

Economic Evaluation Report
for EPO_CC_PERFUSION

August 13, 2024

1. EXECUTIVE SUMMARY (2024 prices)

Total Capital Investment	59,085,000 \$
Capital Investment Charged to This Project	59,085,000 \$
Operating Cost	34,210,000 \$/yr
Revenues	114,199,000 \$/yr
Batch Size	77,422.76 mg EPO
Cost Basis Annual Rate	4,567,943 mg EPO/yr
Unit Production Cost	7.49 \$/mg EPO
Net Unit Production Cost	7.49 \$/mg EPO
Unit Production Revenue	25.00 \$/mg EPO
Gross Margin	70.04 %
Return On Investment	110.34 %
Payback Time	0.91 years
IRR (After Taxes)	67.51 %
NPV (at 7.0% Interest)	403,637,000 \$
EPO = Flow of Component 'EPO' in Stream 'rHuEPO BDS'	

2. EQUIPMENT SPECIFICATION AND FOB COST (2024 prices)

Main Equipment

Quantity/ Standby/ Staggered	Name	Description	Unit Cost (\$)	Cost (\$)
1 / 0 / 2	BR-102	Disposable Bioreactor Skid Container Volume = 2575.00 L	326,000	978,000
1 / 0 / 0	RBS-102	Rocking Bioreactor Skid Container Volume = 200.00 L	323,000	323,000
1 / 0 / 0	SBR-101	Disposable Seed Bioreactor Skid Container Volume = 500.00 L	310,000	310,000
1 / 0 / 0	C-103	Gel Filtration Column Column Volume = 19.35 L	235,000	235,000
1 / 0 / 0	C-101	PBA Column Column Volume = 3.13 L	188,000	188,000
1 / 0 / 0	C-102	PBA Column Column Volume = 2.37 L	188,000	188,000
1 / 0 / 0	RBS-101	Rocking Bioreactor Skid Container Volume = 50.00 L	104,000	104,000
1 / 0 / 0	G-101	Centrifugal Compressor Compressor Power = 1.36 kW	102,000	102,000
1 / 0 / 0	DE-103	Dead-End Filter Filter Area = 20.00 m2	101,000	101,000
1 / 0 / 0	DF-104	Diafilter Membrane Area = 22.94 m2	99,000	99,000
1 / 0 / 2	V-105	Skid for Disposable Large Bag Container Volume = 2000.00 L	91,000	273,000
2 / 0 / 0	V-103	Skid for Disposable Large Bag Container Volume = 2000.00 L	91,000	182,000
2 / 0 / 4	V-104	Skid for Disposable Large Bag Container Volume = 2000.00 L	91,000	546,000
1 / 0 / 0	V-145	Skid for Disposable Large Bag Container Volume = 500.00 L	78,000	78,000
1 / 0 / 0	V-144	Skid for Disposable Large Bag Container Volume = 500.00 L	78,000	78,000
1 / 0 / 0	V-101	Skid for Disposable Large Bag Container Volume = 400.00 L	69,000	69,000
1 / 0 / 0	DE-105	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-104	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-106	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-107	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-108	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-109	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000

1 / 0 / 0	DE-110	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-111	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-112	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-113	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-101	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-116	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-117	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-118	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-115	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-119	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-120	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-121	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-122	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-123	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-124	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-125	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	DE-114	Dead-End Filter Filter Area = 10.00 m2	57,000	57,000
1 / 0 / 0	V-141	Skid for Disposable Large Bag Container Volume = 200.00 L	56,000	56,000
1 / 0 / 0	V-140	Skid for Disposable Large Bag Container Volume = 200.00 L	56,000	56,000
1 / 0 / 0	V-148	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-142	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-143	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-147	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-146	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-149	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-139	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000

1 / 0 / 0	V-138	Skid for Disposable Large Bag Container Volume = 100.00 L	54,000	54,000
1 / 0 / 0	V-111	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-112	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-113	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-114	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-115	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-116	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-117	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-118	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-119	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-120	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-121	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-126	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-127	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-130	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-131	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-132	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-133	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-134	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-135	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-136	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-137	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-128	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-129	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-110	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000
1 / 0 / 0	V-109	Skid for Disposable Large Bag Container Volume = 50.00 L	43,000	43,000

