General Terms and Conditions of Supply and Payment

Valid from: 25 January 2019

A. Scope

(1) Complementing the individual contractual agreements and the statutory provisions, these General Terms and Conditions of Delivery and Services (GTC) shall apply to our deliveries and services for the entire commercial transactions between us and the purchaser, the ordering party or principal, hereinafter Principal.

(2) We expressly object to general terms and conditions of trade/delivery of the Principal. They shall only bind us in the event that we agree to them in writing. Nor shall they be deemed incorporated into the contract by acceptance of an order. Silence on our part shall not be deemed acceptance of such general terms and conditions of trade/delivery. These GTC shall apply even if we accept payment or render services while being aware of conflicting or diverging conditions of the Principal.
At the latest, the Principal expresses its consent to our Conditions by taking delivery of our goods or our services.

(3) If these GTC become a part of contracts with the Principal by being incorporated legally, they shall, in the event of continued business relations between us and the Principal, also apply to all future contracts without renewed incorporation into the contract until our new GTC become valid.

(4) In general, all agreements that are or will be made between us and the Principal must be put in writing for reasons of greater verifiability.

B. Scope of the Contract

(1) Our offers are without obligation and non-binding. All transactions and conclusions of contract shall only become binding for us if they are confirmed in writing or the ordered services are executed. This shall also apply to amendments, modifications or supplemental agreements.

(2) The type and scope of the services owed by us shall be governed by the agreements reached, the provisions applicable at the time of the conclusion of the contract being taken as a basis unless explicitly agreed otherwise.

(3) If we render services, we shall only owe our services, but not a specific result to be achieved therefrom, unless explicitly agreed otherwise in writing.

(4) If the body of rules, including but not limited to the technical regulations (such as cGMP (EU-GMP/AMWHV[1]), is modified during the course of performance, this shall not imply a modifica-

[1] Verordnung über die Anwendung der Guten Herstellungspraxis bei der Herstellung von Arzneimitteln und Wirkstoffen und über die Anwendung der Guten fachlichen Praxis bei der Herstellung von Produkten menschlicher Herkunft, German statutory instrument on the application of good manufacturing practice of medicinal products and active pharmaceutical ingredients and the application of Good professional practice in manufacturing of products of human origin, also called Arzneimittel- und Wirkstoffherstellungsverordnung

tion of the services owed by us. To the extent that this is possible and they are aware of them, the contracting parties will, however, inform each other about the intended or implemented modifications during the period of performance. The contracting parties will mutually agree on any necessary extension or modification of our obligation of performance.

(5) The Principal must, in good time, take any and all measures, make any and all declarations or make any and all documents available that are necessary to facilitate us to perform under the contract.

C. Holding Harmless

The Principal guarantees that it has acquired all rights to the documents or products respectively submitted to us and that no third party rights, including but not limited to, trademark and patent rights are infringed, and that it is not prevented from exploiting the aforementioned documents or products respectively by being bound otherwise or any legal prohibitions. The Principal will indemnify and hold us harmless in the event that any claims are asserted by third or if any measures are taken by the authorities relating to the use of the aforementioned items under the contract.

D. Modifications, Test Parameters

(1) In the case of lacking or incorrect information by the Principal, we reserve the right to appropriately modify the scope of the performance. Any disadvantages thus incurred, including but not limited to, disadvantages due to costs or damages, shall be borne by the Principal.

(2) For orders, whose proper execution requires deviations from the specifications in the relevant order in terms of scope and/or duration, we are entitled to adapt performance according to the prices as amended from time to time to such extent as required by the professional and proper execution of the order. The provision in B (4) shall remain unaffected by this.

(3) For tests that involve the application of specific measured or control values or any other test parameters, the relevant test methods must be determined and accepted by both parties prior to beginning of delivery. If no methods are determined, our test methods shall apply.

