



# **Additional Product Endorsement – Allopathic Drug Manufacturing Loan Licence from Food Safety and Drug Administration Department**

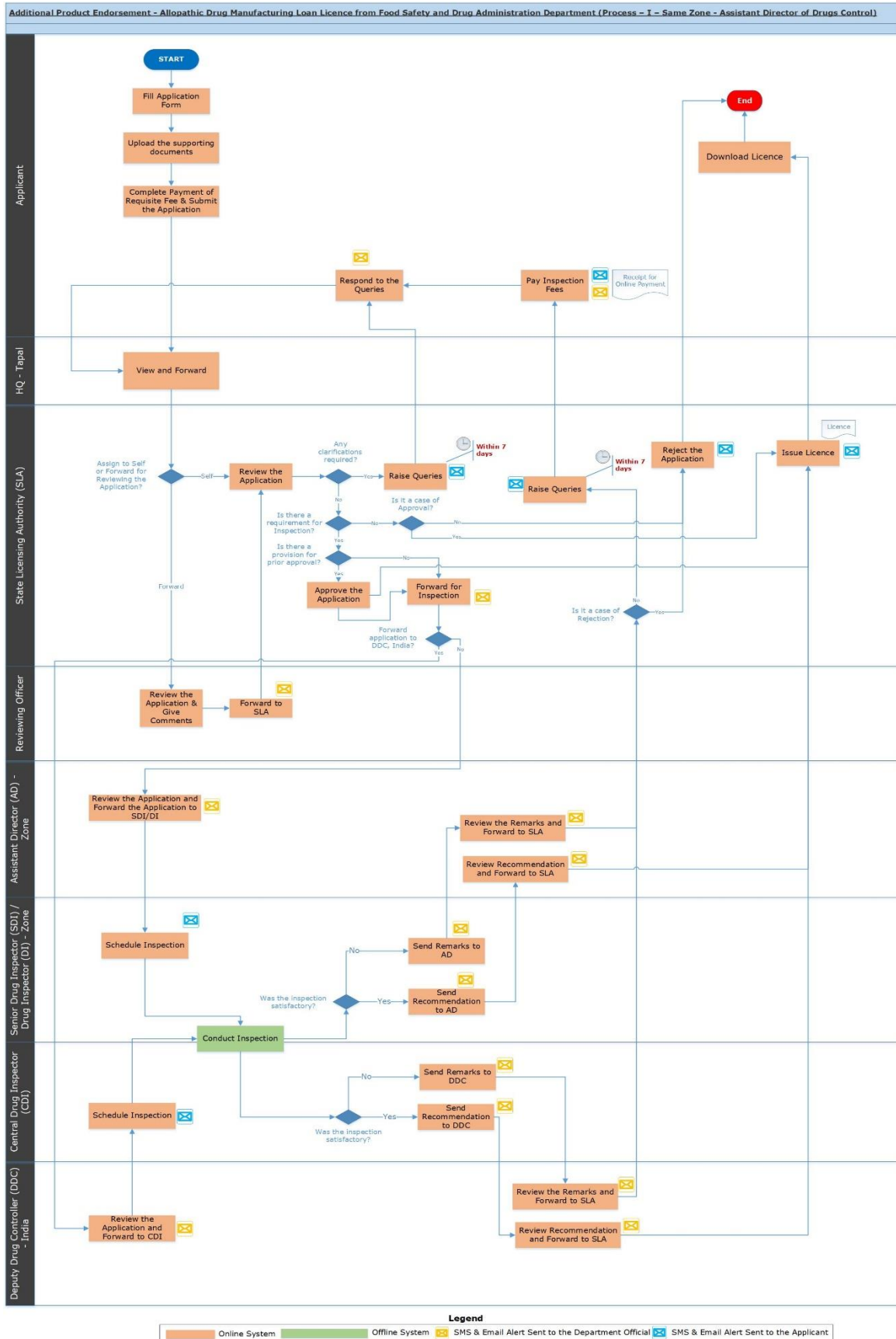
Procedure, List of Supporting Documents and Fees

