NAME OF THE COMPANY:

ADDRESS:

WAREHOUSE ADDRESS:

VAT NUMBER

IBAN

BIC/SWIFT

Contact person:

TEL.:

FAX:

E-Post / Email:

COMPANY ACTIVITIES:

- [ ] Wholesale with pharmaceuticals

- [ ] Import/Export outside EU/EEA (both only export)

- [ ] Other activities (List) including those that require a manufacturing authorisation:

with/from

- [ ] Human medicines
- [ ] veterinary medicines
- [ ] Blood/blood products
- [ ] Nutraceuticals
- [ ] controlled substances/narcotics
- [ ] Animal vaccines
- [ ] Materials whose handling is subject to special documentation requirements
- [ ] Other:

Introduction

1.1 Information on suppliers

- [ ] Pharmaceuticals are sourced from:
- [ ] Pharmaceutical manufacturers / MAH, domestically
- [ ] Pharmaceutical manufacturers / MAH, rest of EU /EEA
- [ ] Pharmaceutical manufacturers / MAH, third country
- [ ] Wholesalers domestically
- [ ] Wholesalers rest of EU / EEA

☐ Other such as brokers, agents. Please specify:

1.2 Date of the last official GDP inspection:

1.3 Name of the inspecting authority:

1.4 Forwarding a current wholesale distribution authorisation:

When was the current wholesale distribution authorisation issued?

Please enclose a copy ☐ already sent

Do you trade with narcotics or blood products?

☐ yes ☐ no

Do you have the required authorisations?

☐ yes ☐ no

If "yes": Please enclose a copy of the authorisation / ☐ already sent

1.5 ISO Certification

☐ yes ☐ no ☐ n/a

If "yes": Please enclose a copy / ☐ already sent

1.6 Date of the last Audit by a company:

☐ n/a

1.7 Name of the auditing company:

☐ n/a

Further information

2.1 Please name the responsible person according to GDP

		Y	N	NA	Description
2.2.1	Is a working GDP QS system implemented according to the type and scope of the activities performed?	☐	☐	☐	
2.2.2	Is the management actively involved in this system?	☐	☐	☐	
2.2.3	Are the written process descriptions regularly checked and updated if necessary?	☐	☐	☐	
2.2.4 a)	Is it guaranteed in an appropriate manner that Pharmaceuticals are only acquired from - qualified, - authorised - licensed suppliers?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	
b)	The quality is not negatively affected during storage and transport?	☐	☐	☐	
c)	Deliveries can be tracked and recalls can be performed (is there a Written recall plan)?	☐	☐	☐	
d)	The relevant authority and parallel distributor are immediately notified of occurrences of falsified pharmaceuticals (counterfeits)	☐	☐	☐	
e)	Parallel distributor is immediately notified of occurrences of recalls?	☐	☐	☐	

2.2.5 What is your strategy to prevent the purchase of probably falsified pharmaceuticals/counterfeits?

2.3 Personnel

		Y	N	NA	Description
2.3.1	Have rules been set on the responsibilities and competencies of the person(s) responsible in a verifiable manner?	☐	☐	☐	
2.3.2	Is the instruction of new employees guaranteed? How?	☐	☐	☐	
2.3.3	Do the employees receive instruction on a regular basis?	☐	☐	☐	

2.3.4. How do you authorise the quality assurance staff?

2.3.5. What is your policy to raise awareness of your staff against counterfeit?

2.4 Facilities, Rooms and equipment, storage

		Y	N	NA	Description
2.4.1	The company has special storage areas for				
	Refrigerated storage	☐	☐	☐	
	Freezer storage	☐	☐	☐	
	controlled substances (narcotics)	☐	☐	☐	
	Hazardous materials / cytostatics	☐	☐	☐	
2.4.2	Are the premises suitable according to type, state and set-up? How?	☐	☐	☐	
2.4.3	Are the premises protected from access by unauthorised parties?	☐	☐	☐	

2.4.4 Are rooms and facilities regularly cleaned? ☐ ☐ ☐

2.4.5 Is there sufficient protection against pests? ☐ ☐ ☐

2.4.6 Are appropriate climatic conditions guaranteed in the storage premises:

2-8 °C ☐ ☐ ☐

not above 25°C (e.g. 15-25°C)? ☐ ☐ ☐

2.4.7
a) Are the cool climatic conditions (2-8°C)

