

Questionnaire for Contract Manufacturing / Outsourcing

Dear Customer,

To help us fill your order with the utmost degree of accuracy, efficiency and according to your needs, we would appreciate it if you would complete this questionnaire as precisely as possible and send it back to us. Thank you very much.

Company	Contact person
Street	
Area Code, City	
Country	
Phone	Fax
E-mail	Homepage

Product name/Code
Batch size
Annual need
Date of delivery

Order is a
<input type="checkbox"/> commercial batch <input type="checkbox"/> stability batch
<input type="checkbox"/> product development <input type="checkbox"/> clinical sample

1. Galenic form <input type="checkbox"/> lyophilised parenteral <input type="checkbox"/> aseptically filled, liquid parenteral <input type="checkbox"/> sterilized, liquid parenteral <input type="checkbox"/> other lyophilised product <input type="checkbox"/> other liquid product <input type="checkbox"/> other _____	2. Type of active ingredient <input type="checkbox"/> cytostatic <input type="checkbox"/> antibiotic (except β -Lactam) <input type="checkbox"/> hormone <input type="checkbox"/> other _____
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3. Processing instructions are available <input type="checkbox"/> yes <input type="checkbox"/> no If yes, please attach.

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4. Active ingredients name and specification

quantity / vial _____

active ingredient provided by the customer yes no

safety data sheet available yes no

release of the active ingredient by Biofactor customer

special properties _____

(i.e. toxicity, instability, etc.) _____

5. Inactive ingredients

inactive ingredient provided by the customer, please list

inactive ingredient to be provided by Biofactor, please list

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<p>6. Sterile filtration</p> <p>material of filter _____</p> <p>type or brand of filter _____</p> <p>prefiltration</p> <p>double filtration</p>	<p><input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>_____ <input type="checkbox"/> not known</p> <p>_____ <input type="checkbox"/> not known</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p>
<p>7. Preparation and filling</p> <p>filling quantity / vial (in ml or g) _____</p> <p>lyophilisation programme available</p> <p>duration of lyophilisation programme _____ hrs</p> <p>preparation under nitrogen</p> <p>filling under nitrogen</p> <p>other specific requirements</p> <p>if yes, which _____</p> <p>_____</p>	<p>_____ <input type="checkbox"/> not known</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>_____ hrs</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p>
<p>8. Primary packaging</p> <p>8.1 Vials</p> <p><input type="checkbox"/> moulded glass</p> <p><input type="checkbox"/> tube glass</p> <p>size _____ ml</p> <p>specific requirements _____</p> <p>_____</p> <p>vials are provided by the customer</p>	<p><input type="checkbox"/> transparent</p> <p><input type="checkbox"/> brown</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p>

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10. Controls

10.1 In-process-controls

Standard controls such as temperature, pH, filling amount, integrity of the filter, density, etc. are performed.

other IPC controls?

which?

methods available

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> yes | <input type="checkbox"/> no |

10.2 End controls

by Biofactor

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
|------------------------------|-----------------------------|

product specification available

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
|------------------------------|-----------------------------|

control concerning

- | | |
|--|--|
| <input type="checkbox"/> sterility | <input type="checkbox"/> water content |
| <input type="checkbox"/> endotoxins (LAL) | <input type="checkbox"/> content other methods |
| <input type="checkbox"/> pyrogens (rabbit test) | <input type="checkbox"/> purity other methods |
| <input type="checkbox"/> content HPLC | <input type="checkbox"/> visible particles |
| <input type="checkbox"/> purity HPLC | <input type="checkbox"/> other |
| <input type="checkbox"/> uniformity of the mass | _____ |
| <input type="checkbox"/> uniformity of the content | _____ |

methods can be performed

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
|------------------------------|-----------------------------|

reference substances supplied by the customer

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
|------------------------------|-----------------------------|

Stability tests

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> yes | <input type="checkbox"/> no |
|------------------------------|-----------------------------|

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11. Specific requests

storage of the final product in a cool place yes no

temperature: _____ °C

protection from light necessary yes no

other requests

12. Additional information

Date

Signature / Stamp