

Export Service Inquiry Form

PREISMUSTER

1. Basic Documentation (CPP, GMP/GDP)

CPP Certificate (Certificate of Pharmaceutical Product)

Translation needed in _____

Apostille (Hague Convention)

legalized by embassy

Other: _____

Manufacturing license

copy/scan

legalized Copy

Translation needed in _____

Apostille (Hague Convention)

legalized by embassy

Other: _____

GMP Certificate (Good Manufacturing Practice)

copy/scan

legalized Copy

Translation needed in _____

Apostille (Hague Convention)

legalized by embassy

Other: _____

GMP Contract Manufacturing

- copy/scan
- legalized Copy
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

Manufacturing license Contract manufacturer

- copy/scan
- legalized Copy
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

GDP contract manufacturer

- copy/scan
- legalized Copy
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

GDP Certificate (Good Distribution Practice)

- legalized Copy
- copy/scan
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

Special Requirements/Notes:

2. Regulatory Documents

Do you need support for obtaining and preparing:

Modul 1		Modul 2	<input type="checkbox"/>	3.2.P.4	<input type="checkbox"/>
1.0 Cover letter	<input type="checkbox"/>	2.3.S	<input type="checkbox"/>	3.2.P.5.1	<input type="checkbox"/>
1.1 Tracking Table	<input type="checkbox"/>	2.3.P.	<input type="checkbox"/>	3.2.P.5.2	<input type="checkbox"/>
1.2 Application Form	<input type="checkbox"/>	2.4	<input type="checkbox"/>	3.2.P.5.3	<input type="checkbox"/>
QP declaration	<input type="checkbox"/>	2.5	<input type="checkbox"/>	3.2.P.5.4	<input type="checkbox"/>
Elemental Impurities	<input type="checkbox"/>	Modul 3	<input type="checkbox"/>	3.2.P.5.5	<input type="checkbox"/>
Nitrosamine	<input type="checkbox"/>	3.2.S	<input type="checkbox"/>	3.2.P.5.6	<input type="checkbox"/>
1.3.1 SmPC	<input type="checkbox"/>	3.2.P.1	<input type="checkbox"/>	3.2.P.6	<input type="checkbox"/>
1.3.2 PIL	<input type="checkbox"/>	3.2.P.2.1	<input type="checkbox"/>	3.2.P.7	<input type="checkbox"/>
1.3.3 Labelling	<input type="checkbox"/>	3.2.P.2.2	<input type="checkbox"/>	3.2.P.8.1	<input type="checkbox"/>
1.3.4 Readability testing	<input type="checkbox"/>	3.2.P.2.3	<input type="checkbox"/>	3.2.P.8.2	<input type="checkbox"/>
1.3.6 Braille	<input type="checkbox"/>	3.2.P.2.4	<input type="checkbox"/>	3.2.P.8.3	<input type="checkbox"/>
1.4.1 Expert Quality	<input type="checkbox"/>	3.2.P.2.5	<input type="checkbox"/>	Modul 4	<input type="checkbox"/>
1.4.2 Expert Non-Clinical	<input type="checkbox"/>	3.2.P.2.6	<input type="checkbox"/>	Modul 5	<input type="checkbox"/>
1.4.3 Expert Clinical	<input type="checkbox"/>	3.2.P.3.1	<input type="checkbox"/>	E-CTD	<input type="checkbox"/>
1.5. Information on bibliographic/generic applications	<input type="checkbox"/>	3.2.P.3.2	<input type="checkbox"/>		
1.6 Environmental Risk Assessment	<input type="checkbox"/>	3.2.P.3.3	<input type="checkbox"/>		
1.8.1 Pharmakovigilance system	<input type="checkbox"/>	3.2.P.3.4	<input type="checkbox"/>		
1.8.2 Risk Management-Plan	<input type="checkbox"/>	3.2.P.3.5	<input type="checkbox"/>		

3. Country-Specific Labels and Box Inserts

- Primary packaging
- Carton/Box
- Package insert

- Packaging in German
- Packaging in other languages:

- printed Mockup must be approved by authority

Special Features:

- With serialization features (Track & Trace, security features)
- Accessible design (Braille, large print)

4. FINAL REMARKS

Special requirements or special features:

Signature and Confirmation

Data Protection Declaration:

I confirm that I have read and understood the data protection provisions and agree to the storage and processing of my data.

- Confirmation read and accepted

Signature of Applicant

Date

Contact Person (if different)