1 / 0 / 0	V-106	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-108	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-124	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-122	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-123	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-107	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	V-125	Skid for Disposable Large Bag Container Volume = 10.00 L	43,000	43,000
1 / 0 / 0	DF-102	Diafilter Membrane Area = 0.07 m2	40,000	40,000
1 / 0 / 0	DF-101	Diafilter Membrane Area = 0.40 m2	40,000	40,000
1 / 0 / 0	DF-103	Diafilter Membrane Area = 0.23 m2	40,000	40,000
1 / 0 / 0	AF-101	Air Filter Rated Throughput = 14932.28 L/h	10,000	10,000
1 / 0 / 0	SDLB-101	Skid for Disposable Large Bag Container Volume = 500.00 L	5,000	5,000
		Unlisted Equipment		1,805,000

Auxiliary Equipment

TOTAL 9,025,000

3. FIXED CAPITAL ESTIMATE SUMMARY (2024 prices in \$)

3A. Total Plant Direct Cost (TPDC) (physical cost)

1. Equipment Purchase Cost	9,025,000
2. Installation	3,776,000
3. Process Piping	3,159,000
4. Instrumentation	3,610,000
5. Insulation	271,000
6. Electrical	903,000
7. Buildings	4,061,000
8. Yard Improvement	1,354,000
9. Auxiliary Facilities	3,610,000
TPDC	29,768,000

3B. Total Plant Indirect Cost (TPIC)

10. Engineering	7,442,000
11. Construction	10,419,000
TPIC	17,861,000

3C. Total Plant Cost (TPC = TPDC+TPIC)

TPC	47,628,000
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3D. Contractor's Fee & Contingency (CFC)

12. Contractor's Fee	2,381,000
13. Contingency	4,763,000
CFC = 12+13	7,144,000

3E. Direct Fixed Capital Cost (DFC = TPC+CFC)

DFC	54,773,000
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4. FACILITY-DEPENDENT COST - PROCESS SUMMARY

Cost Item	Annual Cost (\$)	%
Depreciation	5,203,000	50.48
Maintenance	722,000	7.00
Insurance	548,000	5.31
Local Taxes	1,095,000	10.63
Factory Expense	2,739,000	26.57
TOTAL	10,307,000	100.00

5. MATERIALS COST - PROCESS SUMMARY

Bulk Material	Unit Cost (\$)	Annual Amount		Annual Cost (\$)	%
Air	0.00	98,542	kg	0	0.00
AIX_CIP_BUFFER	14.54	582	kg	8,458	0.08
AIX_ELUTION_BUF	10.84	738	kg	7,998	0.07
AIX_EQ_BUFFER	10.59	1,478	kg	15,654	0.15
AIX_REG_BUFFER	12.37	945	kg	11,691	0.11
AIX_WASH2_BUF	10.65	921	kg	9,808	0.09
AIX_WASH_BUFFER	39.62	589	kg	23,350	0.22
Biomass	0.00	0	kg	0	0.00
CO2	0.00	42,232	kg	0	0.00
Formulation Buf	10.25	27,580	kg	282,652	2.64
GFC_CIP_BUFFER	10.85	3,440	kg	37,329	0.35
GFC_EQ_BUFFER	10.76	6,850	kg	73,698	0.69
GFC_REG_BUFFER	12.37	3,502	kg	43,334	0.41
GFC_SANITIZATIO	11.68	3,472	kg	40,538	0.38
HIC_EQ_BUFFER	25.22	2,595	kg	65,452	0.61
HIC_REG2_BUFFER	30.79	457	kg	14,084	0.13
NaOH (1 M)	2.04	1,459	kg	2,980	0.03
SF Media	1,342.00	5,673	kg	7,613,444	71.24
Storage Buffer	52.59	4,156	kg	218,549	2.04
VA (Low pH)	61.09	4	kg	267	0.00
WFI	10.00	221,848	kg	2,218,484	20.76
TOTAL				10,687,771	100.00

