PROCEDURE AND TIMELINES FOR
GRANT/RENEWAL DRUG LICENSE FOR DRUG MANUFACTURING

PROCEDURE FOR APPLICATION APPROVAL (DEPARTMENTAL)

- **Step-1:** Application along with all the documents mentioned in checklist shall be submitted to **Licensing Authority** (Himachal Pradesh Drug Administration).

- **Step-2:** Now, Licensing Authority assigns the application to respective **Drug Inspector** for scrutinizing the documents and for Inception procedure.

- **Step-3:** Now, DI (Drug Inspector) will share the inspection report with Licensing Authority based on the inspection held. If the inspection report is positive, then it would move to licensing Authority for final disposal of Approval certificate. Otherwise, applicant will be asked for clarification on objections raised.

- **Step-4:** Once the application got final approval, then Licensing Authority (SDC) finally issues the approval certificate for Drug Manufacturing to the applicant.

The Public Service Guarantee Notification link:

http://dhsr.hp.gov.in/?q=online-mandate-order-drug-licenses

Application workflow with Time-lines:

From the submission of online application from portal to final dispense of an approval certificate, department has proposed a timeline of **21 Working days** which is further bifurcated as below:

- **Application, list of required documents mentioned in Checklist has to be submitted to the Licensing Authority.**
- **Scrutiny of documents by the Licensing Authority**
- **Allotment to the Drugs Inspector concerned for physical inspection of the premises.**

(5 Days)

- **Physical inspection of the premises by the Drugs Inspector**
- **Submission of the inspection report to the Licensing Authority.**
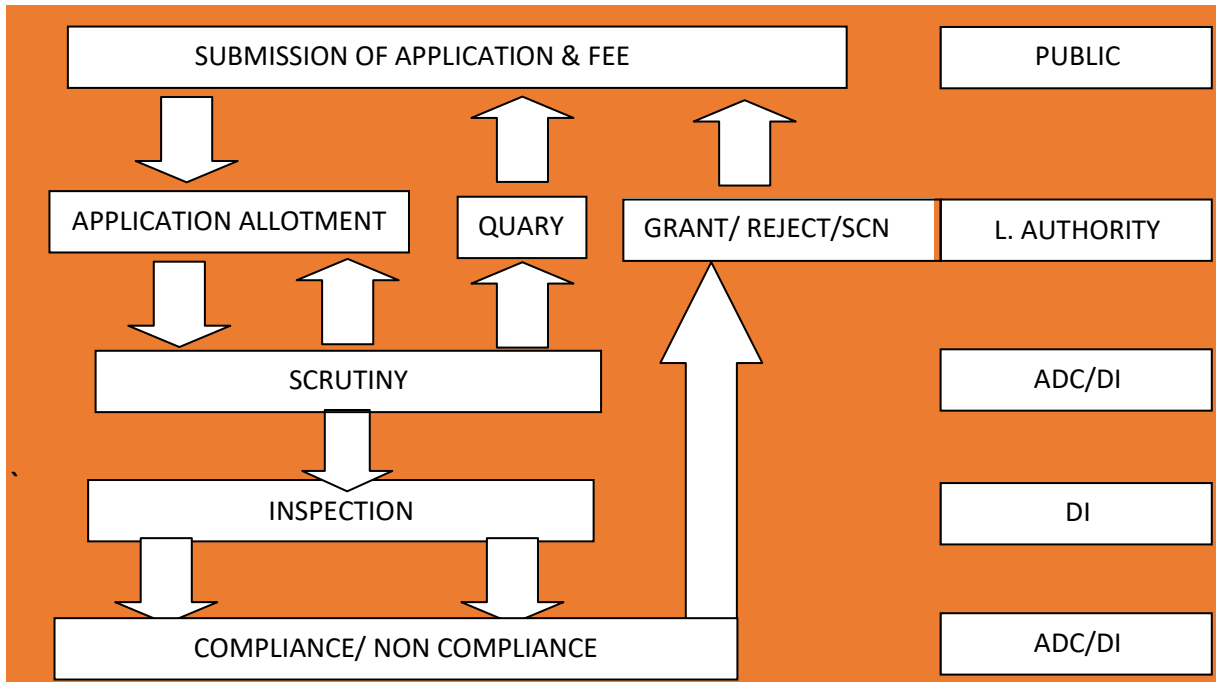
(10 Days)

- **Grant/Renewal/Rejection/Final Disposal of the license by the Licensing Authority.** SS

(6 Days)

