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# Project Report: Pharmaceutical Plant Construction

## 1. Executive Summary

The proposed project involves constructing a modern pharmaceutical manufacturing facility to produce high-quality medicines while adhering to Good Manufacturing Practices (GMP).

**Objectives:** - Establish a facility with production capacity of 1,00,000 units/year. - Comply with GLP,GMP, FDA, and local regulatory standards. - Incorporate advanced automation and quality control systems. - Achieve sustainable and energy-efficient operations with introduction of various utility sytems which serve as

## 2. Project Background

The global pharmaceutical industry is expanding, and Sekhmat Pharma Ventures aims to meet growing demands for quality API based drugs such as Gabapentin and Valproic Acid used for treating central nervous disorder and other mental disorders . Current production facilities are insufficient, necessitating a new and improvised plant **Rationale:** - Growing demand in domestic and international markets - Need for upgraded technology to improve efficiency and quality - Compliance with stringent regulatory standards.

## 3. Project Scope

**Scope Includes:** - Construction of production blocks for tablets, capsules, injectables, and liquids - Installation of clean rooms, laboratories, and quality control units - Utility services: water purification, HVAC, power supply - Administrative and support facilities

**Scope Excludes:** - Marketing and distribution activities - External infrastructure beyond the plant premises

**Investor Approvals -** Understanding the financial constraints with in the Plant Productions , Evaluate production requisities , understand the demand of the Product in the upcoming years framed strategies to identify necessary return backs of the Production from the expanded Project to seek approvals and authorizations from Investors.

## 4. Project Location

* **Site:** 85 -88 ,105 -106 ,115 -116 SIPCOT Industrial Estate ,EPIP Park , Gummidipoondi -601201
* **Land Area:** 30 Acres
* **Accessibility:** Proximity to highways, ports, and railway facilities ,being present inbetween state borders of Andhra Pradesh and Tamilnadu
* **Utilities Availability:** Water, electricity,biogas etc

## 5. Project Design & Layout

**Plant Layout Overview:** - Raw Material Storage , Hazardous Waste Storage , Water Stoage , Over head Tanks , Effluent Storage , Production blocks (tablets, injectables, liquids) - Packaging and labeling area - Quality control laboratories - Utilities (WFI, HVAC, power supply, effluent treatment) - Administrative and warehouse blocks

**Design Considerations:** - GMP-compliant workflow - Segregation of production areas - Efficient material and personnel flow

**P&ID Layout:**

**Placeholder for WBS Layout:** > *Insert Work Breakdown Structure (WBS) diagram here.*

## 6. Project Schedule

**Timeline (Gantt Chart Placeholder):** > *Insert Gantt chart here showing all phases from planning to commissioning.*

| Phase | Duration | Key Activities |
| --- | --- | --- |
| Planning & Approval | 2 months | Regulatory approvals, design finalization |
| Site Development | 3 months | Land clearing, leveling, fencing , Plan approval ,site evaluation |
| Civil Construction | 20 months | Building structures, clean rooms,Plumbings and Water resources |
| Utility Construction | 6 months | HVAC, utilities, equipment installation |
| Commissioning & Validation | 3 months | Testing, General Testing , Regulatory inspection |
| Commercial Production | -2 months | Trail production and batch evaluation |

**Total Duration:** 36 months

## 7. Project Cost Estimate

| Component | Cost in Crores |
| --- | --- |
| Land Acquisition | 50 |
| Civil Construction | 30 |
| Equipment & Machinery | 28 |
| Utilities & Services | 15 |
| Automation & IT | 10 |
| Contingency (10%) | 5 |
| **Total** | 138 |

**Funding Sources:** - Internal resources: 10% - Bank loans: 50% - Investors: 40%

## 8. Regulatory & Compliance Requirements

* WHO-GMP and ISO 9001 certification
* National regulatory authority approvals (FDA, CDSCO)
* Environmental clearance
* Occupational health and safety compliance (OHSAS)

## 9. Risk Analysis

| Risk | Mitigation Measures |
| --- | --- |
| Delay in approvals | Early engagement with authorities |
| Budget overrun | Detailed cost estimation, contingency fund |
| Vendor delays | Pre-order critical machinery |
| Environmental compliance issues | Continuous monitoring and audits |
| Workforce shortage | Recruitment plan & training programs |

## 10. Project Benefits

* Increased production capacity and revenue
* Compliance with international quality standards
* Job creation
* Enhanced corporate image
* Future expansion potential

## 11. Conclusion

The pharmaceutical plant construction project is a strategic investment to meet market demand, maintain high quality, and enhance operational efficiency. Careful planning, regulatory compliance, and effective risk management will ensure a successful, sustainable, and profitable facility.

## Appendices / Placeholders for Diagrams

1. **Gantt Chart** – [Insert image or MS Project export]
2. **P&ID Diagram** – [Insert image/PDF]
3. **WBS Diagram** – [Insert image/Excel or PowerPoint export]