- validated, ☐ ☐ ☐

- monitored and ☐ ☐ ☐

- recorded in the storage areas? ☐ ☐ ☐

2.4.7
b) Are the other climatic conditions < 25°C (e.g. 15-25°C)

- validated, ☐ ☐ ☐

- monitored and ☐ ☐ ☐

- recorded in the storage areas? ☐ ☐ ☐

2.4.8 In case of temperature deviations: Is there an functional alarm system installed

2-8 °C ☐ ☐ ☐

not above 25°C (e.g. 15-25°C)? ☐ ☐ ☐

2.4.9 Is a procedure specified for dealing with faults during storage of the pharmaceuticals requiring cold storage? ☐ ☐ ☐

2.4.10 Are cold chain products packed at 2-8°C? ☐ ☐ ☐

2.4.11	Are there separate or secure areas determined for quarantined, counterfeited or reclaimed pharmaceuticals	☐	☐	☐	
2.4.12	Are cytostatics and hazardous materials adequately stored?	☐	☐	☐	
2.4.13	Is it ensured that no expired pharmaceuticals are shipped out?	☐	☐	☐	

2.5 Sourcing and delivery

		Y	N	NA	Description
2.5.1	Is the temperature controlled and reported during				
	incoming cold transports (2-8°C)	☐	☐	☐	
	incoming other transports (not above 25°C)?	☐	☐	☐	
2.5.2	Is the quality of the pharmaceuticals ensured during transport from your source to your warehouse, e.g. cold chain products?	☐	☐	☐	
2.5.3	Are the pharmaceuticals protected during transport and protected from the access of unauthorized parties during incoming transports from your source to your warehouse?	☐	☐	☐	
2.5.4	Are product integrity, compatibility with the order and the delivery permit checked when the product is accepted?	☐	☐	☐	
2.5.5	Loading for supply: Are cold chain products transferred immediately from 2-8°C area to fridged truck?	☐	☐	☐	

2.6 Documentation

		Y	N	NA	Description
2.6.1	Do the delivery documents for the purchase and delivery have the following information?				
a)	Delivery date	☐	☐	☐	

b)	Name, quantity and strength of the pharmaceutical	☐	☐	☐	
c)	Name and address of the supplier and recipient	☐	☐	☐	
d)	Batch number and expiry date, where applicable	☐	☐	☐	
2.6.2	Are the required records kept on				
a)	Reclaim	☐	☐	☐	
b)	Return	☐	☐	☐	
c)	Destruction	☐	☐	☐	
d)	Recalls?	☐	☐	☐	
2.6.3	Are records kept for at least 5 years?	☐	☐	☐	
2.6.4	Can it be ensured that electronic data records are safely stored during the total required storage period and can be made available to read within a reasonable period of time?	☐	☐	☐	
2.6.5	Are records kept to document that products are in free circulation in the EEA	☐	☐	☐	

2.7 Returned pharmaceuticals Does not concern Recalls for which there are separate procedures

		Y	N	NA	Description
2.7.1	Are returned pharmaceuticals stored separately?	☐	☐	☐	
2.7.2	Is a written test instruction available that must be applied to returned pharmaceuticals before they can be restoraged in the warehouse including the following criteria?	☐	☐	☐	
a)	Receipt of the purchase from an authorized company	☐	☐	☐	
b)	Explanation of the returning party that the pharmaceuticals can legally be placed on the market, have not left his sphere of responsibility and have been properly stored and handled?	☐	☐	☐	

c)	Inspection for integrity and check of original containers	☐	☐	☐	
d)	Sufficient remaining shelf life	☐	☐	☐	
e)	Check of marketability	☐	☐	☐	
2.7.3	Are the organisational processes recorded in written procedures?	☐	☐	☐	
2.7.4	Is the personnel especially trained?	☐	☐	☐	

2.8 Self-inspections

		Y	N	NA	Description
2.8.1	Are self-inspections performed regularly?	☐	☐	☐	
2.8.2	Can it be ensured that all relevant areas are checked?	☐	☐	☐	
2.8.3	Are records kept on self-inspections and the remedy of deficiencies?	☐	☐	☐	

Date

Name of responsible person according GDP, in block letters

Signature

Stamp