LICENSE GRANT/ RENEWAL APPLICATION WORK FLOW

SUBMISSION OF APPLICATION & FEE	PUBLIC
APPLICATION ALLOTMENT → QUARY → GRANT/ REJECT/SCN	L. AUTHORITY
SCRUTINY	ADC/DI
INSPECTION	DI
COMPLIANCE/ NON COMPLIANCE	ADC/DI

INSPECTION WORKFLOW (DEPARTMENTAL)

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│     INSPECTION      │          │       DI        │
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│  COMPLIANCE  │  │  NON COMPLIANCE  │
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│ KEEP RECORD  │  │ ISSUE SCN      REPLY OF SCN      │   │       LA        │
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              │  NON SATISFACTORY  │   │    SATISFACTORY    │
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          │  SUSPENSION/CANCELLATION │  │    KEEP RECORD     │
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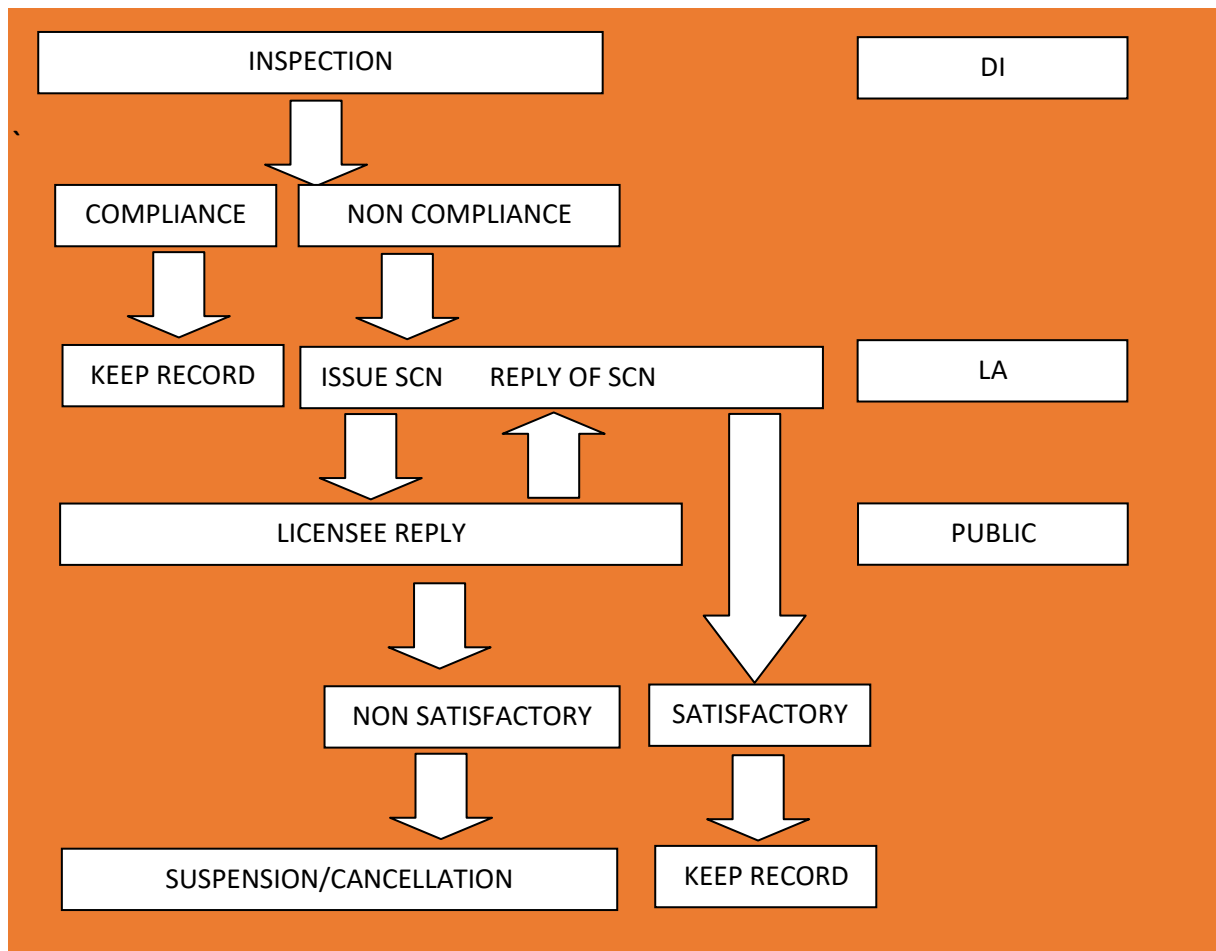
- LA- Licensing Authority
- SDC –State Drug Controller
- ADC-Additional Drug Controller
- DI- Drug Inspector