NOTE: Bulk material consumption amount includes material used as:

- Raw Material
- Cleaning Agent
- Heat Transfer Agent (if utilities are included in the operating cost)

6. UTILITIES COST (2024 prices) - PROCESS SUMMARY

Utility	Unit Cost (\$)	Annual Amount	Ref. Units	Annual Cost (\$)	%
Std Power	0.10	43,203	kW-h	4,320	88.49
Cooling Water	0.10	1,150	MT	115	2.35
Chilled Water	0.50	206	MT	103	2.11
Hot Water	0.40	91	MT	36	0.75
Freezing Agent	2.00	154	MT	308	6.30
TOTAL				4,882	100.00

7. LABOR COST - PROCESS SUMMARY

Labor Type	Unit Cost (\$/h)	Annual Amount (h)	Annual Cost (\$)	%
Operator	69.00	94,660	6,531,530	100.00
TOTAL		94,660	6,531,530	100.00

8. VARIOUS CONSUMABLES COST (2024 prices) - PROCESS SUMMARY

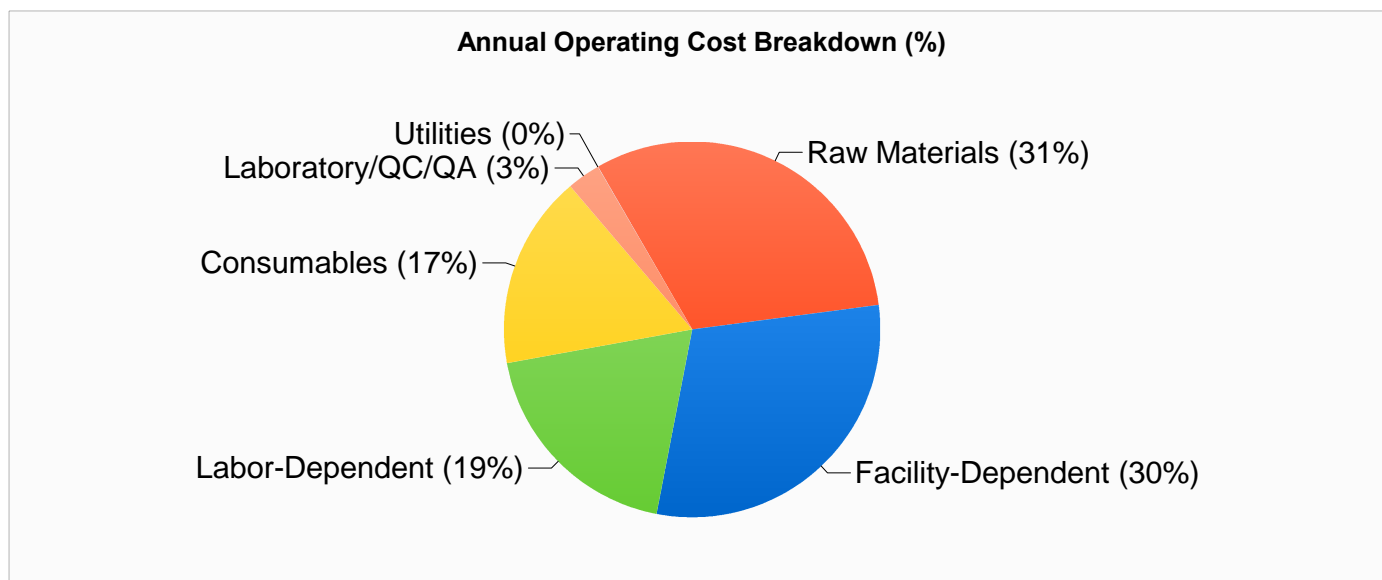
Consumable	Units Cost (\$)	Annual Amount		Annual Cost (\$)	%
5 mL Test Tube	0.50	59	item	30	0.00
100 mL T-Flask	1.70	708	item	1,204	0.02
2.2 L Roller Bottle	6.00	118	item	708	0.01
Dft DEF Cartridge	1,000.00	1,475	item	1,475,000	25.88
Dft Membrane	400.00	1,395	m2	558,100	9.79
DEAE SEPHAROSE Fast Flow	1,636.27	6	L	9,072	0.16
Butyl-Sepharose Fast Flow	3,960.00	4	L	16,646	0.29
Sephacryl S-200 HRXX	1,296.80	34	L	44,417	0.78
200 L Cell Bag	490.56	59	item	28,943	0.51
2000 mL Shake Flask	1.80	18	item	32	0.00
50 L Cell Bag	245.28	59	item	14,471	0.25
Bag for Mixing 400 L	1,400.00	59	item	82,600	1.45
SUSB Bag 500 L	11,000.00	59	item	649,000	11.39
2KL Bag for Mixing	1,400.00	295	item	413,000	7.25
10 L Bag	162.00	649	item	105,138	1.85
Bag for Mixing 50 L	900.00	708	item	637,200	11.18
Bag for Storage 50 L	400.00	531	item	212,400	3.73
2KL SUB	14,236.00	59	item	839,924	14.74
Bag for Storage 500 L	850.00	177	item	150,450	2.64
Bag for Mixing 100 L	1,000.00	236	item	236,000	4.14
Bag for Storage 100 L	500.00	236	item	118,000	2.07
Bag for Mixing 200 L	1,200.00	59	item	70,800	1.24
Bag for Storage 200 L	600.00	59	item	35,400	0.62
TOTAL				5,698,535	100.00

