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CROSS FLOW AND CHROMATOGRAPHY WORKSHEET (CFCW)

Completed By: Date:

CUSTOMER INFORMATION			
Company Name:			
<input type="text"/>			
Address:			
<input type="text"/>			
City:	State:	Zip:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Name:		Title:	
<input type="text"/>		<input type="text"/>	
Contact E-mail Address:			
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TESTING INFORMATION

Services Needed: Tangential Flow Filtration (TFF) Chromatography

Will a Non-Disclosure Agreement be needed for this service? Yes No

Desired Test Objective :

PRODUCT INFORMATION

Product Name (to appear in protocols and reports):

Generic Name (if applicable):

Component of Interest (Product)

Molecular Weight Kd / Size nm

Concentration g/L

Stability

Temperature Limitations

Stabilizers Required

pH Limitations

Solubility

 g/L

Additives Required to Maintain Solubility

COMPLEXITY OF SAMPLES:

Total Concentration (sample mass)

 g/L

Other Components (major impurities)

Buffer / Solvent Composition

Buffer Salt / Solvent

Concentration

pH

pH adjusted with

Additives (i.e. antifoam, detergents, solvents)

Sample Age and History

Sample Origin

Cell Culture / Fermentation Biological Fluid Tissue Extract Other

How is Sample Prepared (previous purification steps)?

Biological Fluid Untreated

Culture Fluid / Fluid Fermentation Broth

What is cell line?

Mammalian

Bacterial (E. coli)

Yeast

Other

PRODUCT INFORMATION (Cont.)

- Viability of Cells
- Cell Concentration / Density
- Product in Cells Product in Culture Fluid

- From Chromatography
- Precipitation Centrifugation
- Other

Is Sample Filtered? Yes No Filter Porosity μm

When was sample prepared?

PROCESS OBJECTIVES

Concentration

1. Final Concentration Factor Required?
2. Final Volume?

Diafiltration (buffer exchange or desalting)

1. Percent Removal or Exchange Required?
2. Number of Diafiltration Volumes Required?

Fractionation

1. Molecular Weights of Components?
2. Required Degree of Separation?

Cell Harvest

1. Cell Concentration and /or Diafiltration (washing)? Yes No
2. Clarification (product in filtrate)

Virus Reduction

1. Virus to be Removed (size of virus)?
2. Required Log Titer Reduction?

Endotoxin Removal

1. Below What Level? EU / mL

PROCESS CONDITIONS / DATA
(FOR TANGENTIAL FLOW FILTRATION & CHROMATOGRAPHY APPLICATIONS ONLY)

Is this a New Process? Yes No

Sample Volume? Initial Final Concentration Factor

Retentate Flow Rate L / min.

CFF L/min./ft.²

Filtrate Flux Rate

1. Controlled with Filtrate Pump? Yes No

2. Initial L/m²h/ft.

3. Initial

Pressures

1. Initial P_{Feed} psi P_{Retentate} psi, P_{F Filtrate} psi, P_{F Filtrate} psi

2. Final P_{Feed} psi P_{Retentate} psi, P_{F Filtrate} psi, P_{F Filtrate} psi

Process Temperature °C

Process Time hr. min.

Process Recovery %

CLEANING
(FOR TANGENTIAL FLOW FILTRATION & CHROMATOGRAPHY APPLICATIONS ONLY)

Cleaning Regime

1. Cleaning Agent

2. Temperature °C

3. Time hour min.

4. Cycles

NWP after Cleaning

Membrane Recovery %

SCALE-UP OBJECTIVES
(FOR TANGENTIAL FLOW FILTRATION & CHROMATOGRAPHY APPLICATIONS ONLY)

Process Volume

1. Initial 2. Final 3. Concentration

Process Time hr. min.

Additional Information / Comments:

ENPRO USE ONLY

Approved By:

Date:

CFCW Job #: