

# Project Overview

The proposed project will be the state-of-art facility which will be complied with the US-FDA, UK-MHRA, TGA-Australia and WHO-cGMP regulations.

The facility will house incoming docks, raw & packaging materials, warehousing, sampling, dispensing & weighing areas, oral solid & liquid dosage manufacturing units, injectable unit, infusions unit, ophthalmics unit, packaging and labelling areas in the same facility.

The proposed facility will have the separate and dedicated area for Penicillin, Cephalosporin and anticancer drugs.

In addition, analytical lab for quality operations and Research & Development, locker / changerooms, offices and other necessary amenities will be housed in the facility.

The facility will be a Greenfield construction. The site will be developed for manufacturing blocks, HVAC system, utilities, pipe racks, roadways, parking spaces, front garden, security check points, officer's dormitory etc.

## **The Proposed Manufacturing Facility will have the following blocks or units:**

General Block: This block will have the following sections –

- 1- Tablet (coated / uncoated) Section
- 2- Hard Gelatin Capsule Section
- 3- Soft Gelatin Capsule Section
- 4- Oral Liquid (Syrup, Suspension, Solution & Pediatric Drops) Section
- 5- Oral Dry Powder for Suspension Section
- 6- Sterile Section (Ampule, Vial & Lyophilized Powder for Injections)
- 7- Cream & Ointment (Steroid / non-Steroid) Section
- 8- Oral Rehydration Salt (ORS) Section
- 9- Suppository Section having cool room (2° to 8° C )
- 10- Raw and Packing Materials Warehouse
- 11- Packaging Section
- 12- R&D Lab
- 13- Analytical Lab
- 14- Microbiology Lab

Penicilin Block: This block will have the following sections –

- 1- Tablet (coated / uncoated) Section
- 2- Hard Gelatin Capsule Section
- 3- Dry Powder for Suspension Section
- 4- Raw and Packing Materials Warehouse
- 5- Packaging Section

Cephalosporin Block: This block will have the following sections –

- 1- Tablet (coated / uncoated) Section
- 2- Hard Gelatin Capsule Section
- 3- Dry Powder for Suspension Section
- 4- Sterile Section (Ampule, Vial & Lyophilized Powder for Injection)
- 5- Raw and Packing Materials Warehouse
- 6- Packaging Section

Infusion Block: This block will have the following sections –

- 1- Small & Large Volume Parenteral Section
- 2- Electrolytes & Nutrients Section
- 3- Raw and Packing Materials Warehouse
- 4- Packaging Section

Ophthalmic Block will have the following sections –

- 1- Antibiotic Section
- 2- Steroid Section
- 3- Non-Steroid Section
- 4- Microbiology Lab
- 5- Raw and Packing Materials Warehouse (controlled temperature)

Anticancer Block:

- 1- Antiretroviral Section
- 2- Cytotoxic Antibiotic Section
- 3- Cytotoxic Metabolites Section
- 4- Cytotoxic Immuno-suppressants & other Immuno-suppressants
- 5- Anti-lymphocyte Monoclonal Antibodies Section
- 6- Other Immuno-modulating Drugs Section
- 7- Raw and Packaging Materials Warehouse (controlled temperature)
- 8- Packaging Section
- 9- R&D Lab
- 10- Analytical Lab
- 11- Microbiology Lab

**Total area to be developed including Core Manufacturing Area:**

1000 sqm. Considering 200 – 250 products in different dosage forms (actual size will be dependent on production capacity and number of products).

**The dosage forms to be manufactured:**

Tablet (coated/uncoated), soft gelatin capsule, hard gelatin capsule, oral liquid (syrup, suspension, solution, pediatric drops), oral dry powder for suspension, lyophilized powder for injection, cream, ointment, suppository, injection, infusion, eye/ear drops and eye/ear ointment.

