STEPS FOR GRANT OF RETAIL/ WHOLESALE LICENSE BY APPLICANT.

APPLICANT APPLY FOR PASSWORD AND USER ID THROUGH ONLINE SYSTEM



AFTER RECEIPT OF PASSWORD AND USER ID, APPLICANT UPLOAD NECESSARY DOCUMENTS.



PAY PRESCRIBE FEES THROUGH GRAS SYSTEM (GOVERENMENT RECEIPT ACCOUNTING SYSTEM)



AFTER PAYMENT OF FEES, THROUGH GRAS SYSTEM, PRINT PAYMENT RECEIPT AND UPLOAD THE SAME IN SYSTEM.THEN E-SEND APPLICATION TO DEPARTMENT.



APPLICATION IS RECEIVED BY CONCERNED AREA LICENSING AUTHORITY AND ASSISTANT COMMISSIONER.



ALLOTMENT OF APPLICATION.

AFTER RECEIPT OF APPLICATION, LICENSING AUTHORITY
ALLOCATES IT, FOR INSPECTION TO THE DRUGS
INSPECTOR.



INSPECTION STAGE.
AFTER RECEIPT OF APPLICATION BY AREA INSPECTOR,
INSPECTS THE PREMISES AND FACILITY AND VERIFYS
THE DOCUMENTS.



VERIFICATION OF UPLOADED DOCUMENTS BY INSPECTORS



INSPECTOR MAKE ENTRIES RELATED TO INSPECTION REPORT



INSPECTOR WILL FORWARD REPORT TO LICENSING AUTHORITY WITH RECOMMENDATION



USER RECEIVES SMS REGARDING FORWARDING OF APPLICATION TO LICENSING AUTHORITY



LICENSING AUTHORITY WILL VERIFY ENTRIES, UPLOADED DOCUMENTS AND INSPECTION REPORT OF INSPECTOR.



LICENSING AUTHORITY WILL MAKE NECESSARY REMARKS REGARDING GRANT OR REJECTION OF APPLICATION.



DRAFT COPIES OF LICENSES VERIFIED BY LICENSING AUTHORITY BEFORE FINAL ORDER OF GRANT OR REJECTION OF APPLICATION.



FINAL ORDER OF GRANT OR REJECTION OF APPLICATION BY LICENSING AUTHORITY.



SYSTEM GENERATED SMS WILL FORWARD TO APPLIACNT



FINAL PRINT OUT OF LICENSES CAN TAKE OUT BY APPLICANT WITH IN THREE DAYS FROM THE GRANT OF LICENSES

Version 3



DRUG SALE LICENSE STANDARD DOCUMENTS AND APPLICATION GUIDELINES

Preface

Food and Drug Administration, Maharashtra State is presenting the guideline Manual for the easy understanding of processing of various applications through online system. Though the system is in service since 2011, from 25th January, 2016, it is made completely paperless. This effort is to bring transparency and uniformity in processing of various applications. The Manual is available in Marathi and English. All the stakeholders are requested to read it properly and follow the online paperless system.

Ensure before applying for Retail or Wholesale Drug store

Before applying ensure following requirements-

1) Area :-

- a) For Retail or Wholesale license- Premises of minimum 10 sq. meter carpet area legally possessed by the applicant, having separate & exclusive entrance.
- b) For Retail and Wholesale combined Premises of minimum 15 sq. meter carpet area legally possessed by the applicant, having separate & exclusive entrance.

2) Qualified Person:-

- a) For retail Medical Store- Services of Registered Pharmacist
- b) For Wholesale Services of Competent person (Who should be preferably graduate with more than one years experience in purchase and sale of drugs) or A Registered Pharmacist.

3) Storage facility:-

- a) A Refrigerator is mandatory for Retail License.
- b) For Wholesale it is as required for storage of drugs proposed to deal with.
- c) Cupboards, racks and others furniture required for storage of drugs.

4) Fees

- a) For Retail Chemist Shop Licenses in Form 20 & 21 (Allopathic) as well as License in Form 20C (Homeopathy) is issued. Therefore for Fresh or Renewal of retail license fee of Rs. 3250/- is required.
- b) For Wholesale Shop Licenses in Form 20B & 21B (Allopathic) is issued. Therefore for Fresh or Renewal of Wholesale license fee of Rs. 3000/- is required. For Wholesale License of Homeopathic drug License in Form 20D (Homeopathy) is issued. For Fresh or Renewal of Wholesale Homeopathic license fee of Rs. 250/- is required.
- c) For Retail Sale of Schedule X drugs License Form 20F is required. Fee of Rs. 600/- is applicable to this license. For Wholesale License to sale Schedule X drugs, license in Form 20G is required fee of Rs. 1200/- is applicable.