E. Details, Suitability, Ownership of Documents

(1) Any kind of consulting, both written and spoken, will be provided to the best of our knowledge based on our experience.
Details about our services or products, including but not limited to, those in our brochures, catalogues, other documents and electronically displayed media, such as the Internet, including but not limited to, details about the suitability and use of our services and products do not contain themselves contain any representations and are not binding, unless explicitly designated as being binding in our offer or an order confirmation. They do not release the Principal from conducting its own tests and trials.
This includes but is not limited to, the Principal not being released from checking the suitability of our services, products and recommendations for the intended and any further purposes of

use. This applies, including but not limited to, adherence to statutory and official provisions when using our services and products.

(2) Reports, opinions, analysis results and other documents, as well as specimen, samples and any other items we provide for execution of the order will remain our property and must be returned to us upon request. We reserve any and all rights, including but not limited to copyrights, to them. They must not be made accessible to third parties or used for any purpose other than the purpose for which they have been made available to the Principal. This applies particularly, but not only, documents designated as confidential. The Principal must obtain our express written approval prior to forwarding documents to third parties.

F. Delivery Periods and Delivery Dates

(1) Delivery periods shall commence upon receipt of our order confirmation at the Principal's, but not before full clarification of any and all details of the order and receipt of all information or documents to be supplied by the Principal; this applies to delivery dates accordingly.
If the subject matter of the order is changed by mutual consent, the delivery date will become invalid and must be newly agreed.

(2) Commencement of the agreed delivery period requires the full clarification of all conditions that are substantial for performance. Adherence to our obligations to perform shall require, including but not limited to, proper performance of the Principal's obligation in good time. Otherwise, the delivery period will be extended by an appropriate term.

(3) The delivery periods stated by us are approximate, unless a binding delivery date was explicitly agreed. If we are responsible for the delayed delivery and we have been set an appropriate additional time limit without success, the Principal may withdraw from the contract. Unanticipated events (laid down in detail in Section K) shall lead to an appropriate extension of the delivery period.
We reserve the right to partial and subsequent deliveries to the extent that may be reasonably expected from the Principal. If we are unable to perform even after an appropriate extension of the delivery period, both the Principal and we are entitled to withdraw from the contract. The provision in Section K shall apply to claims of the Principal for damages due to delayed delivery.

G. Remuneration

(1) The prices depend on the offer. They are quoted in euros, net, exclusive of statutory value-added tax. For our services, our current service rates shall apply, which the Principal may request from us.

(2) The prices stated in our offers are exclusively related to the services and expressly do not include:
   a) Expenses for the involvement of third parties that are required to render performance. This refers, including but not limited to, fees of involved authorities, authentications and translation costs, as well as shipping charges.
   b) Costs and expenses for required legal advice and/or legal representation.
   c) Travel costs as well as costs and expenses for presentation on site.

(3) We are entitled to appropriately adapt the agreed price if modifications occur prior to or upon the execution of the order because the statements given or the documents provided by the Principal were faulty and/or the customer wishes other modifications.
(4) We are entitled to request an appropriate advance payment upon conclusion of the contract. Interest will not be paid for this.
(5) Invoices shall be due 2 weeks after the date of the invoice, but no later than 2 weeks after receipt at the Principal's. They are payable without deduction. In the event of failure to pay, the Principal shall be in default of payment after the due date, even in the absence of a reminder.
(6) Early payment discounts and discounts shall not be granted.

H. Set-off, Rights of Retention

(1) The Principal is only entitled to set-off against claims that are undisputed, acknowledged or determined by final court judgment.
(2) Assignment of receivables against us requires our approval.
(3) The Principal shall have a right to retention only if the counterclaim is based on the same contractual relation and acknowledged, undisputed, ready for decision or determined by final court judgment, or if we have fundamentally violated obligations under the same contractual relation despite a written warning and not offered appropriate collateral. If our performance is undisputedly defective, the Principal shall only be entitled to withhold payment to such extent the retained amount is in appropriate proportion to the defects and the anticipated costs for remedy of the defect.