9. WASTE TREATMENT/DISPOSAL COST (2024 prices) - PROCESS SUMMARY

THE TOTAL WASTE TREATMENT/DISPOSAL COST IS ZERO.

10. ANNUAL OPERATING COST (2024 prices) - PROCESS SUMMARY

Cost Item	\$	%
Raw Materials	10,688,000	31.24
Labor-Dependent	6,532,000	19.09
Facility-Dependent	10,307,000	30.13
Laboratory/QC/QA	980,000	2.86
Consumables	5,699,000	16.66
Waste Treatment/Disposal	0	0.00
Utilities	5,000	0.01
Transportation	0	0.00
Miscellaneous	0	0.00
Advertising/Selling	0	0.00
Running Royalties	0	0.00
Failed Product Disposal	0	0.00
TOTAL	34,210,000	100.00



11. PROFITABILITY ANALYSIS (2024 prices)

A.	Direct Fixed Capital	54,773,000 \$
B.	Working Capital	1,573,000 \$
C.	Startup Cost	2,739,000 \$
D.	Up-Front R&D	0 \$
E.	Up-Front Royalties	0 \$
F.	Total Investment (A+B+C+D+E)	59,085,000 \$
G.	Investment Charged to This Project	59,085,000 \$

H.	Revenue/Savings Rates	
	EPO in 'rHuEPO BDS' (Main Revenue)	4,567,943 mg/yr

I.	Revenue/Savings Price	
	EPO in 'rHuEPO BDS' (Main Revenue)	25.00 \$/mg EPO

J.	Revenues/Savings	
	EPO in 'rHuEPO BDS' (Main Revenue)	114,198,569 \$/yr
1	Total Revenues	114,198,569 \$/yr
2	Total Savings	0 \$/yr

K.	Annual Operating Cost (AOC)	
1	Actual AOC	34,210,000 \$/yr
2	Net AOC (K1-J2)	34,210,000 \$/yr

L.	Unit Production Cost /Revenue	
	Unit Production Cost	7.49 \$/mg EPO
	Net Unit Production Cost	7.49 \$/mg EPO
	Unit Production Revenue	25.00 \$/mg EPO

M.	Gross Profit (J-K)	79,989,000 \$/yr
N.	Taxes (25%)	19,997,000 \$/yr
O.	Net Profit (M-N + Depreciation)	65,195,000 \$/yr

	Gross Margin	70.04 %
	Return On Investment	110.34 %
	Payback Time	0.91 years

EPO = Flow of Component 'EPO' in Stream 'rHuEPO BDS'