## **Table of Contents**

1	Procedure.....	1
2	Checklist of supporting documents.....	4
3	Fees .....	4

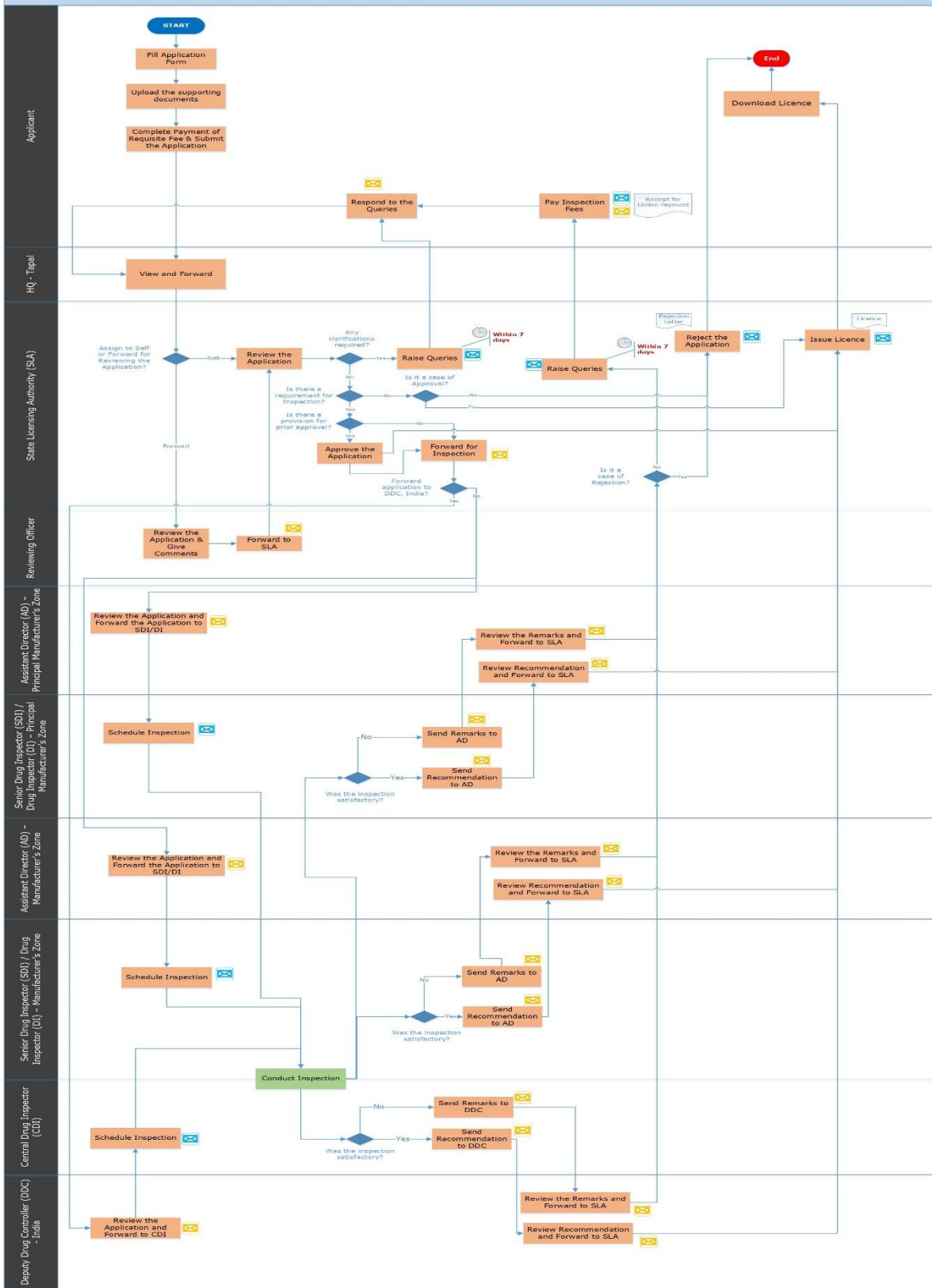
# 1 Procedure

## Process I: Application is received by Same Zone – Assistant Director Drugs Control

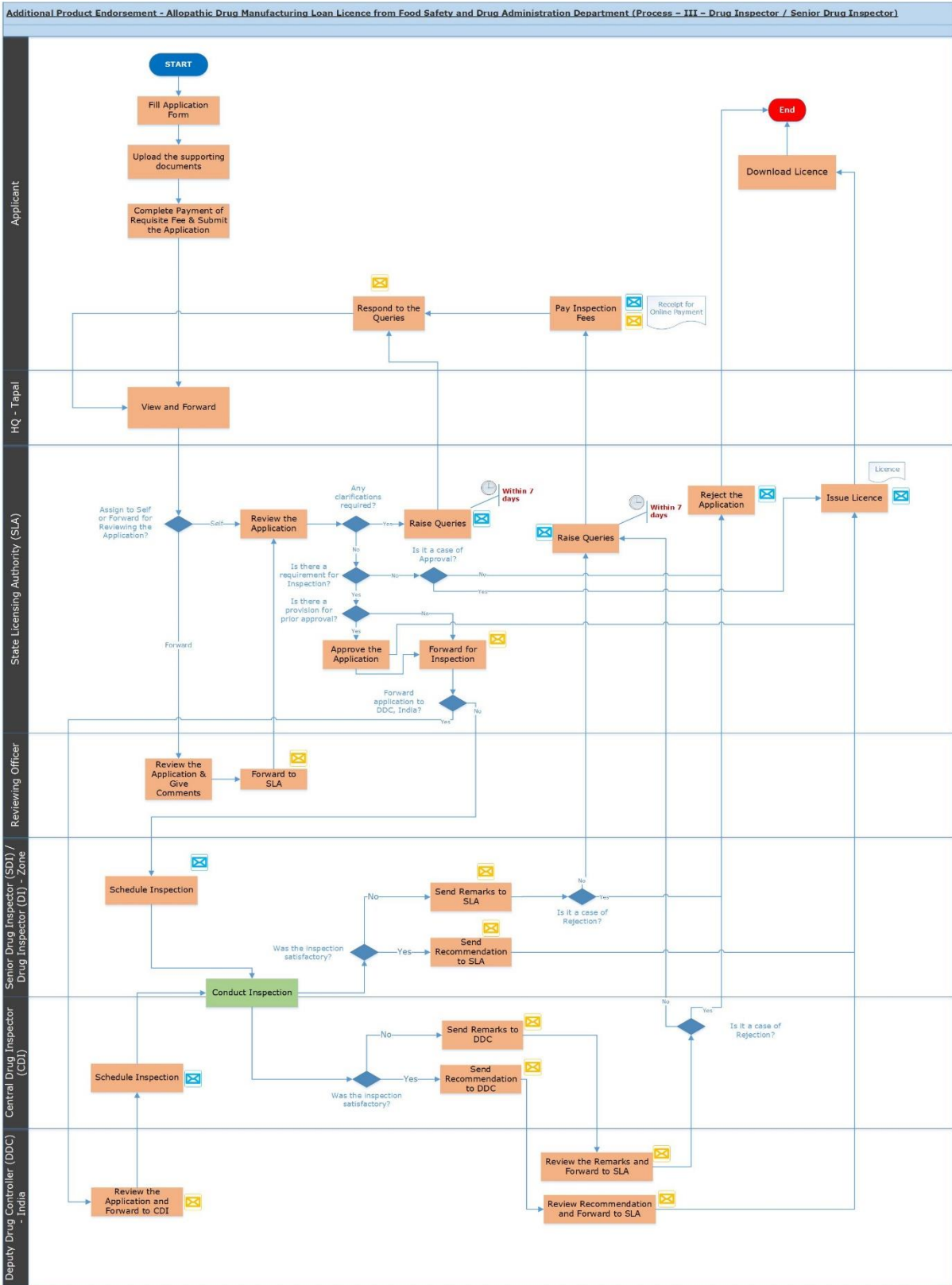


## Process II – Application is received by Different Zones – Assistant Director Drugs Control

Additional Product Endorsement - Allopathic Drug Manufacturing Loan Licence from Food Safety and Drug Administration Department (Process – II – Separate Zone - Assistant Director of Drugs Control)



# Process III: Application is received by Senior Drug Inspector / Drug Inspector – Head Quarters



**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.	Covering Letter stating the intent of the application
2.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)
3.	Drug manufacturing licences Copy, Latest Renewal certificate / Retention Payment receipt
4.	Previously issued Form 29 Copy, if any
5.	List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing
6.	List of analytical instruments and equipment for analysis
7.	Copy of purchase invoices with the details like production capacity, make etc. wherever applicable
8.	Product dossier (for each product)
9.	Form 51/Brand Name affidavit
10.	Agreement with Marketer, if applicable
11.	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

S. No.	Manufacturing Category	Inspection Fees (in INR) <i>To be charged only if a new category is added</i>	Additional Product Fee for each additional Product added (in INR)
1.	Form 25A (Loan Licence to manufacture for sale or for distribution of drugs other than those specified in Schedules C, C (1) and X of the Drugs and Cosmetics Rules, 1945)	1,500	300
2.	Form 28A (Loan Licence to manufacture for sale or for distribution of drugs specified in Schedules C and C (1) (Excluding those specified in Schedule X) of the Drugs and Cosmetics Rules, 1945)	1,500	300

<This space has been intentionally left blank>