The prescribed application forms will be available, after filling complete information, through the system, under 'Print Form' option. Take a printout, sign it and upload along with application documents.

The above information is primary information to start. The list of documents required for various applications are also given in this booklet.

GENERAL INSTRUCTIONS

- 01. All the documents should be scanned in **150 dpi, grayscale/Black & White**, and then should be uploaded at relevant space provided.
- 02. Please show all the original documents to the inspector at the time of inspection.
- 03. Please be sure that, all the information is filled precisely for respective application mentioned under standard document and only then e-send the application. In case of rejection of your application for incomplete information, the fees once paid will be forfeited.
- 04. The licensing authority may ask for any other specific documents if required.
- 05. These guidelines are subject to change as and when required and will be updated from time to time.
- 06. Every application needs to be **'e-send'**, or it will not be forwarded to the office.
- 07. Except in case of death of proprietor, if there is change in proprietor, it will not be treated as **'change in constitution'**. Applicant will have to obtain a fresh license.
- 08. The license in Form 20F or 20G shall be applied separately. Never apply for these licenses with licenses in Form 20, 21, 20B, 21B.
- 09. These are only guidelines. The Provisions of **Drugs and Cosmetic Act 1940 and Rules 1945** shall prevail.
- 10. Please calculate the fee from the chart given in this Booklet.
- 11. In case of "Add / Remove Pharmacist" apply only one Pharmacist at a time. Never add more than one Pharmacist in single application.

FEES CHART

Fees applicable in the State of Maharashtra

			L	ic Fee	Late Fee	
Appl Form	Lic Form	Туре	Fresh	Renewal/ Retention	/month (Only up to 6 months)	Duplicate Copy fee
19			1500	1500	500	150
	21	Retail	1500	1500	500	150
	20B	Wholesale	1500	1500	500	150
	21B	Wholesale	1500	1500	500	150
19B	20C	Retail- Homeopathic	250	250	50	50
	20D	Wholesale- Homeopathic	250	250	50	50
19C	20F	Retail – Sch. 1 Drug	600	600	300	150
	20G	Wholesale - Sch. X Drug	1200	1200	600	150
19A	20A	Retail – Restricted	600	600	300	150
	21A	Retail – Restricted	600	600	300	150
19A*	20A	Retail – Restricted	300	300	150	30
	21A	Retail – Restricted	300	300	150	30
19AA	20BB	Vehicle	500	500	250	150
	21BB	Vehicle	500	500	250	150

^{*} In case of itinerant vendor or applicant who desires to establish a shop in town or village having population 10000 or less.

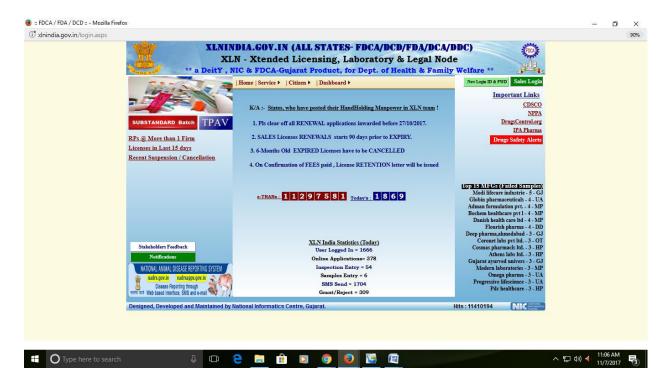
The fees for Change in Constitution, Change in Premises, Additional License, License Renewal are same as that of Fresh License. There is no fee for Change in Registered Pharmacist, Change in Competent person, Change in Name, Addition /Reduction in Premises, Change in Specific Condition and Surrender of License.

For No Conviction Certificate fees will be Rs. 1000/-

HOW TO GET USER ID & PASSWORD

should be allowed.

First open the website http://xlnindia.gov.in preferably in Google chrome / Mozilla firefox or internet explorer version 8 and above. Popup blocker



Click on "New login ID & PWD" button on the right hand side corner. Select 'MH' from drop down menu. Follow the Instructions.