I. Termination

(1) The contract shall enter into force upon signing by both contracting partners and shall be in force until termination by either contracting party.
(2) Routine notice (ordentliche Kündigung) must be given in writing by registered letter with advice of delivery with three months' notice to the end of the year. The right to cancel for good cause remains unaffected.
(3) Amendments and supplements to the contract and its appendices shall be made by mutual consent and must be made in writing.

J. Limitation, Suspension of Limitation

(1) Any and all claims of the Principal against us, regardless of the legal grounds, shall become statute-barred one year after delivery of the performance at the latest. Mandatory statutory limitation periods shall remain unaffected thereof.
(2) The limitation period pursuant to Subsection 1 sentence 1 shall not apply in the event of intent if we have fraudulently concealed the defect, given a guarantee for the quality of the thing, in the event of claims for damages due to injury to life, limb, health or freedom of a person, in the event of claims under the German Product Liability Act (Produkthaftungsgesetz), in the event of a grossly negligent breach of obligation or in the event of a culpable breach of fundamental

obligations under the contract and in the event of applicability of the statutory provisions under the law on sales of consumer goods.

(3) Measures for cure, i.e. delivery of a thing free of defects or the remedy of defects, shall not have the limitation period start anew, but shall solely suspend the limitation period that applies to the initial delivery item by the duration of the executed measure for cure. Execution of cure by us shall not be deemed acknowledgement in terms of Section 212 No. 1 of the German Civil Code (BGB).

(4) The clauses above shall not involve any change in the burden of proof to the disadvantage of the Principal.

(5) Unless explicitly laid down otherwise, the statutory provisions on the commencement of limitation, suspension of expiry, suspension and recommencement of periods shall remain unaffected.

K. Force Majeure

Force majeure events and substantial, unforeseeable hindrances beyond our reasonable control, such as strikes, lockouts, failures by sub-suppliers to meet delivery deadlines or delivery failures by sub-suppliers, interruptions of operations, distribution or supply due to lack of energy, raw materials or workforce, difficulties in the procurement of transportation, traffic interruptions, acts of higher authority, be it at our company or our suppliers, shall release us from our contractual obligations for the duration of such measures and obstacles. Neither shall we be responsible for the conditions above if they occur during any existing default on our part. The Principal will be immediately informed of the commencement and end of such measures and obstacles or the unavailability of the delivery item respectively. If the delivery is delayed by more than 4 weeks due to such measures and obstacles, then the contracting parties are entitled to withdraw from the contract. In the event of a withdrawal, any consideration already rendered will be reimbursed. Further claims are excluded.

L. Limitations of Liability

(I) Breach of Duty due to Defects, Complaints, Liability

(1) Complaints about recognisable defects may only be considered if notification of this is given in writing immediately, but no later than within 8 calendar days after receipt of performance. In the event of failure to do so, performance shall be deemed accepted. Timeliness of the notification shall depend upon the point in time of their receipt at our company.

(2) In the event of justified complaints, our liability shall, as a rule, be limited to cure (Nacherfüllung), i.e. to a replacement delivery or repair at our discretion.
If cure has failed or if we are not able to cure, the Principal shall be entitled to reduce the purchase price or to withdraw from the contract at its discretion. To claims for damages, L (II) shall apply to claims for damages. Any further claims of the Principal other than those stated above shall be excluded regardless of their legal grounds.

