Service Name: Licence for Manufacturing Pharmaceutical Products (Own/Loan Drugs licence)

In India, Licence for Manufacturing Pharmaceutical Products is a permission granted by the respective State Drug Controller/Licensing Authority, allowing a company/firm to manufacture drugs. A loan license means allowing a company to manufacture drugs at a facility owned by another licensed manufacturer. In case of loan licence, the company does not have to own a manufacturing facility; instead, can utilize other existing plant to produce their formulations, provided the facility meets all the regulatory and quality compliance standards. Regulation governing manufacture of drugs are given in the Drugs and Cosmetics Act, 1940 and Rules framed by Government of India. A manufacturer must obtain the license (own/loan) for manufacturing Pharmaceutical Products in Goa. This license is issued by the Directorate of Food & Drug Administration (DFDA), under the provisions of the Drugs and Cosmetics act, 1940 and Rules thereunder.

Sr No	Particulars	Details
1.	**Competent Authority**	Department of Food & Drug Administration, Government of Goa
2.	**URL/s**	Goa-DFDA: https://dfda.goa.gov.in/ ONDLS: https://statedrugs.gov.in
3.	**Type of service**	Pre-Operations
4.	**Act / Rule**	THE DRUGS AND COSMETICS ACT, 1940 https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/ THE DRUG RULES 1945 https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Drugs-Rules/
5.	**Service mode:**	ONLINE MODE
6.	**Online mode notification**	Mandate dtd 25/10/2023 (Pls see the section below)
7.	**Timeline for approval**	30 days. Pls see the timeline section below.
8.	**Validity of approval**	Valid perpetually with retention of licence every 5 years by paying retention fee
9.	**Provision of Deemed Approval:**	Not Applicable
10.	**Auto Renewal**	Not Applicable
11.	**Auto Renewal – URL**	Not Applicable

Step by Step Procedure for approval with timeline

#	Action by User Type	Stages/Steps	Time taken for approval
1.	User / Investor	Once fresh application for manufacture of drugs is received in ONDLS portal the nodal officer allots the file to the Drugs Officers (Reviewing officer) online.	Not Applicable
2.	FDA Department	The hard copy of application inwarded by the applicant is forwarded by entry clerk to Accounts section of the Department for verification of amount paid through e-challan.	1 day
3.		The Accounts Section after verification of amount forwards the file to concerned dealing hand in Technical section.	2 days
4.		The dealing hand registers the application, generates the file number and puts up to the respective Drug Inspector/Reviewing officer.	2 days
5.		The Drugs Inspector scrutinises the documents submitted and scrutinises the product permission requested under the said licences; and puts comments in the noting and forwards the file to the next supervisory Officer that is either Assistant Drugs Controller (ADC) or the Dy. Director, (Dy. Dir) as the case may be.	3 days
6.		The ADC or the Dy. Director; reviews the comments / note submitted by the Drug Inspector and puts additional comments depending on his/her observations if any and forwards the scrutinised application to the Director; who is the Licensing Authority; with recommendation; depending upon the observation made such as: • The deficient documents to be called. • Certain clarifications required in the plan of premises submitted. • Certain clarifications required in the product permission sought. • Premises to be inspected jointly with CDSCO to verify whether the facilities provided comply to schedule M, MI, MII, MIII of the Drugs Rules.	
7.		Director peruses the recommendations and then agrees to the recommendation which is either; • Inspection of premise • To call for compliance of certain deficiencies in documents. Accordingly, the Drugs Inspector along with CDSCO official conducts the inspection of the premises for manufacturing premises and submit the report to the Director along with the recommendations received from CDSCO	20 days

