

Downstream BioProcessing Questionnaire

Please answer the following questions as completely as possible.

I. Customer Information

CONTACT PERSON

COMPANY NAME

DESIGNATION

CONTACT NUMBER

DEPARTMENT

EMAIL ADDRESS

II. Experimental Details

a. General Details

1. The target molecule to be purified

2. Size or M_r of target molecule

3. NaCl/pH/T ranges within which the target molecule is stable

NaCl:

T:

pH:

4. Is the standard (purified target molecule) available?

Yes

No

5. Typical concentration of the target molecule (titer in the case of virus) in the sample that will be provided for the method/process development

6. Main impurities in the sample (Specify concentrations of each)

- DNA
- Proteins
-
- Lipids
- Endotoxin

7. Sample volume/total virus titer is available for the method development

8. Current detection/quantification method for the target molecule

- DNA/protein assays
- SDS PAGE
- qPCR
- Others
- ELISA
- Western blot
- Cell-based assays

9. Desired concentration of the target molecule in the final product

Concentration:

Unit of measurement:

- mg/mL
- total VP/mL
- infection VP/mL
- Others

10. Purity requirements of the final product (Host cell protein/DNA concentration, endotoxin content...)

11. Final formulation buffer

12. Other requirements regarding the method/process to be developed

13. Please describe upstream and downstream process detail or block scheme

II. Experimental Details

b. Virus Products (Skip if not applicable)

14. Virus condition needed

Live
 Attenuated

Killed

15. Virus Type

Wild type strain
 GMO

16. For GMO virus, please provide the detailed data/ document describng preparation of the GMO. (e.g., constructs, vectors, expression system used...)

17. What is the biosafety level of this virus? If safety assessment study is available, please provide the documentation.

Important: Save the completed PDF form (use menu File - Save).