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TECHNICAL INFORMATIONS

TECHNOLOGY TRANSFERENCE TO OBTAIN BENCIL PENICILLINA.

Assistent : Dr. Ermanno Piacenza Presence period : from 09.03.1992 to 20.03.1992

I - STRATEGY

- 1.- TRANSFERENCE OF METHODOLOGY AND PROCESS OF DENCIL PENICILLINA ESCALE.
- 2.- TRAINING IN BENCIL PENICH LINA EXTRACTION AND PURIFICATION PROCESS.

II - DELIVERED DOCUMENTATION AND MEANS

- 1.- THE METHODOLOGY FOR FERNENTATION UP TO A 1,5 m3 LEVEL HAS BEEN DELIVERED.
- 2.- THE THICHNICAL DOCUMENTATIONS FOR BENCIL PENICILLINA EXTRACTION AND PURIFICATION HAS BEEN DELIVERED.
- 3.- A 250 ml. FOR HPLC SYRINGE HAS BEEN DELIVERED (PROCESS CONTROL)

III- WORK DEVELOPMENT

- 1.- BENCIE PENICHTINA ESCALED PROCESS THEORICAL AND PRACTICAL EXPLICATION FROM DELIVERED DOCUMENTATION.
- 2.- PROCESS ESCALL UP TO FERMENTATION PILCO 42 L.
- 3.- QUALITY CONTROL TECHNICAL ASSEMBLY.

IV - ACHIEVED STRATEGY

- 1.- CUBAN TECHNICIANS HAVE DEEM TRAINED ON PRACTICAL KNOWLEDGE ON IMPLEMENTED FERMENTATION TECHNICS.
- 2.- PROCESS CONTROL TECHNICS HAVE BEEN INSTALLED AND SETTLED.

V - MAIN DIFFICULTIES

1.— THE FERMENTATION ON 42 L LEVEL HAS BEEN CONTANTNATED TWICE.

AN ESTERILIZATION TRIAL ON THE FERMENTER HAS BEEN REALIZED WITH REACH MEAN; BUT IT HAS CAUSED NEW CONTAMINATION ON THE FERMENTER.

AFTER A GLOBAL ANALISYS IT WAS ESTABLISHED THAT AIR INSTALLATION ON THE FERMENTER (FILTER INCLUDED) DOESN'T HOLD THE BEST TECHNICAL CONDITIONS.

VI- EXPERTISE CONSIDERATION

- 1.- MUST BE REACHED THAT AIR ARRIVING AT FINAL FERMENTER FILTER WILL BE FREE OF HUMIDITY.
- 2.- IT MUST BE INSTALLED A PRE-FILTER FOR THE AIR THAT IS SUPPLIED TO THE PERMENTER.
- 3.- IT MUST BE INSTALLED A MAJOR CAPACITY FILTER ON THE FERMENTER INCET.

VII- CUBAN PART CONSIDERATION

- 1.- WE ESTIMATE THAT EVEN IF A FULL FERMENTATION HASN'T BEEN INCLUDED CUBAN TECHNICIANS RECEIVED THE NECESSARY KNOWLEDGE TO REALIZE THE FERMENTATION FOR ITS OWN.
- 2.- WE WILL FOLLOW EXPERTISE CONSIDERATION TO GET BEFFER AIR INSTALLATION.
- 3.- THE NECESSARY FERMENTATIONS IN ORDER TO GUARANTEE TECHNOLOGY REPRODUCTIONS HAS BEEN MADE.

TECHNICAL REPORT

TECHNOLOGY TRANSFERENCE TO GET BENCIL PENICHLINA

Expertise : Dr. Ermanno Piacenza

Training period : from 06.07.1990 to 15.07.1990

from 26.08.1990 to 26.09.1990

STRATEGY: GETTING OF BENCIL PENICILLINA ON LABORATORY

ESCALE

DELIVERED DOCUMENTATION AND MEANS.

THE EXPERTISE ON HIS ARRIVAL, ACCORDING TO DWN - CHIMINTER MILANO CONTRACT, DELIVERED FECHNOLOGICAL BOOKS TO GET GENCIL PENICILLINA, AND MATERIALS LIST HERE ATTACHED, FOR EXPERIMENTAL WORK DEVELOPMENT.

WORK DEVELOPMENT

- 1.- BENCIL PENICIFLINA IFCHNOLOGY PROCESS THEORICAL AND PRACTICAL EXPLICATION FROM DELIVERED DOCUMEN-TATION.
- 2.- PREPARATION OF EXPERIMENTAL MEANS TO GET BENCH. PENICILLINA ON LABORATORY FERMENTERS LEVEL
- 3.- PROCESS CONTROL TECHNICAL ASSEMBLY.

ACHIEVED STRATEGY

BENCIL PENICILLINA CONCENTRATION REACHED AFTER 120 HOURS OF FERMENTATION WAS 13.500 UI/ml. THAT HAS BEEN DETERMINATED BY MICROBIOLOGICAL METHOD. THIS VALUE IS INSIDE THE RANGE ESTABLISHED ONT THE TECHNOLOGICAL BOOK DELIVERED BY THE EXPERTISE.

MAIN DIFFICULTIES

INITIAL FERMENTATION PROCESS TEMPERATURE WAS NOT THE CORRECT ONE.

THERE ARE NO INSTALLATION NECESSARY TO GET PERMENTATIONS AT 25 DEGREE C ON FERMENTERS LEVEL.

EXPERTISE AND PROYECT CUBAN TECHNICIANS CONSIDERATIONS.

EXPERTISE

PROPOSED STRATEGY WAS REACHED. I CONSIDER A GOOD EXPERIENCE FOR THE TECHNICIANS AND FOR ALL PROPER INVOLVED ON THIS PROCESS DEVELOPMENT.

- 1.- 1 CONSIDER NECESSARY REFRIGERATION FORTHERT INSTALLA-TION TO GET ADEQUATE TEMPERATURE OURTING FERMENTATION PROCESS.
- 2.- NEW TRIALS MUST BE MADE TO GET BLITER EXPERIENCE ON PROCESS AND MICRODREAMISM.

CUBAN TECHNICIANS.

WE CONSIDER THAT PROPOSED STRATEGY FOR FIRST STEP HAS BEEN REACHED.

CUBAN TECHNICIANS HAVE BEEN TRAINED ON BENCIL PENICITINA TECHNICAL GETTING FROM

FILAMENTOUS FUNGUS

DURING THIS PERIOD OUR TECHNICIANS GOT THE KNOWLEDGE OF THIS FERMENTATION AND OF INCREMENTED FERMENTATION WHICH WILL BE VERY INTERESTING ON FUTURE FERMENTATION PROCESS.

1.- WE CONSIDER VERY IMPORTANT TO INSTALL REFRIGHTATION EQUIPMENT TO GET ESCALE FERMENTATION OF 42 L.

RECEIVED MATERIAL TO GET G. POTASSIUM PENICIPLINA.