

<b>THYMOORGAN-GmbH</b> <b>Pharmazie &amp; Co.KG</b> Schiffgraben 23 D-38690, Vienenburg	Tel: +49 (0) 53 24 77 01 - 0 Fax: +49 (0) 53 24 77 01 30 Email: thymoorgan@t-online.de Homepage: www.thymoorgan.de
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## 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	
<b>1. Galenic form</b> <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 _____	<b>2. Type of active ingredient</b> <input type="checkbox"/> cytostatic <input type="checkbox"/> antibiotic (except $\beta$ -Lactam) <input type="checkbox"/> hormone <input type="checkbox"/> other _____
<b>3. Processing instructions</b> are available <input type="checkbox"/> yes <input type="checkbox"/> no If yes, please attach.	

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## Questionnaire for Contract Manufacturing / Outsourcing

### 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  customer  Thymoorgan

special properties \_\_\_\_\_

(i.e. toxicity, instability, etc.) \_\_\_\_\_

\_\_\_\_\_

### 5. Inactive ingredients

\_\_\_\_\_

\_\_\_\_\_

inactive ingredient provided by the customer, please list

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

inactive ingredient to be provided by Thymoorgan, please list

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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**6. Sterile filtration**

yes       no

material of filter \_\_\_\_\_  not known

type or brand of filter \_\_\_\_\_  not known

prefiltration  yes       no

double filtration  yes       no

**7. Preparation and filling**

filling quantity / vial (in ml or g) \_\_\_\_\_  not known

lyophilisation programme available  yes       no

duration of lyophilisation programme \_\_\_\_\_ hrs

preparation under nitrogen  yes       no

filling under nitrogen  yes       no

other specific requirements  yes       no

if yes, which \_\_\_\_\_

\_\_\_\_\_

**8. Primary packaging****8.1 Vials**

moulded glass       transparent

tube glass       brown

size \_\_\_\_\_ ml

specific requirements \_\_\_\_\_

\_\_\_\_\_

vials are provided by the customer  yes       no

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### 8.2 Stoppers

freeze dry stoppers     injection stoppers

material \_\_\_\_\_

exact name and manufacturer of stoppers \_\_\_\_\_

stoppers are provided by the customer     yes     no

### 8.3 Caps

Aluminium cap

Aluminium-cap with PE-disc

color \_\_\_\_\_

specific requirements \_\_\_\_\_  
\_\_\_\_\_

caps are provided by the customer     yes     no

### 9. Final packaging / Artwork

bulk, without labeling

bulk, with labeling

ready-made packed

artwork / film is provided by the customer     yes     no

### 9.1 Folding cartons

single folding carton

\_\_\_\_ vials / package

folding cartons/corrugated parts provided by the customer     yes     no

packaging with solvent     yes     no

solvent provided by the customer     yes     no

### 9.2 Labels

sample is attached     yes     no

labels are provided by the customer     yes     no

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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?

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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 Thymoorgan

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

product specification available

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

control concerning

- sterility
- endotoxins (LAL)
- pyrogens (rabbit test)
- content HPLC
- purity HPLC
- uniformity of the mass
- uniformity of the content

- water content
- content other methods
- purity other methods
- visible particles
- other

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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

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### 12. Additional information

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**Date**

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**Signature / Stamp**