(II) Damages

(1) We shall be liable for damages regardless of the legal grounds, including but not limited to breach of duties under this obligation and for tortious acts solely in the following cases:
   1. Intent,
   2. In the event of injury of life, body, or health,
   3. To the extent that we have given a guarantee for the quality of performance or a specific result of a performance, and for liability under the German Product Liability Act (Produkthaftungsgesetz) or the mandatory provisions under the Germany Medicinal Products Act (Arzneimittelgesetz),
   4. To the extent that statutory provisions provide for no-fault liability in other cases,
   5. If the Principal cannot be reasonably be expected to accept performance by us in the event of breach of any other obligations as defined in Section 241 subsection 2 of the German Civil Code (BGB),
   6. In the event of grossly negligent breach of duty, and
   7. In the event of breach of fundamental contractual obligations, unless liability is already incurred under Subsection L (I); for the rest, our liability is excluded.
      "Fundamental obligations under the contract" are obligations which protect the Principal's legal positions that are substantial under the contract and which must be granted to the Principal under the contract with regard to the contract's content and purpose; fundamental are also such contractual obligations whose performance is essential to facilitate proper execution of the contract and upon whose performance the Principal usually relies and may be expected to rely.

(2) In the case of Subsection L(I), we shall only be liable for the typical and predictable damage.

(3) Any claims for damages asserted against us due to damage to property or products shall be limited to the amount of our coverage of our commercial third party and product liability insurance amounting to a maximum of 2 million euros. This limitation of liability shall not apply if we are liable due to intent, gross negligence, culpable breach of fundamental obligations under the contract or pursuant to the German Product Liability Act (Produkthaftungsgesetz) and in those cases where the Principal asserts claims for damages based on guarantee or representation of existence of a characteristic given by us, unless the purpose of the guarantee of the quality only refers to the contractual compliance of the underlying delivery, but not the risk of consequential damage.

(4) The duty of replacement is also excluded to the extent that the Principal, on its part, has effectively limited its liability vis-à-vis its customer. In this regard, the Principal will endeavour to limit liability to the extent permissibly under law to our benefit as well.

(5) All aforementioned exclusions and limitations of liability respectively shall, to the same extent, apply to our legal representatives (gesetzliche Vertreter), executives and non-executive employees (leitende und nichtleitende Angestellte) and any other persons used to fulfil its obligations (Erfüllungsgehilfen) as well as subcontractors.

(6) The clauses above shall not involve any reversal of the burden of proof.

M. Secrecy

(1) The Principal undertakes to use the audit reports and information contained therein solely for the purpose of this agreement (see Section O(III) Legal Basics), to maintain secrecy about the information contained therein and not to disclose it in full or in part to third parties. Forwarding any received information to third parties is not permitted without Diapharm's approval in writing, not even under a relevant non-disclosure agreement. Third parties refer to companies that are not affiliated with the Principal.

(2) The Principal is prohibited from directly or indirectly exploiting audit reports, information contained therein or parts thereof in any form whatsoever for commercial, scientific or other purposes without Diapharm's prior written approval.

(3) Furthermore, the Principal undertakes to make audit reports available only to those employees and natural persons or legal entities engaging otherwise for the Principal who necessarily require them for the purpose of this Agreement and who must deal with them because of their position within the company.
These persons shall be bound to secrecy by the Principal to the same extent as laid down in this Agreement, and such obligation to secrecy shall apply even in the time after termination of the contractual relations undertaken with them, insofar as this is legally admissible.

(4) The obligation to secrecy shall not apply to audit reports, information contained therein or parts there, insofar as
   a) the Principal had been aware of them already before or at the time of disclosure by Diapharm,
   b) they were known to the public or generally accessible prior to or at the time of disclosure by Diapharm,
   c) they become accessible to the public without the contribution or fault on the part of the Principal after disclosure by Diapharm,
   d) they had been made accessible to the Principle by a third party authorised to do so without breach of secrecy at any time, or
   e) the Principal has developed them or had them developed regardless of the knowledge of the audit reports,
   f) are used for submission to or for the inspection by authorities.

   The burden of proof for the exclusions shall be borne by the Principal. The secrecy clause shall apply for a term of 10 years commencing at the time of the last order being placed (individual order) under this master agreement.