You will see two Radio buttons.



First button is only for existing licensees. By clicking on this button fill the information precisely and save it. You will receive the user id and password within 24 hours by SMS on your registered mobile number.

For Fresh Licensee, click on the second radio button "Fresh License for New firm". Fill the information precisely, and save it. You will receive the user id & password on your registered mobile number within 24 hours.

Use the user id and password for all further processing. Change the password as and when required.

DOCUMENTS TO BE UPLOADED FOR VARIOUS APPLICATIONS

A) For Fresh Application of Retail/Wholesale license - FRE

1) Application Form No.19/19A/19B/19C as applicable

- a) Application in Form 19 is required for Retail license in Form 20, 21 and Wholesale license in Form 20B & 21B
- b) Application in Form 19B is required for Retail Homeopathic license in Form 20C and Wholesale Homeopathic license in Form 20D.
- c) Application in Form 19C is required for Retail license of Sch. 'X' Drugs in Form 20F and Wholesale license for Sch. 'X' drugs in Form 20G
- d) Application in Form 19A is required for Retail Restricted license in Form 20A, 21A (required only at the places where retail medical shop are not existing)

Note- These forms are statutory forms therefore they should be signed by all the partners

2) Firm's constitution documents

- a) If proprietorship firm upload photo ID
- b) Partnership upload scanned PDF of partnership deed and Registration receipt of fees paid to Registrar of firms.
- c) Pvt. Ltd./ Public Ltd./ LLP.-certificate of incorporation given by Registrar of companies
- d) Trust deed Trust Registration documents given by charity commissioner
- e) HUF HUF deed
- f) Society Society deed and registration certificate from relevant authority.
- g) Government Letter from Head of Department

3) <u>Details of proprietor/partner/ Director/Trustee etc.</u>

a) List of proprietor/partner/ Director/Trustee etc. in the following format

Sr.	Name	Edu.Quali	Designation	Pan	Res.	Phn.	Email	Joining
No.		fication		No.	Add.		ID	date
						Mob.		
						No.		

This format should be signed by responsible person and then it should be uploaded.

4) ID proof

a) Photo id (Adhar/Passport/ Driving License/ Election ID) of all the person mentioned in format given in point no. 3 above

5) Rent/Lease agreement

a) Rent/Lease agreement – This agreement should be duly **registered**. If the premise is rented for less than 5 years, there should be clause of extension with mutual consent. If the premises is given by relative then his consent should be submitted. If the agreement is having more than 5-6 pages then upload first 2, last 2 and 2 other relevant pages.

6) Premises ownership documents

a) The municipal tax receipt/malmatta extract/assessment extract/ sale deed or any other relevant documents issued by competent authority showing the ownership of the premises for which application is being made [if sale deed is big- scan only first 2-3 and last 2-3 pages and upload]

7) <u>NOC</u>

If applicant applies for license in the residential premises situated in a co-operative society- NOC from society, residential premises leased by CIDCO, MHADA or similar Govt./ Semi Govt. Agencies-NOC from that authority.

8) Electricity bill of premises

Latest electricity bill

9) Plan lay out

a) Plan layout- upload scanned copy of premises. It should be drawn on A-4 size paper, mentioning dimensions in meters and

carpet area in sq.mt. showing complete address of premises and signature of authorized person.

- 10) <u>Cold storage proof (If applicable)</u> purchase proof of refrigerator/ cold room / deep fridge
- 11) For Retail License (Documents of Pharmacist)
 - 1) Appointment letter and acceptance letter of pharmacist & his residential proof
 - 2) Registration certificate
 - 3) Self declaration of Pharmacist.
- 12) For whole sale License (Documents of Competent Person)
 - 1) Appointment letter and acceptance letter of Competent Person & his residential proof
 - 2) Educational Qualification (preferably graduate)
 - 3) Experience certificate

B) Change in constitution - C.C.

- 1) Application Form No.19/19A/19B/19C as applicable
- 2) A letter stating the change in constitution
- 3) Firm's constitution documents (As given in A(2) above)
- 4) Details of Proprietor/Partner/Director/Trustee etc. (As given in A(3) & (4) above)
- 5) Revised Rental Lease agreement (if applicable) (As given in A(5) above)
 - a) If the earlier rent agreement is in the name of retiring person as firm, upload new registered rent agreement and premises ownership documents as explained above.
- 6) Premises ownership documents of additional premises. (As given in A(6) above)

C) Change in premises – C. PR.

