



Cell line and Product Information

Please fill out this form as a prerequisite for planning and specifying the major steps of the respective project.

It will also be used as the basic for quotation and further discussion of project details.

All information provided will be treated strictly confidential. A secrecy agreement can be signed.

CLIENT

Company name:

Contact person:

Address:

phone:

fax:

email:

date:

1. CELL LINE

1.1. Type

Murine hybridoma: _____

Hetero hybridoma: _____

Human hybridoma: _____

Parent myeloma: _____

Other: _____

1.2. Name

1.3. Clonality

How many clonings have been carried out?

Number of clonings: _____

Method used: _____

1.4. Security Test

Has the cell line been tested for the following:

Mycoplasma:

Yes Result:

No

Assay system used: _____

Virus:

Yes Result:

No

Assay system used for what virus: _____

1.5. Biological activity and suspected hazard

2. PRODUCT INFORMATION

2.1. Specification

Monoclonal antibody (Ig class, subclass)

Other type of protein
(eg. recombinant or fusion protein, fragment)

Molecular weight

pH stability

pI

3. INFORMATION FOR PRODUCT IDENTIFICATION

3.1. Antigen available

Yes

If yes, in what form

No

3.2. Test system existing

Yes

If yes, what kind

No

4. CELL LINE DELIVERY

4.1. Cryo culture

Normal viability after recovery in culture _____

Number of cells per vial _____

Freezing Medium composition _____

4.2. Suspension

Number of cells per ml _____

4.3. Culture medium presently used

Basal medium _____

Serum

_____ If yes, which type

Conc: _____

Serum-free medium

_____ If yes, which type

More details _____

Other components _____

4.4. Culture system presently used

flask, fermenter or other, size used _____

Final cell density [cells / ml] _____

4.5. Present Cell line condition

Vitality, cell split / hours

Stability Tested

Yes

How long is it stable

No

Has the cell line been optimized for production?

Yes

If yes, in what system

No

4.6. Productivity Information

Product concentration

In flask culture

[mg/l], log phase, overgrowth

Bioreactor

Cell density at harvest

Fermenter

Specific productivity:

[mg/10⁶ cells/day] or

[mg/day]

5. ADDITIONAL INFORMATION

5.1. Product delivery

Batch size _____

Number of batches per time period _____

5.2. Product purification

Protein A

Protein G

Other, please specify _____

5.3. Confectioning

Buffer system, please specify _____

Concentration _____

Purity _____

5.4. Product analysis

Inquired test system, please specify: _____

Test system for product concentration: _____

Test system for product purity: _____

Test system for product activity: _____

Reference sample available Yes

Please specify: _____

No

Other parameter: _____