# Chloramphenicol Palmitate

PRODUCT CODE QUALITY AND STANDARDS	: 33404 : As per standard of Indian Pharmacopoeia
PRODUCTION CAPACITY	: Quantity Rate (Rs.) Value (Rs.) 8 MT 1150 92,00,000 (per annum) (per kg.)
MONTH AND YEAR OF PREPARATION	: January, 2003
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### INTRODUCTION

Chloramphenicol is the specific drug for control and cure of typhoid and broad-spectrum bacterial diseases. Chloramphenicol finds extensive use through tablets and capsules while chloramphenicol palmitate is used to formulate syrups. The structural formula for chloramphenicol-palmitate is represented as:

H NH COCHCI<sub>2</sub>  

$$|$$
  $|$   $|$   
O<sub>2</sub>N - C - C - CH<sub>2</sub> OCO (CH<sub>2</sub>)<sub>14</sub> CH<sub>3</sub>  
 $|$   $|$   $|$   
OH H

It lacks the bitter taste of chloramphenicol. It is hydrolysed in the upper intestinal tract into the parent drug, however, it does not share the topical efficiency of the parent drug. Its toxicity is like that of chloramphenicol. Chloramphenicol palmitate contains 55.5-59.5% of chloramphenicol i.e. approx. 174 mg Chloramphenicolpalmitate is equivalent to 100 mg chloramphenicol. It is an anti-bacterial drug and for an adult, the equivalent of 1.5 to 3.0 g of chloramphenicol daily in divided doses is required, for a child the equivalent of 25 to 50 mg of chloramphenicol per kg. of body weight daily in divided doses is required.

### MARKET POTENTIAL

Chloramphenicol is being produced both in small scale and organized sector. At present in India there are a number of units registered with Secretariat of Industrial Assistance, Deptt. of Industrial Promotion and Policy, Ministry of Commerce and Industry, Government of India, New Delhi. Export of Chloramphenicol has shown increasing trend in recent years. Looking into the demand of Chloramphenicol-palmitate and its export potential, there is a good scope for setting up units in small scale sector.

### BASIS AND PRESUMPTIONS

- 1. The estimates are drawn for a production capacity generally considered techno economically viable for a model type of manufact-uring unit.
- 2. The cost in respect of land and building, machinery and equipment, raw materials and the selling prices of the Chloramphenicol palmitate are those generally obtained at the time of preparation of the project report and may vary depending upon other various factors.
- 3. The wages of the workers are taken as per the prevailing labour wages laws.
- 4. The plant, equipment and machinery required for the manufacture of chloramphenicolpalmitate is either available or can be fabricated indigenously based on the designs, drawing and specifications worked out for the project.
- 5. Interest rate for fixed and working capital has been taken at 14%.
- 6. Scheme is worked out on two shifts basis of eight hours a day and 300 working days in a year.

### IMPLEMENTATION SCHEDULE

Preparation of Project report	1 month
Selection of site	2 months
SSI registration	1 month
Finance/loan from bank or	2 months
Financial Institution	

Power connection/building	3 months
construction	
Machinery procurement	3 months
Trial run	2 weeks
Actual Commercial Production	1 month

### TECHNICAL ASPECTS

#### Process of Manufacture

Chloramphenicol is esterified by condensing with palmitoyl chloride  $(CH_3)_{14}$  COCI) in the presence of pyridine. The crude ester is obtained by pouring the reaction product into a large excess of diluted Hydrochloric acid and the whole mass is filtered. It is then washed with toluene dimethyl formamide. The pure ester is dried, recrystallised and pulverized before packing. Chemical equation of the reaction is as under.

H NH COCHCI 
$$_{2}$$
  
 $| |$   
 $O_{2}N - C - C - CH_{2}OH + CH_{3}(CH_{2})_{14}COCI$   
 $| | |$   
 $OH H \downarrow$   
H NH COCHCI  $_{2}$   
 $| |$   
 $O_{2}N - C - C - CH_{2}OCO (CH_{2})_{14}CH_{3}$   
 $| |$   
 $OH H$ 

#### **Quality Control and Standards**

Chloramphenicol-palmitate is practically insoluble in water, slightly soluble in alcohol, soluble in acetone, chloroform and solvent ether. It is fine white or greyish white powder, it melts between 87° to 95°C. It should conform to the Standard of Indian Pharmacopoeia.

Production Capacity (per annum)

Installed capacity : 8 MT Value : Rs. 92,00,000

## FINANCIAL ASPECTS

### A. Fixed Capital

(i) Land and Building	Value (Rs.)
Land 1000 sq mtrs. @ Rs. 300 sq.mtr	3,00,000
Building (Office, Store, working sheds, Boiler Room, Laboratory etc.	3,50,000
Total	6,50,000

### (ii) Machinery and Equipments

SI. No.	Equipments	Qty.	Value (Rs.)
1.	Stainless steel reactors (500 litres capacity) equipped with a reflux condenser and jacket for steam heating.	2	3,00,000
2.	Air circulated steam heated coiled tray drier, with vacuum drying system.	1	1,50,000
3.	Demineralised water plant	1	50,000
4.	Storage tanks for toluence/ dimethyl-formamide and Hydrochlomic acid	2	2,00,000
5.	Boiler	1	1,00,000
6.	Filteration unit	1	1,00,000
7.	Pulveriser	1	50,000
8.	Laboratory equipments (Spectrophotometer, Thin layer chromatography Centrifuge, oven and other laboratory glassware and equipments		2,50,000
	Total		12,00,000
9.	Erection charge @ 10% of the cost of machinery and equipments		1.20,000
10.	Office furniture and equipments		20,000
	Pre-operative expenses		25,000
	Total		13,65,000
(iii)	Total Fixed Capital		(Rs.)
(13	,65,000 + 6,50,000) =		20,15,000