- 1) Application Form No.19/19A/19B/19C as applicable
- 2) Premises ownership documents (As given in A(6) above)
- 3) Rent/Lease agreement (As given in A(5) above)
- 4) NOC (if applicable) (As given in A(7) above)
- 5) Electricity bill
- 6) Plan lay out (As given in A(9) above)

D) Additional License - Addl. Lic.

- 1) Application Form No.19/19A/19B/19C as applicable
- 2) Registered Pharmacist documents (if wholesaler is applying for retail license)

E) License Retention - RNW.

1) Online Application with copy of receipt of Licence retention fee paid.

F) Change in pharmacist - R.P.

- 1) Registration certificate
- 2) Self declaration duly signed by pharmacist and employer.

G) Change in competent person - C.P.

- 1) Appointment letter and acceptance letter of competent person
- 2) Residential proof Aadhar / Driving License / Voter ID / Pan Card
- 3) Educational qualification certificate (Preferably graduate)
- 4) Experience certificate

H) Change in Name - NAM

1) Document showing the change in name

I) Addition or Reduction in premises - AOP

- 1) Revised Rent/Lease agreement (As given in A(5) above)
- 2) Premises ownership documents (As given in A(6) above)
- 3) Revised plan layout. (As given in A(9) above)

J) Change in specific condition - CSC

- 1) Cold storage proof (As given in A(10) above)
- 2) 24 hrs open application- Only with 3 pharmacists and safety measures.

K) Surrender of License – SUR.

 Letter for surrender of license to be signed by proprietor /Partner / Legal Heir / Director / Authorized signatory. The original license should be submitted to the office by post/courier/personally

L) Duplicate License - DUP.

1) Plain paper application

M)Change in Director - DIR.

1) Form 32 of incoming Director.

N) No conviction certificate - NCC

- 1) Self declaration in the specified format.
- 2) Copy of tender (only relevant pages)

LOGIN PROCESS

You can login in the xlnindia.gov.in by using user id and password.



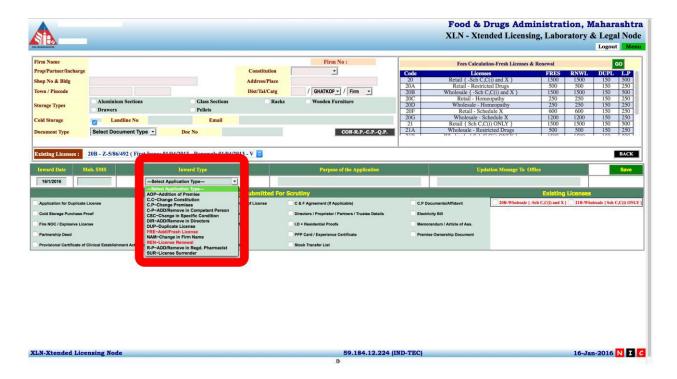
First click on 'prepare/edit online application' tab, situated at left hand corner.



You will see a 'New Inward' button. Click on this button.



Select suitable option from 'Inward Type'. Fill all the information in the screen and save it.



Here select the option for which you are applying. Please complete the data entry byclicking on following tab. Related updation, under taking/ check list, CON/RP/CP(Constitution/Registered Pharmacist/Competent Person). After saving all the data a newbutton will be available on right hand side for printing Form 19/19B/19C/19A. Aftertaking print out of relevant forms, sign the forms and keep scan copy ready. Here in the CON/RP/CP tab affidavit for pharmacist will appear, take print out and it should besigned by both the employer and employee. Keep the scan pdf ready.

Now upload all the documents required for the relevant application. Save it. Now, 'make payment' option will be visible. Click on it, you will be diverted to the 'GRAS' site.

HOW TO MAKE PAYMENT THROUGH 'GRAS' SYSTEM

1. Payment of fees - After every inward application wherever fees are applicable, 'makepayment' tab will appear after inward application is completed. Click on this option. Then new window will appear click on 'make a new payment' tab. It will redirect to 'Gras' site of Government of Maharashtra.

Then select as follows -

Department: Food & Drugs Administration

Payment Type: select menu e.g. Drugs sale License etc.

