



The Economics of Large Scale MCC Producing Generics 2008

James R. Bruno

Chemical and Pharmaceutical Solutions



Critical Parameters

- Equipment Cost
- Capacity
- Chiral Stationary Phase
- Raw Material Costs
- Solvent Costs
- Labor
- Maintenance



Equipment Cost

- 6 by 100 cm unit
- Feed pump to post concentration
- In existing building
- Utilities already installed



\$5-\$8 million



Utilization = $\frac{\text{Kilo of desired product}}{\text{kilo of CSP/Day}}$



Costs

- Coefficient of Separation
 - 1,2,3 5
- Chiral Stationary Phase
 - \$14,000/kilo
- Raw materials
 - \$15-18/kilo



Costs

- Maintenance
 - 3% of the investment
- Raw Materials
 - \$15-\$18/kilo input
- Labor
 - Operators-\$30/hour
 - QC-\$50/hour



$330\text{days} \times 24 \text{ hours} \times (\text{hourly charge}) \times 1.2 \times 1.3$

Represents 4 shifts

And benefits



Efficiency of the CSP

CoS=kilos of desired product

Kilo of CSP



CSP Cost

\$14,000/kilo

CoS	kg of CSP	prod days	kg prod	\$/kilo
1	300	330	99000	\$10.18
2	300	330	198000	\$5.09
3	300	330	297000	\$3.39
5	300	330	495000	\$2.04



CSP Cost

\$28,000/kg

CoS	kg of CSP	prod days	kg prod	\$/kilo
1	300	330	99000	\$20.36
2	300	330	198000	\$10.18
3	300	330	297000	\$6.79
5	300	330	495000	\$4.07



Efficiency

CoS	kg of CSP	prod days	kg prod
1	300	330	99000
2	300	330	198000
3	300	330	297000
5	300	330	495000



Equipment Cost

CoS	SMB	1 year	5 years	\$/kilo
1	7,500,000	99,000	495000	\$15.15
2	7,500,000	198,000	990000	\$7.58
3	7,500,000	297,000	1485000	\$5.05
5	7,500,000	495,000	2475000	\$3.03



Raw Materials

DL-Naproxen

DL	75%	85%
\$15.00	\$20.00	\$17.65
\$18.00	\$24.00	\$21.18



Labor Cost

	Labor Rate	Days/year	hours/day	4th person	Benefits	Cost/year
Operator	30	330	24	1.2	1.3	\$370,656.00
QC	50	330	8	1.2	1.3	\$205,920.00
TOTAL						\$ 576,576.00



Labor Cost per kilo of Product

CoS	5 years	labor
1	495000	\$5.82
2	990000	\$2.91
3	1465000	\$1.94
5	2475000	\$1.16



Maintenance (3% of installation cost)

Equipment	2%	3% CoS		kilos/year	\$/kg
5,000,000.00	100,000.00	150,000.00	2	99,000	\$1.52
7,500,000.00	150,000.00	225,000.00	2	99,000	\$2.27
10,000,000.00	200,000.00	300,000.00	2	99,000	\$3.03



Solvent

CoS	kg/day	liters/day
1	300	60000
2	600	120000
3	900	180000
5	1500	300000



Summary

- Research Cost
- Standard Reaction Bay
- Recover of isomer



Summary

CSP	Depreciation	Raw Material	Labor	Maintenance	Solvent	Energy	Total
\$10.18	\$15.25	\$17.65	\$5.82	\$0.76	\$1.74	\$8.22	\$59.62
\$5.09	\$7.58	\$17.65	\$2.91	\$0.76	\$1.74	\$5.71	\$41.44
\$3.39	\$5.05	\$17.65	\$1.94	\$0.76	\$1.74	\$4.89	\$35.42
\$2.04	\$3.03	\$17.65	\$1.16	\$0.76	\$1.74	\$4.22	\$30.60
CSP	Depreciation	Raw Material	Labor	Maintenance	Solvent	Energy	Total
\$10.18	\$7.58	\$17.65	\$5.82	\$0.76	\$1.74	\$8.22	\$51.95
\$5.09	\$3.79	\$17.65	\$2.91	\$0.76	\$1.74	\$5.71	\$37.65
\$3.39	\$2.53	\$17.65	\$1.94	\$0.76	\$1.74	\$4.89	\$32.90
\$2.04	\$1.52	\$17.65	\$1.16	\$0.76	\$1.74	\$4.22	\$29.09



Naproxen

- 2000 \$125/kg
- 2002 \$ 65/kg
- 2004 \$ 50/kg



Thanks

- Chiral Technologies
- Novasep
- Pharmeco



James R. Bruno

Jamesbruno@capsoln.com