)

Grant of Food Licence

1. Form–B dulycompliedbytheproprietor/partnerorthe authorizedsignatoryalongwithone passport size photograph of Proprietor/ManagingPartner.
2. Blueprint/layoutplanoftheprocessingunitshowingthedimensioninmetres/squaremetres and operation – wise areaallocation.
3. List of Directors with full address and contactdetails.
4. NameandListofEquipmentsandMachineryalongwiththenumber,installedcapacityand horse powerused.
5. PhotoIDandaddressproofissuedbyGovernmentauthorityofProprietor/Partner/Director(s) Authorized Signatory (voter's card/ drivinglicense/passport).
6. List of food category desired to be manufactured. (In case ofManufacturers).
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 ofauthorized representative of Lab who collected the sample and date of collectingsample.
9. Proof of possession of premises. (Sale deed/Rent agreement/Electricity bill,etc.)
10. PartnershipDeed/Affidavit/Memorandum&ArticleofAssociationtowardstheconstitutionof thefirm.
11. CopyofcertificateobtainedunderCoopAct-1861/MultiSafeCoopAct–2002incaseof Cooperatives.
12. NOC from Manufacturer in case ofRe-labellers.
13. Food Safety Management System plan or certificate ifany.
14. Sourceofmilkorprocurementplanofmilkincludinglocationofmilkcollectioncentresetc.in case of Milk and Milk Products processingunit.
15. Source of raw material for meat and meat processingplants.
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 publichealthlaboratoryindicatingthenameofauthorizedrepresentativeofLabwhocollected the sample anddateofcollectingsample,includingsourceofrawwasteandtreatmentplan.
17. Recall plan wherever applicable with details on whom the product isdistributed.
18. NOCs from Municipality or local body and from State Pollution Control Board except in case of notified industrialarea.
19. NOC from HealthDepartment.
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. Coveringletter
2. Application in FormA
3. Plan of the Premises showing layout and areatherein
4. Attested true copy of lease deed/sale deed/Proof ofownership
5. MemorandumofArticlesofAssociationincaseofcompanyalongwiththelistofDirectorsand Addresses
6. AttestedtruecopyofPartnershipDeed: Incaseofpartnershipfirmalongwithlistofpartners andaddress
7. Attested true copy of Municipality/PanchayatNOC
8. AttestedcopyofPowerofAttorneyifgiven: toManageroranyotherpersonin-charge
9. AdditionaltwophotographsoftheProprietor/ManagingPartneroftheFirm/ManagingDirector of theCompany
10. No objection Certificate from the Directorate of Health Services in case of Hotels/Restaurant/Manufacture/re-packersetc.
11. Original Prevention of Food adulteration FoodLicense
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 theapplication.

STRUCTURAL ORGANIZATIONAL CHART OF THE DIRECTORATE OF FOOD AND DRUGS ADMINISTRATION, BAMBOLIM – GOA.