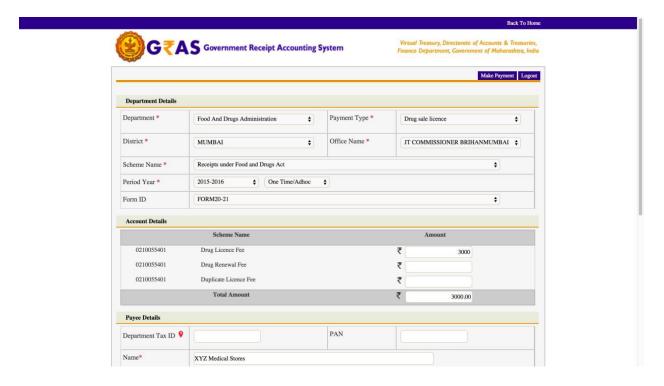
Scheme name: will come automatically

District: select district where license premises is existing

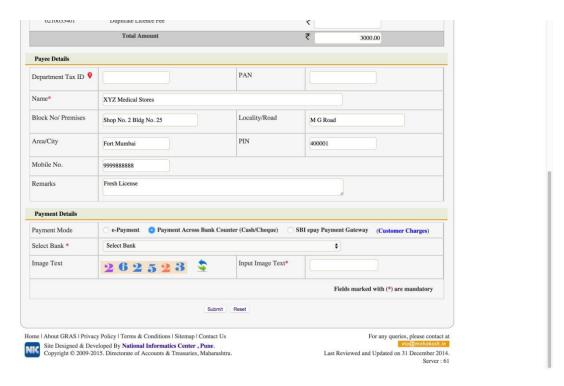
Office name: Select from drop down

Period (Year): current financial year and select - one time / adhoc payment.

Form ID: write license Form No.



Then select the payment option from three radio buttons – i) e-payment, ii) payment across the bank counter, iii) SBI payment gateway.



Fill all the details and take a printout of Challan. Use this Challan for your Inward Application.



Open website https://gras.mahakosh.gov.in or just type GRAS in Google, the site willbe opened.

Click on the 'pay without registration' tab (Those who are already registered on GRAS, can pay by using their user id and password)

2. All the payments must be paid through GRAS SYSTEM ONLY

After paying the fees through GRAS, please fill all the details in the following screen. The GRN number, amount paid should be very accurately filled otherwise the payment will not be certified.



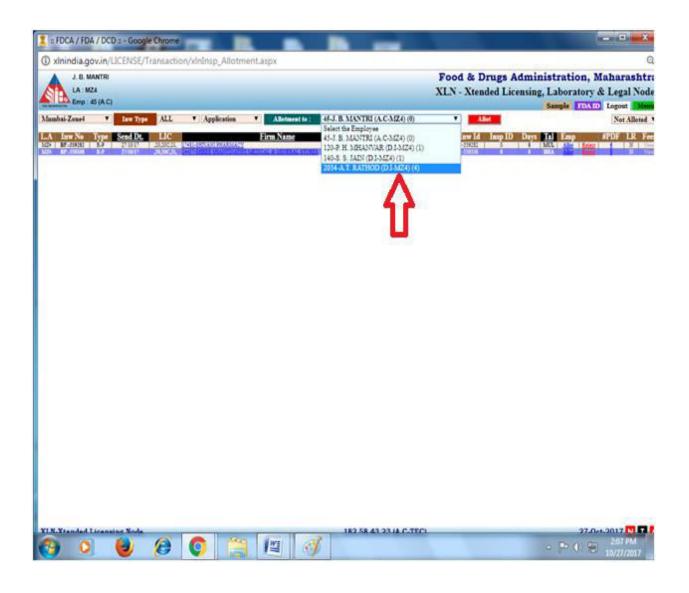
AFTER PAYMENT OF FEES, THROUGH GRAS SYSTEM, PRINT PAYMENT RECEIPT AND UPLOAD THE SAME IN SYSTEM.THEN E-SEND APPLICATION TO DEPARTMENT.

APPLICATION IS RECEIVED BY CONCERNED AREA LICENSING AUTHORITY AND ASSISTANT COMMISSIONER.

Note. Query is raised by inspector or / and Licensing Authority/ Assistant Commissioner in case of incomplete / inadequate information. Applicant receives the application back along with an SMS. Application should be resubmitted by taking corrective actions by the Applicant.

