



# **License to Manufacture Allopathic Drugs for Sale or for Distribution of Drugs from Food Safety and Drug Administration Department**

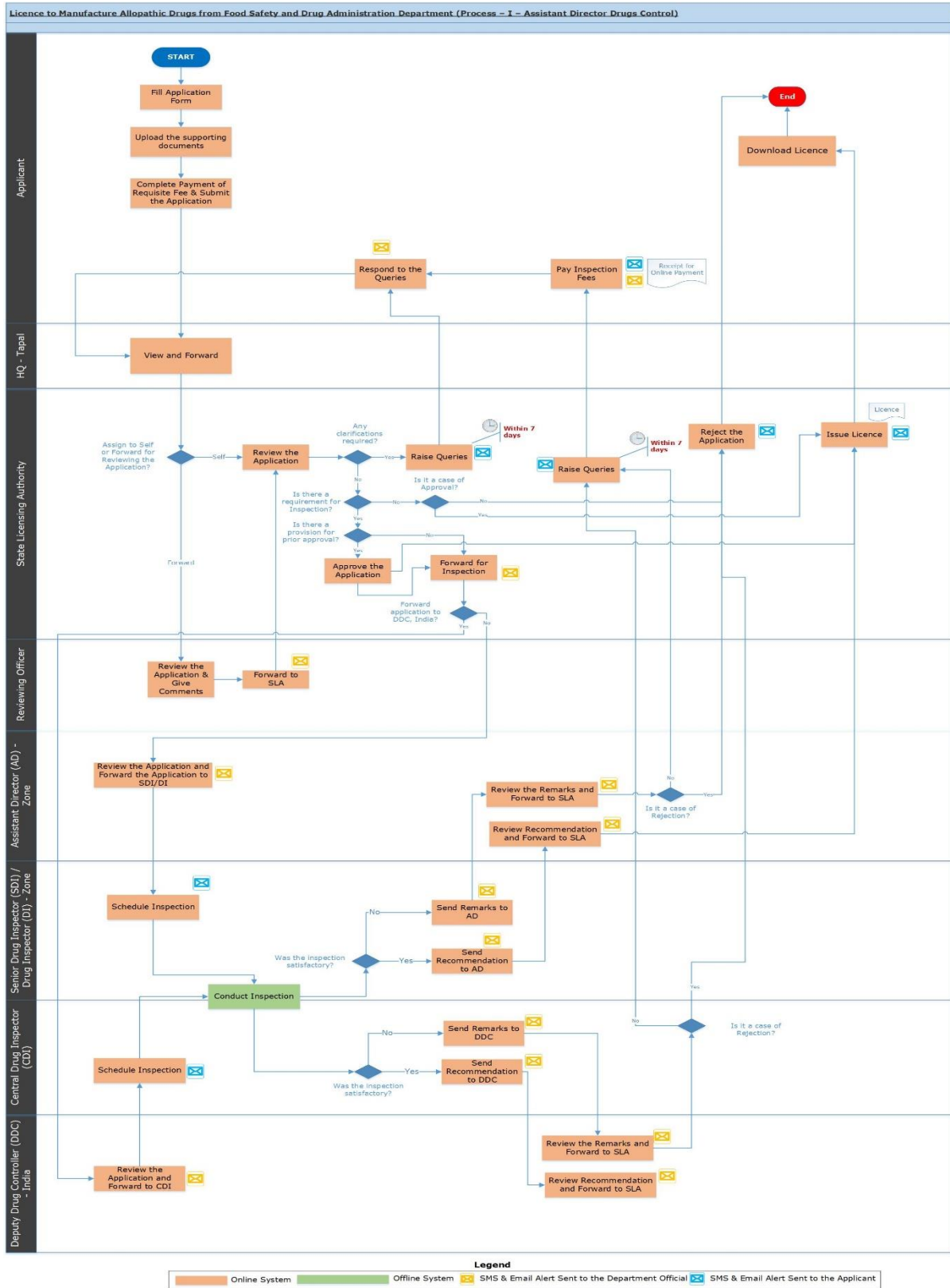
Procedure, List of Supporting Documents and Fees