#	Action by User Type	Stages/Steps	Time taken for approval
8.		Director peruses the report and then agrees to the recommendation which is either; • Grant the licence; or • To call for compliance of certain deficiencies. After compliance of the deficiencies, the Drugs Inspector verifies the compliance submitted and puts up the noting depending upon the observations made and puts up the file to the ADC/Dy. Dir with recommendation either for grant of licence or for verification of the compliance submitted by visiting the premises	
9.		Based on recommendation if the deficiencies are compiled LA agrees/rejects to grant the licences and if agreed licence is generated by the LA online. The e-signed licence is uploaded on ONDLS	2 days
10	ONDLS	System triggers and email and SMS to the user / investor for downloading the certificate.	Real time
11	User / Investor	User / Investor logs in to download the Certificate from ONDLS portal.	Not Applicable

Document Checklist

#	Document	Mandatory / non-mandatory
1.	Covering letter mentioning the complete details of documents submitted.	Mandatory
2.	Application Form with non -judiciary stamp of Rs. 2/- • For Non-Biological Products: Form 24/24A/24B/24C/24D/24E/24F as applicable • For Biological Products: Form 27/27A/27B/27D/27DA – as applicable.	Mandatory
3.	Site Master File	Mandatory
4.	Challan/E-Challan in original, indicating the licence fees paid.	Mandatory
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.	Mandatory
6.	List of Machineries installed with make and Production capacity (Section wise) – as applicable.	Mandatory
7.	List of Instruments/Equipment's in Quality Control (Section wise) – as applicable. (i) Instrumental & Chemical Analysis. (ii) Microbiological Analysis.	Mandatory

#	Document	Mandatory / non-mandatory
	(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. (iv) Along with the relevant documents viz. Educational Qualifications, (v) Experience, Approval, Appointment Letter and Acceptance Letter of the Candidate etc.	Mandatory
9.	N.O.C. from Pollution Control Board – If applicable	Mandatory
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.	Mandatory
11.	Power of Attorney in case Applicant is other than the Proprietor/Partner/Director.	Mandatory
12.	Certified copy of (i) Memorandum & Article of Association of Limited; if Private Limited Company/Limited Company. (ii) Certified copy of Partnership Deed; if Partnership Firm. (iii) Sole Proprietorship declaration in case of Proprietorship Firm.	Mandatory
13.	Letter from Industrial Development Corporation for allotment of Plot – if in Industrial Estate.	Non-Mandatory
14.	Document towards the title of the premises such as Ownership, Rental Lease Deed.	Mandatory
15.	List of products intended to be manufactured in Triplicate (Section wise) on the Letter Head of the Firm.	Mandatory
16.	Additional Information Data Form for each Products applied.	Mandatory
17.	Draft Text of the Carton/Foil/Label of each of the Product applied.	Non-Mandatory
18.	Clearance from Drugs Controller General (India) in respect of New Drug as defined in New Drug Clinical Trial Rules 2019 of the Drugs and Cosmetics Rules 1945.	Mandatory
19.	In case of loan licence wholesale licence is required.	Mandatory
20.	Consent letter from loanee firm to manufacture the drugs for applicant is required for loan licence application.	Mandatory

Fee Applicable

The payment of fee should be made online through the link given below:

https://egov.goa.nic.in/echallanpg/mainpage.aspx

The amount of Rs 7500/- (for 10 products) per licence must be paid to the Head of Accounts-Demand No.53. For retention of license. Fee of Rs 6000/-(for 10 products) for each licence and Rs 300/-for every additional product.

Timeline

The timeline for the service is given below:

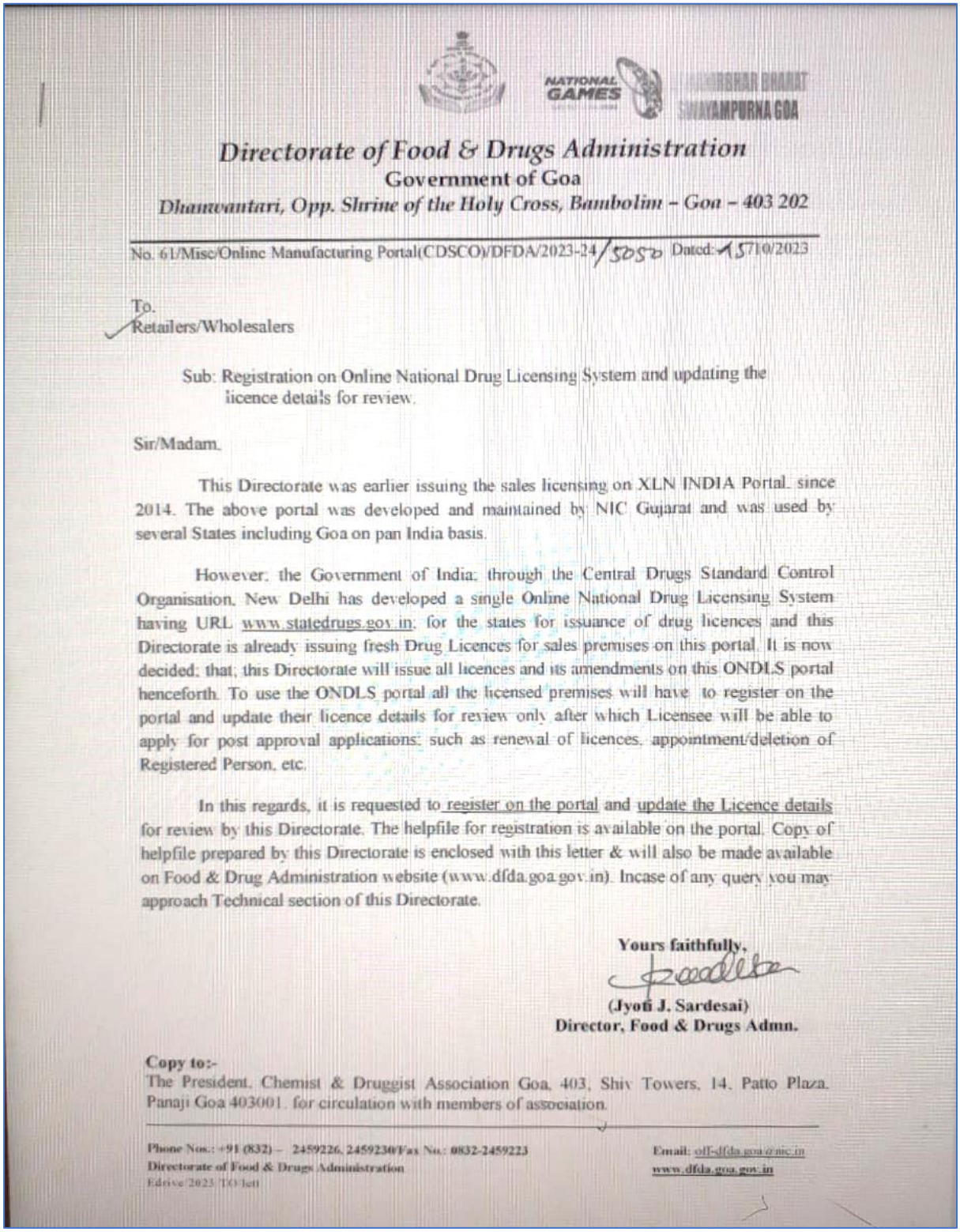
K- Directorate of Food and Drugs Administration				
71	Grant of Drugs Retail Licence	Dy. Director of Food and Drugs Administration	Thirty days	Director of Food and Drugs Administration.
[3][71 A	Grant of Drugs Wholesale License	Dy. Director of Food and Drugs Administration	30 days	Director of Food and Drugs Administration].
72	Grant of Goods Manufacturing Practices Certificate.	Dy. Director of Food and Drugs Administration	Seven days	Director of Food and Drugs Administration.
73	Grant of No Conviction Certificate	Dy. Director of Food and Drugs Administration	Seven days	Director of Food and Drugs Administration.
74	Grant of Free Sales Certificate	Dy. Director Food and Drugs Administration	Seven days	Director of Food and Drugs Administration.