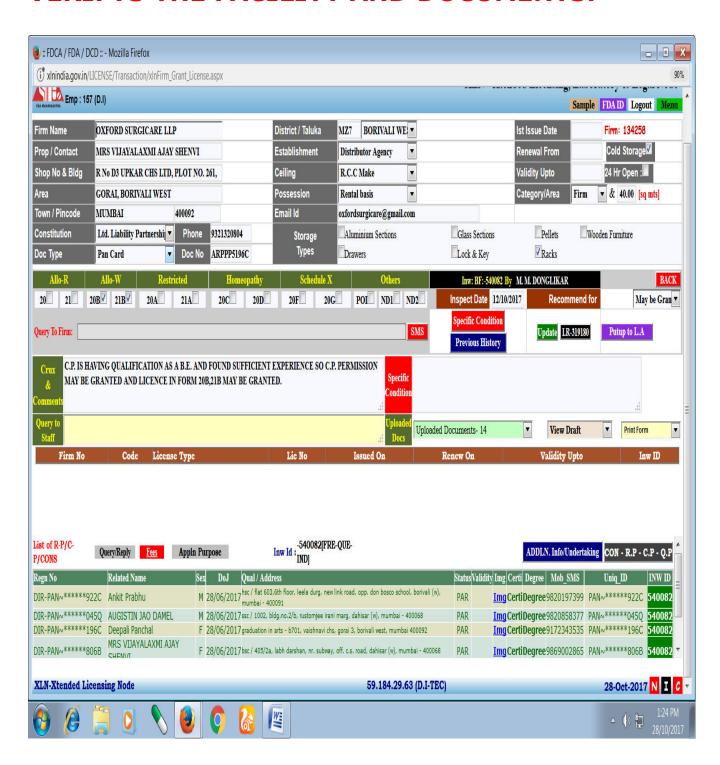
ALLOTMENT OF APPLICATION.

AFTER RECEIPT OF APPLICATION, LICENSING AUTHORITY ALLOCATES IT FOR INSPECTION TO THE DRUGS INSPECTOR.

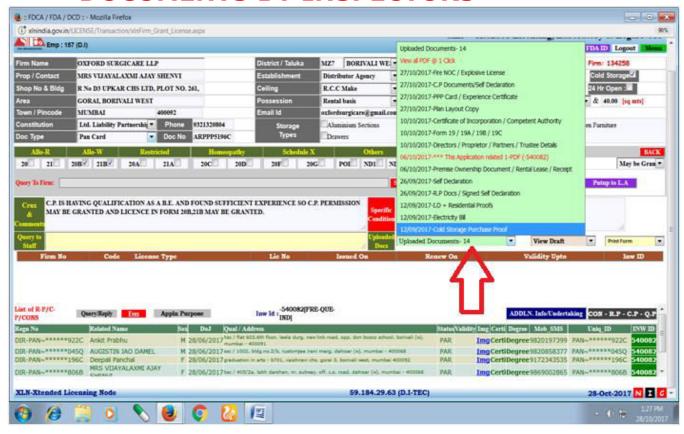


INSPECTION STAGE.

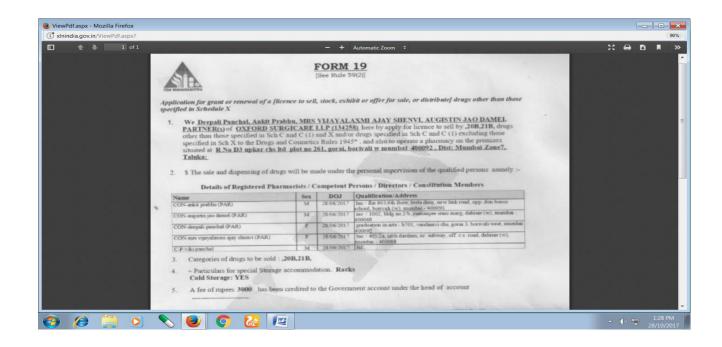
AFTER RECEIPT OF APPLICATION BY AREA INSPECTOR, INSPECTS THE PREMISES AND VERIFYS THE FACILITY AND DOCUMENTS.