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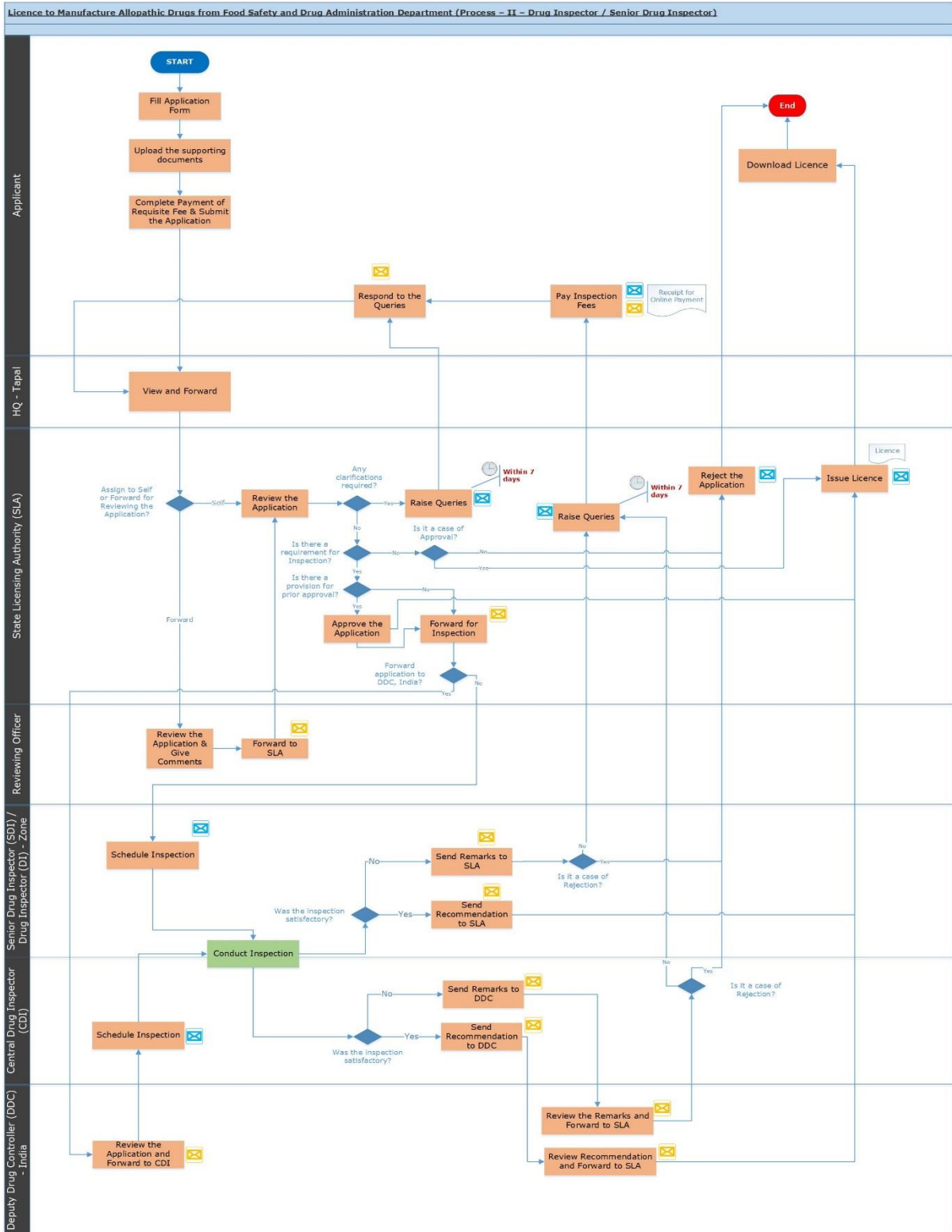
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# 1 Procedure

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



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



**Legend**

- Online System
- Offline System
- SMS & Email Alert Sent to the Department Official
- SMS & Email Alert Sent to the Applicant

## 2 Checklist of Supporting Documents

| S. No. | Document  |
|--------|---|
| 1.     | Filled Form 24 as specified in the Drugs and Cosmetics Rules, 1945  |
| 2.     | Filled Form 27 as specified in the Drugs and Cosmetics Rules, 1945  |
| 3.     | Filled Form 24F as specified in the Drugs and Cosmetics Rules, 1945   |
| 4.     | Filled Form 27B as specified in the Drugs and Cosmetics Rules, 1945   |
| 5.     | Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)  |
| 6.     | Drug manufacturing licences Copy, if any  |
| 7.     | Previously issued Form 29 Copy, if any  |
| 8.     | Document relating to constitution of concerned firm/ Company/ LLP and others.<br><b>Proprietorship:</b> Declaration Form<br><b>Partnership Firm:</b> Partnership Deed<br><b>Limited Liability Partnership:</b> LLP deed, Registration Certificate of ROC<br>Pvt. Ltd. / Ltd: Memorandum and articles of association, Registration Certificate of ROC, Copy of Board resolution<br><b>Trust:</b> Trust deed<br><b>Society:</b> Registration Certificate, By Laws, Copy of Resolution passed<br><b>Hindu Undivided Family:</b> 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   |
| 20.    | List of analytical instruments and equipment for analysis   |
| 21.    | Purchase invoices with the details like production capacity, make etc. if applicable  |

| <b>S. No.</b> | <b>Document</b>  |
|---------------|--|
| 22.           | Product dossier (for each product)   |
| 23.           | Form 51/Brand Name affidavit   |
| 24.           | Agreement with Marketer, if applicable   |
| 25.           | Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items |

### 3 Fees

| <b>S. No.</b> | <b>Fee Type</b>   | <b>License Fees (INR)</b> | <b>Inspection Fees (INR)</b> | <b>Total Fees per category</b> |
|---------------|---|---------------------------|------------------------------|--------------------------------|
| 1             | Form 24 (Drugs other than those specified in Schedule C, C (1) and X of the Drugs and Cosmetics Rules, 1945)              | 6,000                     | 1,500                        | 7,500                          |
| 2             | Form 27 (Schedule C and C (1) excluding those specified in part XB and Schedule X of the Drugs and Cosmetics Rules, 1945) | 6,000                     | 1,500                        | 7,500                          |
| 3             | Form 24F (Schedule X and not specified in Schedule C and C (1) of the Drugs and Cosmetics Rules, 1945)                    | 6,000                     | 1,500                        | 7,500                          |
| 4             | Form 27B (Specified in Schedules C, C (1) and X of the Drugs and Cosmetics Rules, 1945)                                   | 6,000                     | 1,500                        | 7,500                          |

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