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Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Important Questions
Chapter 13 : Good Regulatory Practices

Chapter 13
Good Regulatory Practices
IMPORTANT Questions

Q1. Describe the various types of Drug License.

Ans.

Types of Drug License

- **Manufacturing License** : License issued to a business that manufactures drugs inclusive of allopathic/homoeopathy medicines.
- **Sale License :** License issued for the sale of drugs. It has the following bifurcations: – Wholesale Drug License – Retail Drug License
  - **Wholesale License :** A drug wholesaler must obtain a wholesale licence. Wholesale means the sale of the drug to a person/retailer to further sell it.
  - **Retail License :** A retail license is required for the retail sale of drugs. A retail sale means the sale of drugs or cosmetics for the consumption of the end consumer. Retailers can sell it to a dispensary, hospital, educational, medical, or research institute. Retailers engaged in pharmaceuticals, cosmetics, stand-alone pharmacists, ayurvedic shops, etc need this license.
- **Loan License :** License issued to a business that does not own the manufacturing unit but uses the manufacturing facilities of another licensee.
- **Import License :** License is issued to any dealer importing the products for the manufacturing of drugs or is engaged in the business of importing drugs in India.
- **Multi-Drug License :** License issued to businesses that own pharmacies in multiple states with the same name.

Q2. Write a note on Good Regulatory Practices.

Ans.

→ Good Regulatory Practices (GRP) is processes, systems, tools, and methods for improving the quality of regulations that are internationally recognised.

→ Before government initiatives are implemented, GRP systematically implements public consultation and stakeholder involvement, as well as impact analysis of government proposals to ensure they are fit for purpose and will achieve the goals set out.

Q3. Write a note on GRP in Pharma Manufacturing.

Ans.

GRP in Pharma Manufacturing

1. **Document related to licensing authorities :**
    - Copies of all documents are submitted for grant of licence.
    - Copies of licence related to manufacture of drugs like premises licence , Licences of manufacturing of schedule X schedule C and C1 etc.
    - Inspections record : copies of all inspections done by licensing authorities.
    - NOC (No Objection Certificate) from pollution control board.
2. **Registration and qualification records of chemist**
    - Qualification record
    - Registration certificate
    - Address proof
    - In case of change of chemist and other trained staff the copies of all document of new registered chemist and staffs .
3. **Analytical laboratory records**
    - All approval letters copies of analytical laboratories.
    - Educational and experience certificate of analyst.
    - Approval letter of analytical chemist by State drug controller.
4. **Equipment Cleaning and Use Record**
5. **Records of Raw Materials, (Intermediates, API Labelling and Packaging Materials)**
    - All transaction records related to raw material used.
    - Signature of person in charge cash memo or credit memo.
6. **Records of production including**
    - Drug Name and batch number.
    - The manufacturing date.
    - Quantity of raw material used.
    - Quantity of finished product.
7. **Laboratory Control Records**
8. **Batch Production Record Review**

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