

## **General Terms and Conditions of Delivery and Payment Corden Pharma GmbH**

### **Clause 1: General provisions**

- 1.1 Our entire current and future business relationship, all our deliveries, services, supplementary services, consultancy and provision of information shall proceed exclusively under the General Terms and Conditions specified hereunder. They form part of all contracts we conclude with the Customer. They also apply to all future deliveries, services and quotations even if they are not separately agreed upon.
- 1.2 Terms and conditions of the Customer or a third party shall not be applicable even if we have not expressly precluded their validity in a given instance. Even if we refer to a letter containing or mentioning the Customer's terms and conditions or those of a third party, then this shall not constitute our consent to the applicability of those terms and conditions.

### **Clause 2: Conclusion of a contract, binding character of a quotation, written confirmation, internet-based General Terms and Conditions**

- 2.1 Our quotations are conditional and subject to change unless expressly specified as binding or unless they contain a specific period of acceptance. They are based on the Incoterms in their latest version.
- 2.2 Our Customer shall be committed to the relevant quotation/order for 3 weeks from our receipt of the same.
- 2.3 Changes, amendments and supplementary agreements on all contracts that have been concluded shall only be valid if they have been confirmed by us in writing. This formal requirement cannot be waived through verbal agreements.
- 2.4 If our Customer sends us quotations or orders by electronic means, then our acceptance of a contract / confirmation of an order may proceed in the same manner.
- 2.5 Our General Terms and Conditions are available on the internet, at [www.cordenpharma.de](http://www.cordenpharma.de) and can be downloaded from this site.

**Clause 3: Delivery times, passage of risk, periods of delivery, partial shipment, delivery tolerance and purchase commitment**

- 3.1 Shipping of delivered products shall be ex works (Incoterms in their pertinent latest version) in Plankstadt, unless otherwise specified in writing in specific cases. Irrespective of the mode of transport and the cost bearing arrangement, any shipment of contractual goods shall take place at the Customer's risk. The Customer accepts not only the risk of accidental loss or destruction but also the responsibility of bringing into circulation for the delivered products from the moment these products leave the Plankstadt plant.
- 3.2 Any dates and time limits that are envisaged are no more than approximate unless they have been expressly agreed as fixed dates or time limits. Notwithstanding our rights arising from the Customer's delay, we shall be entitled to an extension of time limits for delivery and performance or to a delay of delivery and performance dates by the period of time during which the Customer has failed to meet its contractual commitments towards us, particularly with regard to the delivery of starting materials that need to be provided by the Customer, a release declaration concerning starting materials and/or the provision of an agreed down payment.
- 3.3 We are entitled to deliver partial shipments if
- the partial shipment can be used by the Customer for the contractually specified purpose,
  - the delivery of the remaining goods is assured, and
  - this does not cause the Customer substantial additional work or expenses (unless we have expressly declared that we shall bear the costs).
- 3.4 We may increase / reduce shipments by up to 10% of the agreed total delivery volume, which shall be reflected in the invoice. The Customer undertakes to accept goods that are delivered within these tolerance limits and shall not derive any claims from such deliveries. An increased or reduced shipment that is still within the legal limits shall not permit the Customer to present a notice of defect or a complaint unless otherwise specified in the manufacturing instructions. Minor deviations in colour and shape on delivered products and packaging may occur for reasons of production engineering and do not therefore constitute defects.

- 3.5 We shall not be liable for delayed delivery until we have received a written warning from the Customer and until an adequately extended time limit granted by the same has expired.
- 3.6 The Customer is entitled to terminate an individual order if, after the failed expiration of the extended time limit detailed in Clause 3.5 the Customer has given at least one week's written warning and we have still not delivered within this time limit.
- 3.7 If the Customer does not accept goods that are ready for despatch or collection or if despatch or collection is delayed for reasons not within our responsibility, then the risk shall pass to the Customer from the moment the latter has been notified of readiness for despatch or collection. In such a case we are entitled to invoice the Customer for the goods and to store them at the Customer's risk and expense. We shall then charge 1% of the relevant net order value per each commenced month, counting from the date of notification of readiness for collection or despatch.
- 3.8 In the event of circumstances which are not within our responsibility and which make it impossible or unreasonably difficult for us to conduct manufacturing or delivery, we shall be exempt from this commitment for the duration of the impediment plus a reasonable set-up period even if such circumstances have occurred on the part of a subcontractor. We shall notify the Customer immediately of such reasons and provide the Customer with a new expected delivery date ("new delivery date"). If the said reasons lead to a delay in performance, then the Customer shall not be entitled to derive compensation claims from this circumstance. In particular, we shall not be held liable for mobilisation, civil unrest or industrial strife at our own facilities or at third-party facilities; neither shall we be held liable for delays in the deliveries which we receive ourselves or for natural disasters. Neither shall such circumstances be our liability if we are already behind schedule. If delivery still has not taken place by the new delivery date, then we shall be entitled to cancel the individual order either wholly or in parts; any payments that have already been made by the Customer shall be returned by us immediately.