**Approximate budgeted cost for the Proposed Project:**

<b>Name of the Project</b>	<b>Value in Million USD</b>
General Products Block (Annexure - II)	9.50
Penicillin Block(Annexure - III)	2.05
Cephalosporin Block (Annexure - IV)	3.50
Infusion Block (Annexure - V)	3.15
Ophthalmic Block (Annexure - VI)	1.95
Anticancer Block (Annexure - VII)	5.50
Consultancy Fee (Annexure - I)	4.35
<b>Total Cost of the Project</b>	<b>30.00</b>

**Note:** Below costs are not included in above blocks or unit of the project:

- 1- Land and Land Development Cost
- 2- Civil Work Cost
- 3- Local regulatory Affairs Cost
- 4- Vehicle Cost

## Annexure – I

The following consultancy services will be provided:

- 1- Feasibility Study, Market Segmentation & Product selection based on market demand
- 2- Development of Project concept Paper including Project Profile
- 3- Concept development
- 4- Detailed Engineering: Architectural, Civil Work, Electrical HVAC, Mechanical & Piping, LV System (Fire Alarm, Smoke Detector, CCTV & Access Control), Fire hydrant Service, Effluent treatment Plant
- 5- Landscaping
- 6- Validation of Process & Equipment
- 7- Preparation of User Requirement Specifications (URS)
- 8- Machinery and Equipment Procurement Assistance
- 9- Product Formulation Development
- 10- Marketing Strategy Development
- 11- Promotional Strategy Development
- 12- Sales Policy Development

## Annexure – II

Approximate budgeted cost for General Block:

Sl. No.	Particulars	Value in Million USD
01	HVAC (Chiller, AHU, FCU, Dehumidifier, BMS etc.) Sandwich Panel & Self levelling Floor Epoxy (SLF) Paint	1.85
02	Process Machinery & Equipment (granulation suite, tablet compression, coating machine, capsule filling, blister packing, strip packing, injectable line, dry syrup filling, auto liquid filling line, ORS line, soft gel capsule line, suppository line, dispensing booth etc.)	3.80
03	Utility Machinery (generator, transformer, HT&LT switch gear, distribution panel, switch & line, lighting equipment, piping & plumbing, boiler, air compressor, water treatment plant (WTP), PW distribution line, Effluent Treatment Plant (ETP), Fire Fighting Equipment & Fire Alarming System, CCTV Security System etc.)	1.75
04	Quality Control Lab & Microbiology Lab Equipment (HPLC, GC, AAS, FTIR, Lab furniture etc.)	0.85
05	R & D Lab Equipment & Machinery (HPLC, hardness tester, friability tester, dissolution tester, granulation suite, tablet press, coating, stability chamber etc.)	0.80
06	Warehouse Rack and Equipment (rack, cabinet, pallets, fork lift, hand pallet truck, cold room, sampling booth etc.)	0.25
07	Canteen & Kitchen	0.10
08	Office Furniture & Fixtures	0.10
<b>Total Amount</b>		<b>9.50</b>

### Annexure – III

Approximate budgeted cost for Penicillin Block:

<b>Sl. No.</b>	<b>Particulars</b>	<b>Value in Million USD</b>
01	HVAC (Chiller, AHU, FCU, Dehumidifier, BMS etc.), Sandwich Panel & Self Levelling Floor Epoxy (SLF) Paint	0.65
02	Process Machinery & Equipment (Granulation Suite, Tablet Compression, Coating Machine, Capsule Filling, Blister Packing, Dry Syrup Filling, Dispensing Booth etc.)	1.00
03	Utility Machinery (LT Switch Gear, Distribution Panel, Switch & Line, Lighting Equipment, Piping and Plumbing, PW Distribution Line, Fire Fighting Equipment & Fire Alarming System etc.)	0.20
04	Warehouse Rack and Equipment (rack, cabinet, pallets, fork lift, pallet truck, cold room, sampling booth etc.)	0.15
05	Miscellaneous	0.05
<b>Total Amount</b>		<b>2.05</b>

### Annexure – IV

Approximate budgeted cost for Cephalosporin block:

<b>Sl. No.</b>	<b>Particulars</b>	<b>Value in Million USD</b>
01	HVAC (Chiller, AHU, FCU, Dehumidifier, BMS etc.), Sandwich Panel & Self Levelling Floor Epoxy (SLF) Paint	0.85
02	Process Machinery & Equipment (Granulation Suite, Tablet Press, Tablet Coating, Auto Capsule Filling, Injection Vial Filling Line, Blister Packing, Dry Syrup Filling Line, Dispensing Booth etc.)	1.80
03	Utility Machinery (LT Switch Gear, Distribution Panel, Switch & Line, Lighting Equipment, Piping and Plumbing, Water Distribution Line, Fire Fighting Equipment & Fire Alarming System etc.)	0.60
04	Warehouse Rack and Equipment (rack, cabinet, pallets, fork lift, hand pallet truck, cold room, sampling booth etc.)	0.15
05	Miscellaneous	0.10
<b>Total Amount</b>		<b>3.50</b>

## Annexure – V

Approximate budgeted cost for Infusion Block:

<b>Sl. No.</b>	<b>Particulars</b>	<b>Value in Million USD</b>
01	HVAC (Chiller, AHU, FCU, BMS etc.), Sandwich Panel & Self Levelling Floor Epoxy (SLF) Paint	0.90
02	Process Machinery & Equipment (Infusion Filling Line, Bottle Washing & Sterilization Line, Terminal Sterilization Line, Autoclave, Dispensing Booth etc.)	0.95
03	Utility Machinery (LT Switch Gear, Distribution Panel, Switch & Cable, Lighting Equipment, Piping & Plumbing, WFI Generation Distribution Line, Fire Fighting Equipment & Fire Alarming System etc.)	1.05
04	Warehouse Rack and Equipment (rack, cabinet, pallets, fork lift, hand pallet truck, cold room, sampling booth etc.)	0.15
05	Miscellaneous	0.10
	<b>Total Amount</b>	<b>3.15</b>

## Annexure – VI

Approximate budgeted cost for Ophthalmic Block:

<b>Sl. No.</b>	<b>Particulars</b>	<b>Value in Million USD</b>
01	HVAC (Chiller, AHU, FCU, Dehumidifier, BMS etc.), Sandwich Panel & Self Levelling Floor Epoxy (SLF) Paint	0.75
02	Process Machinery & Equipment (solution Preparation Tank, Filter Unit, Transfer Vessel, Container Filling & Cap Sealing, Cream & Ointment Section etc.)	0.75
03	Utility Machinery (LT switch Gear, Distribution Panel, Switch & Cable, Light, Piping & Plumbing, Water Distribution Line, Fire Fighting Equipment & Fire Alarming system etc.)	0.30
04	Warehouse Rack and Equipment (rack, cabinet, pallets, hand pallet truck etc.)	0.05
05	Miscellaneous	0.10
	<b>Total Amount</b>	<b>1.95</b>

## Annexure – VII

Approximate budgeted cost for Anticancer Block:

<b>Sl.No.</b>	<b>Particulars</b>	<b>Value in Million USD</b>
01	HVAC (Chiller, AHU, FCU, Dehumidifier, BMS etc.), Sandwich Panel & Self Levelling Floor Epoxy (SLF) Paint	1.35
02	Process Machinery & Equipment (Granulation Suite, Tablet Section, Capsule Section, Injection Vial Filling Line, Blister Packaging, Dispensing Booth etc.)	2.75
03	Utility Machinery (LT Switch Gear, Distribution Panel, Switch & Line, Lighting Equipment, Piping & Plumbing, Water Distribution Line, Fire Fighting Equipment & Fire Alarming System etc.)	1.15
04	Warehouse Rack and Equipment (rack, cabinet, pallets, fork lift, hand pallet truck, cold room, sampling booth etc.)	0.15
05	Miscellaneous	0.10
	<b>Total Amount</b>	<b>5.50</b>