

A top-down view of various medical supplies including a stethoscope, a blister pack of white pills, several loose white capsules, two glass ampoules, a white digital thermometer, and a white syringe, all arranged on a teal background.

# MEDICINE (PHARMACEUTICAL) INDUSTRY

*Prepared by Priya Consultancy*



## *Company Registration*

- *Company Incorporation – Pvt Ltd / LLP (pharma sector में preferred)*
- *GST Registration*
- *Udyam/MSME Registration (subsidies & schemes के लिए)*
- *PAN, TAN, IEC (for export)*
- *EPF & ESIC Registration (employee compliance)*
- *Professional Tax (state-specific)*

# *Licenses & Approvals*

- *Drug Manufacturing License – State Drug Control Authority (under Drugs & Cosmetics Act, 1940)*
- *Factory License – Labour Department*
- *GMP (Good Manufacturing Practices) Compliance – mandatory for pharma units*
- *Pollution Control Board Approvals – CTE & CTO*
- *Fire NOC – Fire Department*
- *PESO License – if using solvents/flammables*
- *Wholesale Drug License / Retail License – अगर distribution भीकरेंगे*
- *Import Export Code (IEC) – for global trade*
- *Medical Device Rules – अगर devices बनातेहैं*



# Certifications

- *WHO-GMP Certification – pharma export में must*
- *ISO 9001 – Quality Management*
- *ISO 14001 – Environmental Management*
- *ISO 45001 – Health & Safety*
- *ISO 17025 – Pharma Testing Labs*
- *US FDA / EU GMP / MHRA – अगर US/Europe export करना है*
- *AYUSH License – अगर Ayurvedic/Homoeopathic medicines manufacture करेंगे*
- *Social Compliance Certifications – SA8000, SEDEX.*



# *Digital Systems*

- *Website Development – corporate profile, product portfolio, certifications display*
- *ERP Software – pharma ERP (inventory, batch records, GMP compliance, HR, quality control)*
- *IPR Requirements:*
  - *Trademark – brand & product names*
  - *Patent – innovative formulation/process*
  - *Copyright – packaging design, manuals*
- *Barcode & QR Code – GS1 India registration (medicine packaging  mandatory track & trace)*

# *Plant, Machinery & Equipment*

**Tablet Section** – granulator, tablet press, coating machine, blister packing

**Capsule Section** – capsule filling, polishing, inspection machine

**Liquid Section** – syrup manufacturing, filtration, filling line

**Ointment Section** – ointment/cream mixing & filling plant

**Sterile Section (Injectables)** – cleanroom, autoclave, vial filling, lyophilizer

**Utilities** – boilers, AHU (Air Handling Units), water purification (RO, WFI), HVAC systems

**ETP/STP** – effluent treatment for pharma waste



# *Testing Laboratory*

- *Quality Control Lab – HPLC, GC, UV Spectrophotometer, FTIR, Dissolution Apparatus*
- *Microbiology Lab – Laminar airflow, Incubators, Autoclaves*
- *Stability Testing Lab – controlled humidity & temperature chambers*
- *In-process testing facility – for batch testing as per GMP*

# *Trainings*



- *GMP & GLP Training*
- *SOP Training (Standard Operating Procedures)*
- *Fire & Safety Training*
- *Hazardous Chemicals & First-aid Training*
- *Social Compliance Training (workers welfare, labor rights)*
- *Equipment Operation & Preventive Maintenance Training*

# *Documents Required*

- *Company Incorporation (COI, MOA, AOA, PAN, GST)*
- *Site Master File & Plant Layout*
- *Drug Manufacturing License Application with SOPs*
- *Pollution Control NOC (CTE, CTO)*
- *Fire Safety Plan & Insurance Certificates*
- *GMP Compliance Documents & Validation Reports*
- *EPF & ESIC Registration Certificates*
- *Trademark & Patent Papers*
- *Barcode/QR Code Registration Certificate*
- *Quality Manual & ISO Certificates*
- *Employee Health & Safety Records*
- *Product Dossiers (formulation details, testing reports)*

# *Consultancies*

- *Pharma Project Consultant* – plant design, equipment selection
- *Regulatory Consultant* – drug license, WHO-GMP, US FDA filing
- *Environmental Consultant* – EIA, CTE/CTO
- *Fire & Safety Consultant*
- *ISO & Social Compliance Consultant*
- *ERP & Website Consultant*
- *IPR Consultant* – patents, trademarks, copyright



A top-down view of various medical supplies on a teal background. On the left, there are two glass ampoules, a white digital thermometer, and a white syringe. In the center, a silver stethoscope is positioned. To the right of the stethoscope is a blister pack of white round tablets, with several more tablets scattered nearby.

**Thank you!**

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