This provision shall not affect the application of statutory termination and cancellation rights or the statutory regulations concerning the handling of a contract under an exclusion of the obligation to perform (e.g. if performance or remedial action is impossible or unreasonable). Neither shall this provision affect the application of the remaining termination and cancellation rights for the Customer or for ourselves under this Agreement.

- 3.9 If products are delivered on Euro-pallets, then the same number of mint-condition Euro-pallets shall be handed over in exchange. Any shortfall shall be replaced at the market price of new Euro-pallets, fresh from the factory.

**Clause 4: Prices, due date, delay, retention, offset, discount, rebate**

- 4.1 Unless otherwise specified in writing in a specific instance, all our prices are generally ex works Plankstadt (Incoterms in their latest valid version) and are exclusive of any shipping and packaging expenses or value-added tax.
- 4.2 All invoices are based on the product quantities delivered by us.
- 4.3 Invoiced amounts are payable by the Customer within 30 days of the date of the invoice. The official date of receipt shall be the date on which an amount is received by us. Bills and cheques shall not be considered paid until they have been cashed in; they may only be used upon our prior approval. All costs incurred in cashing in cheques and bills are charged to the Customer.
- 4.4 If the Customer fails to settle a due invoice, then we shall be entitled to bill for interest on arrears at a rate of 8 percentage points above the prevailing base rate of the European Central Bank (ECB) from the due date onwards and without sending a further reminder. This provision does not affect the assertion of further claims. In the event of payment arrears we shall be entitled to withhold production or delivery arising from all the Customer's outstanding orders.
- 4.5 We are entitled to make the delivery of outstanding products or services dependent upon advance payment or upon the payment of a security deposit if we learn after the conclusion of the Agreement that there are circumstances which substantially reduce the Customer's creditworthiness or which jeopardise the Customer's outstanding payments to us, arising from the relevant contract (including outstanding payments from other orders placed by the Customer). Deferred claims arising from products or services already delivered shall become payable immediately and shall entitle us to retain outstanding products and services until the relevant payment has been received.
- 4.6 The Customer shall only be entitled to the right of offset or retention if its counter-claims have been legally established in a non-appealable way or if they have been

recognised by us. The Customer is not entitled to withhold payments on account of counterclaims arising from other agreements that have been concluded.

- 4.7 As soon as the Customer is in arrears, it shall forfeit any discounts or rebates that have been granted.

**Clause 5: Warranty, limitation of liability and exclusion of warranty**

- (1) The parties hereby agree that the agreed specifications of delivered products shall serve as the exclusive criteria for determining their quality. Public statements, recommendations and third-party advertising shall not constitute contractually compliant specifications of product qualities. Samples manufactured by us shall be regarded as no more than representative.
- 5.2 We accept no warranty for product defects due to poor quality and/or processing faults of the starting materials procured by the Customer or by a third-party instructed to do so by the Customer.
- (3) If an analysis conducted by the Customer shows that delivered products do not meet the specifications agreed for those products, then a joint analysis shall be conducted, involving a Customer's analyst and one of our own analysts. If two months have passed after we have received the results of the analysis specified in sentence 1, yet no consensus has been achieved between the Customer's analyst and our own analyst, then the parties shall instruct the *Zentrallaboratorium Deutscher Apotheker* (Central Laboratory for German Pharmacists), Eschborn to test the relevant delivered products. The costs charged for the analysis by this neutral arbitration facility shall be paid by the losing party at the proportion with which it lost the case.
- 5.4 Obvious defects of delivered products shall be notified by the Customer without undue delay, latest within 5 working days of the delivery of those products. Non-apparent defects shall be notified by the Customer as soon as they have been identified and no later than within 5 working days of discovery. Such notifications of defects shall be presented in writing, with the statement of reasons. If these time limits are exceeded, the Customer shall no longer be entitled to assert warranty claims in respect of the relevant defects. If a delivered item is defective, we may choose whether to provide a credit note or remedial action through the removal of the defect (remedy of defect) or whether to provide a defect-free item instead (replacement delivery). However, this shall only apply to the remedy of a defect if such remedy is feasible and

if it is permitted and reasonable under pharmaceutical safety considerations. This provision shall not affect our right to refuse remedial action under the statutory conditions.

