Test License to Manufacture Allopathic Drugs from Food Safety and Drug Administration Department

Procedure, List of Supporting Documents and Fees

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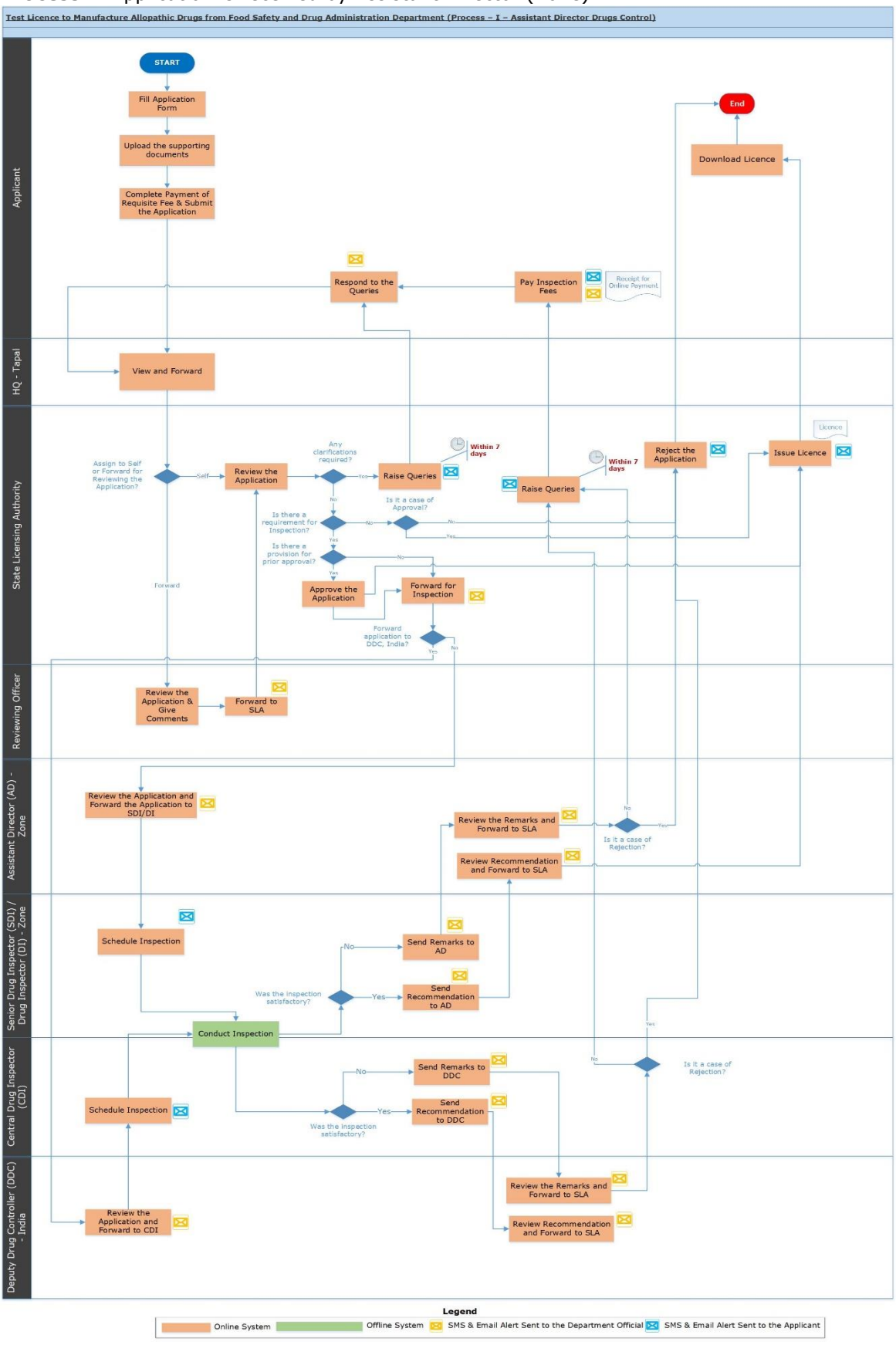
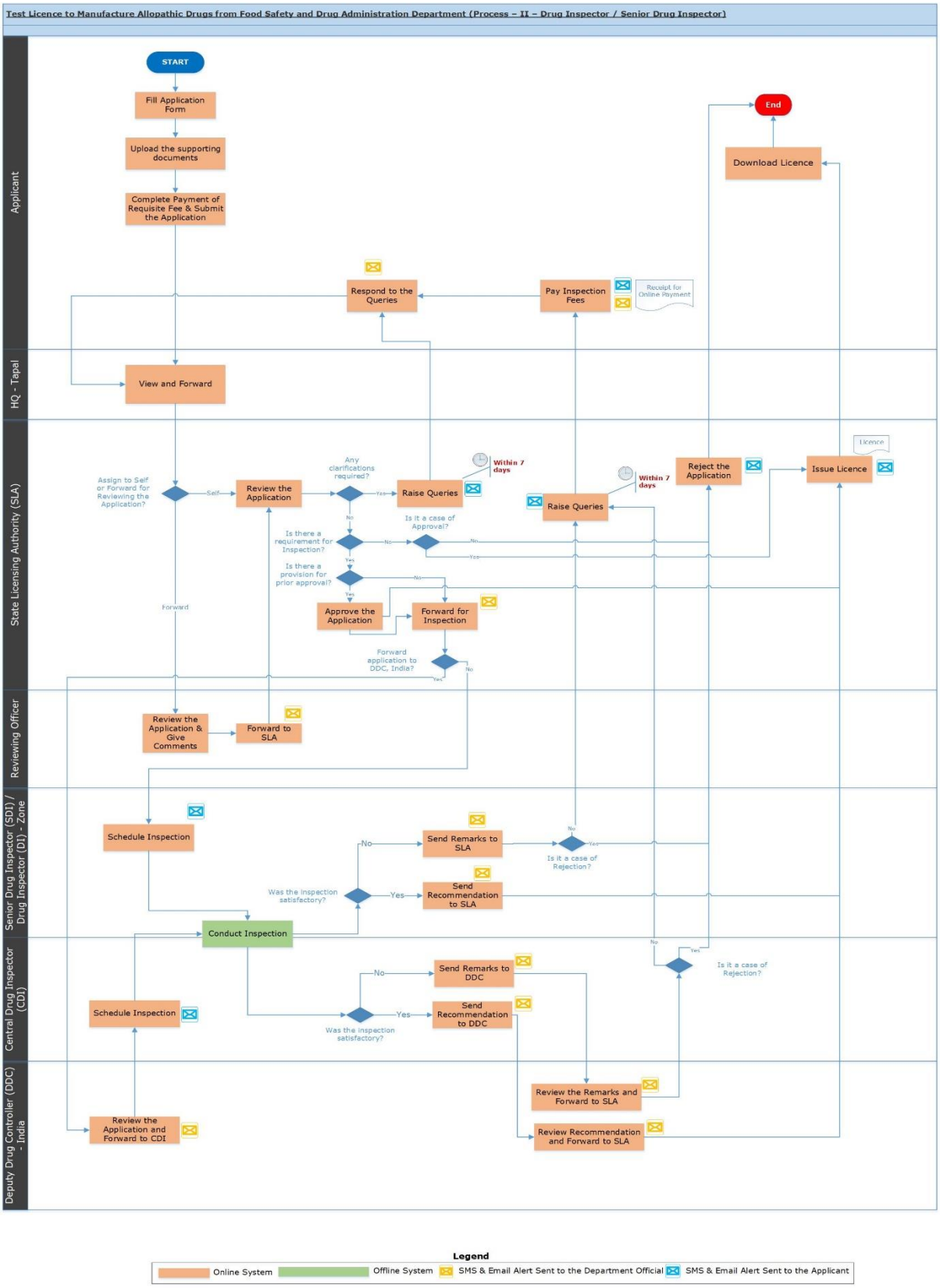
1 Procedure