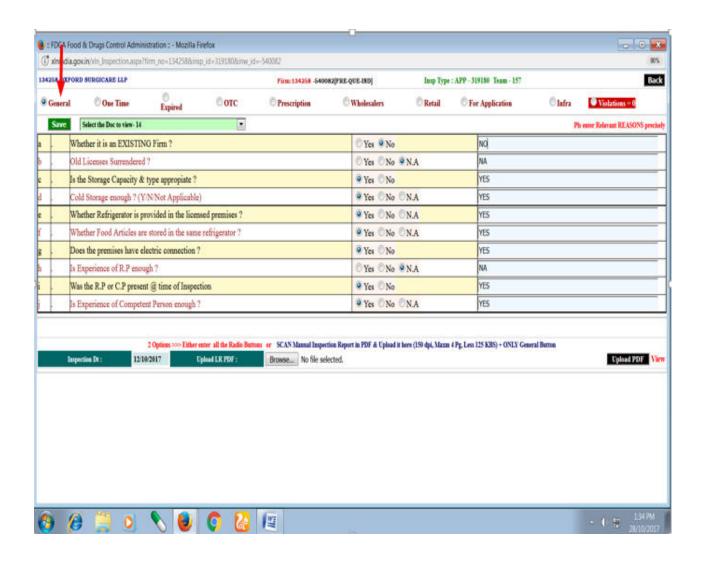
1. VERIFICATION OF UPLOADED DOCUMENTS BY INSPECTORS



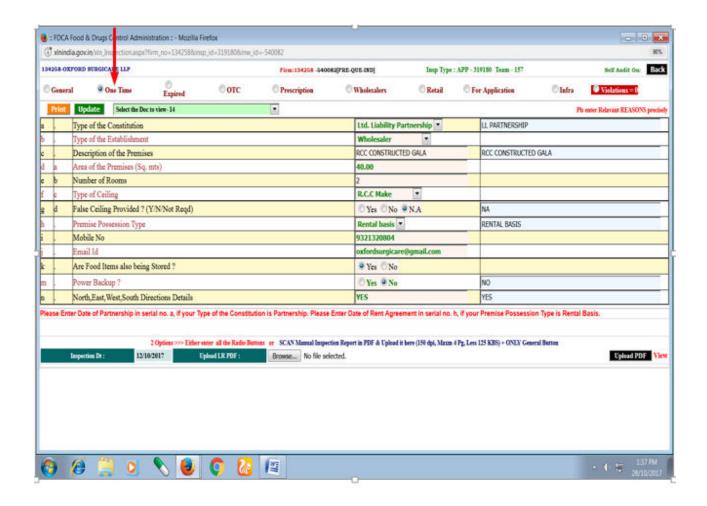
4. VIEW OF UPLOADED DOCUMENTS.



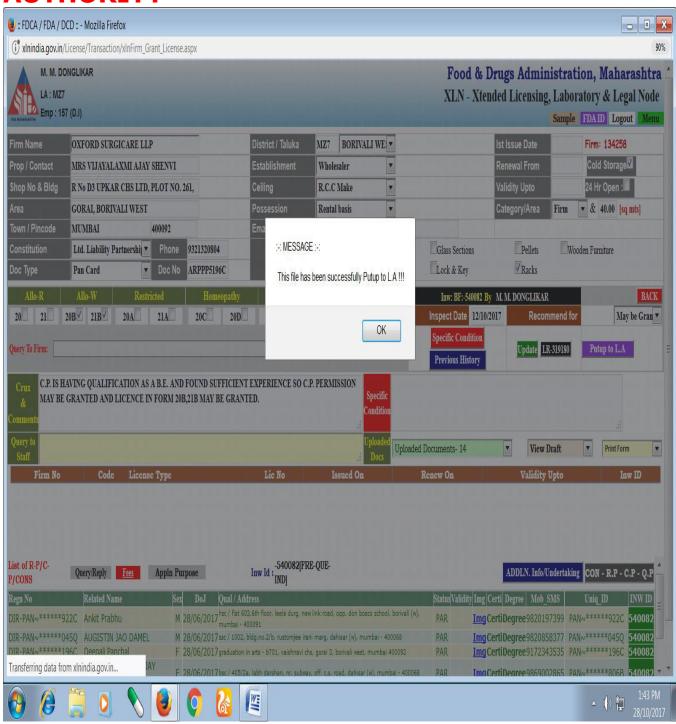
INSPECTION ENTRY DETAILS.



