Recombinant t-PA production process expressed in *E. coli*

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SUSTAINABILITY ANALYSIS

This project consists on a complete sustainable analysis of recombinant t-PA production process. The objective is to elucidate its viability. Economic, environmental and social aspects of its production are further explored. First, the economic analysis allows us to determine whether the synthesis of the protein is cost-efficient. On the other hand, possible toxic effects are assessed to prevent damage in the environment. Finally, a social analysis is carried out to concur with laws and normative that may affect production of the protein, both regional or international.

ECONOMIC ANALYSIS

The economic feasibility of the project is analyzed in order to assess if gains are enough compared to the expenses. Costs are split in fixed or variables, which determine the expected time frame to recover the initial investment**(1)**. We have also analyzed the design sensibility to variations of the value of the parameters affecting critically the process viability: interest, sales and rt-PA price. Thus, the sensibility of the study is improved.

Fixed capital

INTRODUCTION	Value (Cost at 2013 in $)	% Regarding direct fixed capital
Direct cost (DC)	557,112,000	54
Indirect cost (IC)	334,267,000	32
Total cost(TC=DC+IC)	891,379,000	
Contractor and contingency fee(CCF)	133,707,000	13
Direct fixed capital cost (DFC=CCF+TC)	1,025,086,000	100

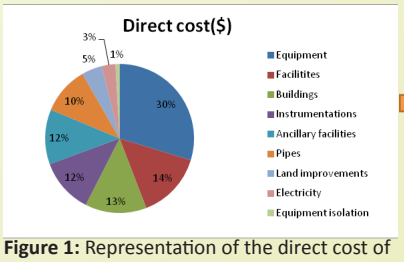

Figure 1: Representation of the direct cost of the procces. Based on data from superpro

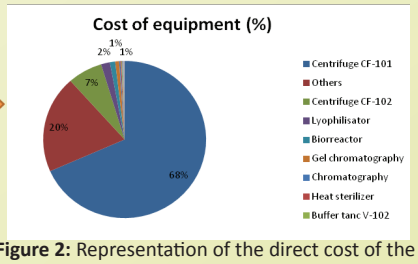

Figure 2: Representation of the direct cost of the equipment in %**(1)**. Based on data from superpro

Economic summary

INTRODUCTION	Value
Total capital investment	1,938,656,000 $
Cost of operation	733,487,000 $/year
Sales **(1)**	977,875,000 $/year
Annual production	46.33 kg/year
Unit cost production	15,830,873.43 $/kg
Price for sales	21,105,527.64 $/kg
Gross margin	25%
Return of inversion	12.59 %
Payback time	7.94 year
TIR (with taxes)	7.11 %
VAN (7% interest)	30,353,000 $

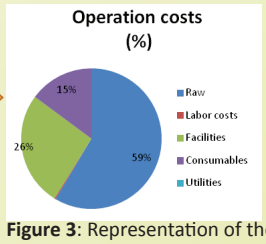

Figure 3: Representation of the opetaration cost in %. Based on data from superpro

This process can be carried out with benefits.

Sensibility analysis

Parameter		Value	Probability
rt-PA Price	Optimistic	17000-18000	12.5%
	Moderate	18000-20000	70%
	Pessimistic	20000-21000	12.5%
VAN Interest	Optimistic	7%-8%	13,6%
	Moderate	8%-10%	68,3%
	Pessimistic	10%-11%	13,6%
Sells forecasts	Optimistic	90%-100%	15,7%
	Moderate	70%-90%	63,8%
	Pessimistic	50%-70%	13,6

The aim of this analysis is to avaluate project's risk to changes in the value of the most important parameters affecting its economy.

The graphic shows that even with a **pessimistic prevision** (values with high interests and price and low sales) this project has chances around 80% to succed and provide gains in a reasonable time frame.

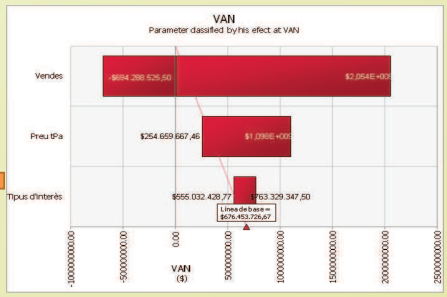

Figure 4: Representation of the importance of the factors.

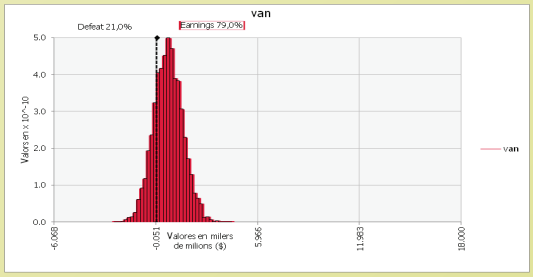

Figure 5: Sensibility analysis of VAN. Based on data from @risk

SOCIAL ANALYSIS

A qualified staff with the proper skills is needed in order to run efficiently the production process.
It directly involves 6 employees (acording to *Superpro* data). Additional staff will be contracted in order to develop research and direction of the plant. It is expected a proper salary according to the Chinese laws. The factory will comply all the patenting laws informing about its activities to the international community.

ENVIRONMENTAL ANALYSIS

COMPONENT ANALYSIS

COMPONENT	INPUT	OUTPUT	TREATMENT
Glucose	23.70 kg	2.40 kg	In each batch, 21.30 kg of glucose are consumed. We intend to recirculate all the output glucose. It would be useful have the plant near a glucose supplier to reduce the transport's costs.
IPTG	2.8 kg	2.8 kg	This is a very expensive reactive, so it is neccessary to recirculate all the IPTG to the economic viability of the process.
Biomass	1.2 kg	2.0 kg	A purge method is required to eliminate the debris and the biomass produced that cannot be recirculated.
Water	19584 kg	19594 kg	Is necessary a waste water treatment
Buffers	Buffers mainly consist on acids or basics. It will be easy to obtain salts and make them precipitate.		

WASTE WATER TREATMENT

Due to the presence of proteins and nucleic acids our wastewater has amount quantity of nitrogen and phosphor. In order to treat them the following steps were added to the conventional treatment **(2)**:

- In order to reduce the quantity of nitrogen is necessary to transform it to atmospheric nitrogen with an oxidation state of zero. It is possible to make it in two steps. A step of nitrification with a whole oxidation to nitrate using oxygen. Microorganisms implicated are *Nitrosomonas* and *Nitrobacter* oxidizing to nitrite and oxydizing amonium to nitrate respectively. This is followed with a second anaerobic step which reduces the nitrate to atmospheric nitrogen.
- Iremoving phosphates will be done by precipitation A key aspect is the plant location. It allows the decision of build a special water station or use facilities available on the area. In any case is contemplated in the investment.

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