Process I: Application is received by Assistant Director (Zone)



Process II - Application is received by Drug Inspector / Senior Drug Inspector (Head Office)



2 Checklist of Supporting Documents

S. No.	Document
For Existing Drug Manufacturing License Holders	
1.	Filled Form 30 as specified in the Drugs and Cosmetics Rules, 1945
2.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)
3.	Drug manufacturing licences Copy
4.	Previously issued Form 29 Copy, if any
5.	Copy of valid DSIR (Department of Scientific and industrial research) approval certificate (if any)
6.	Product dossier (for each product)
7.	Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items
For those who do not have a Drug Manufacturing License	
8.	Document relating to constitution of concerned firm/ Company/ LLP and others. **Proprietorship**: Declaration Form **Partnership Firm**: Partnership Deed **Limited Liability Partnership**: LLP deed, Registration Certificate of ROC Pvt. Ltd. / Ltd: Memorandum and articles of association, Registration Certificate of ROC, Copy of Board resolution **Trust**: Trust deed **Society**: Registration Certificate, By Laws, Copy of Resolution passed **Hindu Undivided Family**: HUF deed
9.	Biodata (with photograph) of the Applicant (s)
10.	Address / ID Proof of the Applicant (s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card.
11.	Biodata (with photograph) of the Technical Staff (s)
12.	Educational qualification certificate(s) of the Technical Staff (s) (Starting from Minimum Educational Qualification as specified in the Drugs and Cosmetics Rules, 1945)
13.	Experience Certificate of the Technical Staff (s)
14.	Digitally Signed Self-Certification by each Technical Staff stating that He / She is a fulltime employee of the Firm under consideration
15.	Address / ID Proof of the Technical Staff (s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card
16.	Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt)
17.	Rental agreement of the premises, if applicable
18.	Plan of the premises- with details of partitions, measurements - Section wise with location of machineries
19.	List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing

S. No.	Document
20.	List of analytical instruments and equipment for analysis
21.	Purchase invoices with the details like production capacity, make etc. if applicable

3 Fees

S. No.	Fee Type	Amount(INR)
1	Fees per Product	250

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