INSPECTION ENTRY

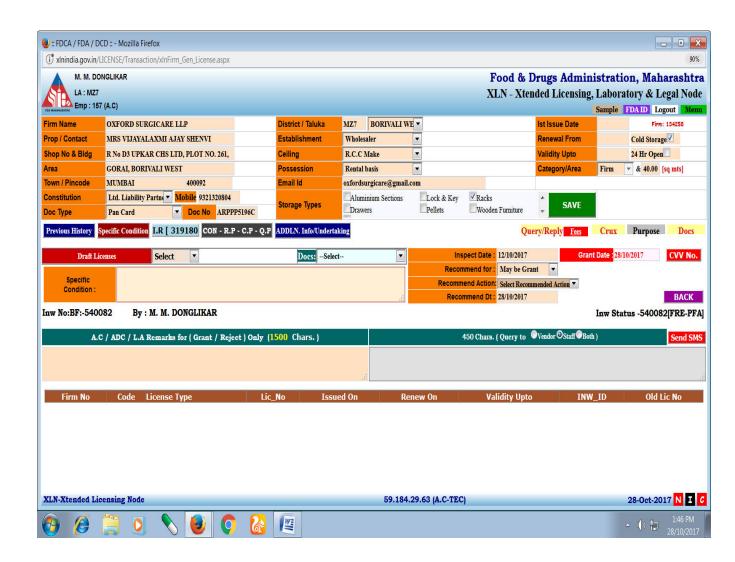


REPORT SUBMISSION TO LICENSING AUTHORITY

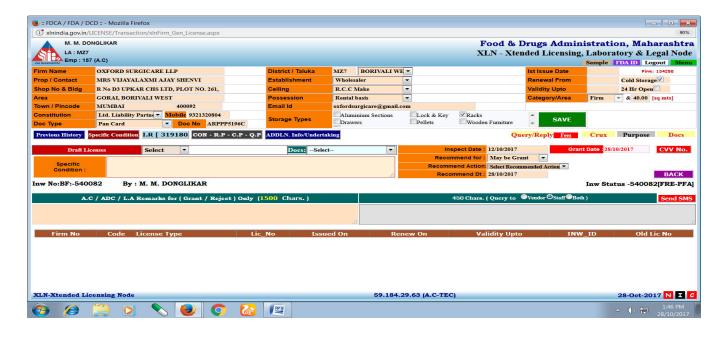


ACTION BY LICENSING AUTHORITY

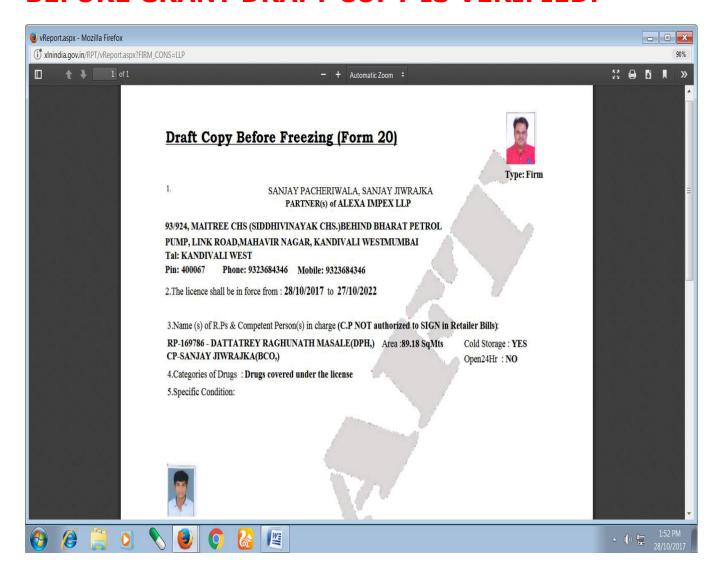
LICENSING AUTHORITY WILL VERIFY ENTRIES, UPLOADED DOCUMENTS AND INSPECTION REPORT OF INSPECTOR.



REMARKS OF LICENSING AUTHORITY.



BEFORE GRANT DRAFT COPY IS VERIFIED.



FOR GRANT OR REJECT OF APPLICATION.



PRINTING LICENSE/LETTERS/CERTIFICATES BY APPLICANT

After grant or rejection of your application, you will receive an SMS about the same. Take a print out of the approval/rejection from 'Print License' option for fresh license andrenewal and click 'MISC approvals' for other approvals within 5 days. You will receivelicenses/approvals with the valid esignature and official seal.



COVERING LETTER AND LICENSE WITH ADHAAR AUTHENTICATED eSIGNATURE OF LICENSING AUTHORITY HAVING THIRD PARTY APPROVAL VERIFICATION (TPAV) NUMBER.