2465

URL: Sr. II No. 31 Extraordinary No. 3 (LOW RESO) (goa.gov.in)

Service Mode:

The circular from Goa-DFDA mandating the same is given below:



Directorate of Food & Drug Administration
Government of Goa
Dhanwantari, Opp. Shrine of the Holy Cross, Bambolim – Goa – 403 202

No. 61/Misc/Online Manufacturing Portal(CDSCO)/DFDA/2023-24/5052 Dated: 15/10/2023

To,
Retailers/Wholesalers

Sub: Registration on Online National Drug Licensing System and updating the licence details for review.

Sir/Madam,

This Directorate was earlier issuing the sales licensing on XLN INDIA Portal since 2014. The above portal was developed and maintained by NIC Gujarat and was used by several States including Goa on pan India basis.

However, the Government of India, through the Central Drugs Standard Control Organisation, New Delhi has developed a single Online National Drug Licensing System having URL www.statedrugs.gov.in; for the states for issuance of drug licences and this Directorate is already issuing fresh Drug Licences for sales premises on this portal. It is now decided, that, this Directorate will issue all licences and its amendments on this ONDLS portal henceforth. To use the ONDLS portal all the licensed premises will have to register on the portal and update their licence details for review only after which Licensee will be able to apply for post approval applications, such as renewal of licences, appointment/deletion of Registered Person, etc.

In this regards, it is requested to register on the portal and update the Licence details for review by this Directorate. The helpfile for registration is available on the portal. Copy of helpfile prepared by this Directorate is enclosed with this letter & will also be made available on Food & Drug Administration website (www.dfda.goa.gov.in). Incase of any query you may approach Technical section of this Directorate.

Yours faithfully,

(Jyoti J. Sardesai)
Director, Food & Drugs Admn.

Copy to:-
The President, Chemist & Druggist Association Goa, 403, Shiv Towers, 14, Patto Plaza, Panaji Goa 403001, for circulation with members of association.

Phone Nos.: +91 (832) – 2459226, 2459230/Fax No.: 0832-2459223
Directorate of Food & Drugs Administration
Email: off-dfda.goa@nic.in
www.dfda.goa.gov.in

The circular issued by the Goa Investment Promotion and Facilitation Board (Goa-IPB) is given below:

GOA@60

GOA INVESTMENT PROMOTION AND FACILITATION BOARD (GOA-IPB)
1ST FLOOR, SPACES, EDC PATTO PLAZA, PANAJI, GOA – 403 001
Email: ceo-ipb.goa@gov.in / ipb.goa@gmail.com

No. 15/2019/Goa-IPB/EoDB/515 Dated: 25/01/2021

MEMORANDUM

In furtherance of the notification No.3/02/2015-IND/64 dated 25/01/2021issued by the Department of Industries, Government of Goa, the Goa Investment Promotion and Facilitation Board (Goa-IPB), State's implementation agency for Ease of Doing Business, hereby issues the following mandates as outlined below:-

1) Further to point 3 of the above mentioned notification, the online system for Public Consultation has been implemented in the State to ensure the following for all proposed regulations in the State:

i. Legal basis
ii. Necessity
iii. Business friendly policies
iv. The drafts of proposed acts, rules or regulations should be made available for a minimum period of 30 days

All departments of the State Government are to note the above four points while drafting and proposing any legislation, rules or regulations.

2) Furthermore, the online single window system and all online services should have the following features:

i. End-to-end online application and submission
ii. Online payment and document submission
iii. Online status tracking and department comments
iv. Online certificate issuance and download
v. Facility for online verification of certificates/ licenses/ permits by third parties

All Departments of the State Government and their IT vendors concerned should make sure that any service made online should have above mentioned features for the online systems used and developed by them.

Vandana Rao
(Vandana Rao, IAS) 25.01.21
Chief Executive Officer,
Goa Investment Promotion &
Facilitation Board

Page 1 of 2

URL: Notification_2.PDF (goaonline.gov.in)

Risk-based classification

Risk Classification is not applicable.

Additional Remarks: The procedural steps indicated above is uniform for all types of establishments, irrespective of risk category, size of firm, business location or type of investor (Foreign or Domestic).