### Working Capital (per month)

### (i) Personnel

SI. No.	Designation	No.	Salary	Amount (Rs.)
1.	Chemist/Pharmacist	1	4,500	4,500
2.	Manager/commercial Assistant	1	3,400	3,400
3.	Analytical Chemist	1	2,500	2,500
4.	Sales Representative	2	3,000	6,000
5	Accountant/ Clerk	2	2,000	4,000
6	Skilled Workers	4	2,000	8,000
7.	Semi-skilled Workers	3	1,500	4,500
8.	Boiler Attendant	1	2,500	2,500
9.	Watchman and Peon	2	1,000	2,000
		Total		37400
	Perquisites @ 15%			5610
		Total		43,010
		or Say		43,000

(ii) Raw Materials Including Packaging Requirement (per month)

Particulars	Ind./I/ Imp.	- 0	Rate (Rs.)	Value (Rs.)
Chloramphenicol	Ind.	405	1100 4	4,45,500
Palmitoyl Chloride	do	324	65	21,060
Chemicals like pyridine Toluene, dimethyl formamide	do	LS		30,000
Packing material		LS		9,500
	Тс	otal	1	5,06,060
	or	Say	ł	5,06,100
(iii) Utilities (per r	nonth)			(Rs.)
Electricity and fuel				30,000

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Electricity and fuel		30,000
Water		1,000
	Total	31,000

(iv) Other Expenses (per month)	(Rs.)
Postage and stationery	1,000
Telephone	2,000
Consumable stores	2,000
Repairs and maintenance	1,500
Transportation	2,500

Other Expenses (per month)	(Rs. )
Advertisement and publicity	5,000
Insurance	700
Miscellaneous	2,000
Total	16,700

#### B. Working Capital (per month)

1. Raw Material	Rs. 5,06,100
2. Salary and wages	Rs. 43,000
3. Utilities and other expenses	Rs. 47,700
Total	Rs. 5,96,800

4. Working Capital (for 3 Months)Rs. 17,90,400 596,800 x 3 =

#### C. Total Capital Investment

(i) Working capital for 3 month	Rs. 17,90,400
(ii) Land and Building	Rs. 6,50,000
(iii) Machinery and Equipments	Rs. 13,65,000
Total	Rs. 38,05,400

### FINANCIAL ANALYSIS

1. Cost of Production	(Rs)	
(i) Working capital for 1 year	71,61,600	
(ii) Depreciation on building @ 5%	17,500	
(iii) Depreciation on machineries equipments @ 10%	and 1,20,000	
(iv) Depreciation on office furniture and 4,000 equipments @ 20%		
(v) Interest on total Capital investment @ 14%	5,32,756	
Total	78,35,856	
Or say	78,36,000	

#### 2. Sales Turnover (per annum)

Item	Qty.	Rate (Rs)	Value (Rs)
Chloramphenicol- palmitate	8M.T.	1150	92,00,000

3. Net Profit (per annum)

#### Profit = Sale turnover – Cost of production

= Rs. 13,64,000

- 4. Net Profit Ratio
  - = Net profit per year × 100 Sales turnover

$$= \frac{13,64,00 \times 100}{92,00,000}$$

- = 14.82%
- 5. Rate of Return

$$= \frac{\text{Net profit per year} \times 100}{\text{Capital investment}}$$

$$= \frac{13,64,00 \times 100}{38,05,400}$$

= 35.84%

#### 6. Break-even Point

(i) Fixed Cost	(Rs.)
(a) Depreciation on machinery and equipment	1,20,000
(b) Insurance	8,400
(c) Depreciation on building	17,500
(d) Interest on total capital investment	5,32,756
(e) 40% of other contingent expenses	76,800
(f) 40% of salary and wages	2,06,400
Total	9,61,856

#### (ii) B.E.P.

$$= \frac{\text{Fixed cost} \times 100}{\text{Fixed cost} + \text{Profit}}$$

$$= \frac{9611856 \times 100}{961856 + 1364000}$$

= 41.3%

### Addresses of Machinery and Equipment Suppliers

- M/s. Chemical Plant and Equipments Naroda, GIDC, Ahmedabad, (Gujarat)
- 2. M/s. Cadmach Machinery GIDC, Phase IV, Vatva, Ahmedabad.
- 3. M/s.Sethi Engineering Works 27/772, Zorawar Singh Marg, New Delhi.

4. M/s. Rank and Co. Wazirpur Industrial Area, New Delhi-110052.

Addresses Raw Material Suppliers

- M/s. National Solvent Corporation Devi Dayal Road, Muland, Mumbai.
- 2. M/s. Excel India Ltd. 184-187 S.V Road,

Jogeshwari, Mumbai.

- M/s. Cemet Ltd.
   214, Hans Bhawan, Wing No. 1, Bahadur Shah Zafar Marg, New Delhi.
- 4. M/s. Manish Organic Ltd. National Chambers, Ashram Road, Ahmedabad.