N. Jurisdiction, Applicable Law, Place of Performance, Invalidity, Data Privacy

(1) The place of the exclusive local and international jurisdiction for all disputes arising from this contractual relation by and between the parties shall be the court having territorial jurisdiction at our registered office, i.e. Münster. This shall also apply to disputes regarding deeds, bills of exchange or cheques. However, we are also entitled to sue the Principal at its registered office.

(2) For contractual relations with the Principal, the law of the Federal Republic of Germany shall apply exclusively. The application of the UN Convention on Contracts for the International Sale of Goods (CISG – Vienna Sales Convention) of 11 April 1980 is excluded.
(3) Unless otherwise agreed, the place of performance shall be our registered office in Münster.
(4) In the event that a provision of these GTC and the other agreements reached is or becomes invalid, the validity of the remaining provisions shall not be affected. The contracting partners shall endeavour to replace the invalid clause by such clause that corresponds as closely as possible to the economic purpose and legal meaning of the original wording by considering the pertinent statutory provisions.
(5) Within the scope of the business relation, we save personal data of the Principal by means of electronic data processing pursuant to the Federal Data Protection Act (Bundesdatenschutzgesetz).

O. Special Conditions for Audits

I. Subject Matter of the Agreement

(1) Subject matter of the contract forming the basis of these GTC is the coordination of execution of independent audits of API manufacturers and sale of the relevant audit reports by Diapharm to the Principal. As a rule, Diapharm commissions the company blue inspection body GmbH as an independent, accredited inspection body to carry out such audits and prepare the audit report. If, in exceptional cases, blue inspection body GmbH is not or cannot be commissioned, Diapharm will contact the Principal and discuss the further procedure with the Principal.
(2) These provisions govern the basic matters between the contracting parties regarding coordination of individual and shared audits respectively and the acquisition of the relevant API audit reports.
(3) An individual order for the acquisition of an audit report, as stated above, on the qualification of an API manufacturer or for auditing of an API manufacturer's compliance with GMP in the production of one or several specified APIs or excipients shall be placed by the Principal making an order in writing to Diapharm (individual order).

II. Contracting Partners

(1) Diapharm is a consulting company focusing on Regulatory Affairs and offers pharmaceutical companies services relating to healthcare products. Diapharm coordinates, including but not limited to, the execution of independent audits of manufacturers of pharmaceutical APIs and excipients; such audits being conducted as individual or as joint audits for the customers, and, in this context, provides audit reports of these audits from selected API manufacturers. The audit reports are, as a rule, created by the company blue inspection body GmbH, a company accredited according to ISO/IEC standard 17020 (see below) to inspection API and excipient manufacturers.
(2) The Principal is a medicinal products manufacturer that manufactures or has manufactured and distributes medicinal products within Europe. The Principal is obliged to confirm GMP compliance for the APIs it uses. This confirmation must be issued by the Principal's Qualified

Person (QP). Details are given in Section III, “Legal Basis”. The Principal intends to have audits conducted to ensure GMP compliance by third parties (what is called "third party audits”).

III. Legal Basis

(1) APIs that are used for the manufacture of medicinal products within Europe or Germany, respectively, must be manufactured according to GMP requirements. These requirements are laid down in the Directive 2001/83/EC1 and in Section 13, subsection 3 of the German statutory instrument on manufacture of medicinal products and APIs (AMWHV) of November 2006. GMP Compliance of the APIs used must be confirmed in writing by the medicinal products manufacturer. This confirmation must be issued by the medicinal products manufacturer's Qualified Person. This provides the basis for the obligation for appropriate qualification of the API suppliers and consequently also the execution of relevant on-site audits of the API suppliers.

(2) The requirements for audits at API suppliers are determined by the EMEA Guidance INS/GMP/313538/2006, by EMEA’s Q&A document about supplier audits, by the German statutory instrument on manufacture of medicinal products and APIs (AMWHV) and by the EU-GMP-Guideline Part II (corresponding to the Guideline ICH Q7A). These documents stipulate, inter alia, that the audit plan shall be set up following a comprehensible risk evaluation and that the audits shall be conducted following a standard operating procedure on planning, executing, reporting and follow up.

(3) EMEA's Q&A document on supplier audits make it clear that commissioned audits by third parties, so-called "3rd party audits”, are possible as well. Joint use of audit reports ("shared audits") is also possible. The following conditions must be met in the event of commissioned audits:

- Qualification of the auditor by the medicinal products manufacturer
- Creation of audit reports
- Evaluation of the audit reports by the medicinal products manufacturer
- Availability of the audit reports for inspection by authorities
- Contractual commitment of medicinal products manufacturer and auditor
- Ruling-out of conflicts of interest

The execution of audits by third parties is also allowed by the German statutory instrument on manufacture of medicinal products and APIs (AMWHV).

IV. Third-party inspection body

(1) Diapharm commissions a third-party inspection body which is an accredited, independent inspection organisation for execution of API audits worldwide. This inspection body is accredited according to ISO/IEC 17020 (“Requirements for the operation of various types of bodies performing inspection“) as a contract auditor for the field “Inspections of starting material and active pharmaceutical ingredient manufacturers for pharmaceutical products and assessment of conformity with international GMP rules“.

(2) Following its quality management system, the third-party inspection body creates audit reports for its customers based on the EU community format for submission to authorities and - depending on the order – also monitors the API manufacturers' compliance with GMP.

(3) According to the awarded accreditation, the third-party inspection body is an independent inspection body ("type A" inspection body). The audited company and the commissioned body do not maintain a business relationship. The inspection body will check this aspect and any other potential conflicts of interest prior to the beginning of the audit and record the result in writing.

(4) The third-party inspection body follows a QM system which takes into account all relevant legal provisions (see also Section III "Legal Basis") on the proper execution of audits. The Principal is entitled to inspect this QM system.

(5) Diapharm shall ensure that the selected inspection body and the inspection body's inspectors execute the API audits on-site based on their accreditation and following their QM system, and that they are suitable and sufficiently qualified. The Principal is entitled to verify the auditors' qualification. However, the inspection body shall assign inspectors to a planned audit at its own discretion following its inspection policy and is authorised to exchange them at short notice, as the case may be.

V. Rights and Duties of the Principal

(1) The Principal is obliged to contribute to the preparation and execution of the audits to the best of its ability, i.e., for example, to inform the contracting parties being part of the pharmaceutical value-added chain of the awarding of audit contracts to third parties, to disclose these contracting parties to Diapharm and – if required – to issue written confirmations authorising Diapharm to execute the audits.
The Principal will support Diapharm prior to the audit and submit existing documents to facilitate reasonable execution of the audit. These include, but are not limited to,

- Quality handbook (excerpt)
- Organisation chart of the company
- Filled in, up-to-date quality/company questionnaire
- Manufacturing process
- Drug Master File (DMF) open part
- Product specification
- Product Quality Review (PQR)
- Additional certificates, if applicable
- List of SOPs incl. important SOPs such as
  - Change management
  - Deviations
  - Supplier qualification
  - Batch releases
  - Self-inspection
  - Complaints / corrective and preventive measures
  - Validation / qualification

(2) The Principal is entitled to exert an influence on the audit by formulating questions in advance.

VI. Rights and Duties of Diapharm

(1) Diapharm receives the individual order from the Principal and shall ensure its proper execution by commissioning an inspection body. Diapharm will not owe a specific result to be achieved in terms of an audit report mandatorily confirming conformity with the regulations, but solely proper and flawless work (open-ended audit report).

(2) Diapharm will coordinate with the Principal whether an audit is an individual audit or a joint audit.

(3) As a rule, Diapharm will render its services at a fixed price laid down in the individual order. As a rule, all prices are quoted plus statutory value-added tax. The exact terms of payment are laid down in the individual order for each order.

(4) The evaluation of the CAPA Plan is included in the agreed price. A follow-up of the CAPA measurements can be offered for an extra cost.