- 5.5 The Customer shall forfeit its warranty claims if the Customer or a third party has conducted its own removal of defect or if it has attempted to do so and if such attempts have been undertaken without our prior consent.
- 5.6 We are entitled to make the remedial action which we owe dependent upon receiving the due purchase price from the Customer. However, the Customer is entitled to retain part of the purchase price at an appropriate ratio in relation to the defect.
- 5.7 If the remedial action finally fails after two attempts ("failure of remedy") or if we miss the time limits set for remedial action, then the Customer may, at its discretion, either merely reduce the purchase price or cancel the purchase or rather demand compensation. However, the Customer shall not be entitled to cancellation in the event of a negligible defect.
- 5.8 If, after our failure of remedy, the Customer opts for compensation, then the delivered item shall remain in the Customer's possession, provided that this is reasonable for the latter.
- 5.9 The Customer shall initially accept delivered goods even if they are defective and may only return those goods to us upon receiving our consent.
- 5.10 The Customer's warranty claims for defective goods are limited to the expiry of the lifetime of the delivered products (expiration date), although this limit shall occur no earlier than one year after the delivery of the relevant product.
- 5.11 The Customer's warranty claims shall expire if the relevant delivered products have been impaired by improper storage or handling on the part of the Customer, unless improper storage or handling was not the direct cause of the damage.
- 5.12 If delivered products have been made by us from formulas supplied by the Customer or set up by us at the Customer's request and approved by the latter, we accept no warranty or liability for therapeutic, pharmacological, toxicological or other properties impacting the efficacy of the products or any effects on their application or durability, unless expressly assured by us in writing. This shall not affect the application of clause 11.

5.13 The Customer shall only be entitled to damage compensation or to compensation for unnecessary expenses under the specifications detailed in clause 11; otherwise such claims are excluded.

**Clause 6: Other limitations to the right of cancellation**

With the exception of warranty provisions for defects in delivered products (clause 5), the Customer shall only have a right of cancellation if it proves fault attributable to ourselves. Fault shall only be assumed in the event of intentional or grossly negligent conduct committed by ourselves, by our representatives or by our vicarious agents.

**Clause 7: Liability for the permissibility of production and distribution, duty to provide information, duty to investigate, licensing documents**

7.1 We take no liability for the permissibility of the manufacturing or distribution of delivered products made under contract nor for the consequences of their application or for their use under the pertinent legal regulations, particularly under the provisions of the German Medicines Act (*Arzneimittelgesetz*), the German Food and Commodity Act (*Lebensmittel- und Bedarfsgegenstände-Gesetz*) and any statutory rules and orders based on the same, unless we have signed a written undertaking to comply with certain manufacturing and control regulations. If we have made such a commitment, then our liability shall be based on clause 11 and on our warranty provided in clause 5.

7.2 The Customer undertakes to give us advance on-time written notification if the medicinal products that are to be manufactured by us or the starting materials used for the manufacturing of such products are subject to other regulations over and above the German Medicines Act (*Arzneimittelgesetz*), such as – in particular – the German Narcotics Act (*Betäubungsmittelgesetz*). If special risks are involved in the processing of starting materials procured by the Customer or by a third party instructed by the Customer, then the Customer shall notify us of such risks in writing. The Customer shall, in particular, provide us with the relevant safety datasheet.

7.3 Any starting materials provided by us shall be examined by us for no more than their correct identity. Should further-reaching examinations be required – i.e. for quality,

purity, chemical composition, etc. – then we are only obliged to conduct the same upon an express written agreement.

- 7.4 The manufacturing of delivered products shall comply with the specifications detailed in the licensing documents. The Customer shall therefore provide us with the relevant content of the licensing documents in due time. If the Customer wants specific requirements to be applied in manufacturing, then it shall notify us in writing and conclude a written agreement with us on the observance of such additional requirements. This also applies to any of the Customer's special requirements, such as the validation of a manufacturing process, stability reviews or annual reviews.

#### **Clause 8: Additional costs**

The Customer shall bear any costs incurred in connection with later changes to manufacturing instructions and with changes arising from regulatory requirements, including, in particular, administrative orders.

#### **Clause 9: Reservation of ownership, Collection**

- 9.1 The reservation of ownership, agreed below, serves to secure all current and future accounts receivable claimed by us from the Customer arising from the individual orders placed with us by the Customer.
- 9.2 Products delivered by us to the Customer shall remain our property until the complete payment of all secured claims. Delivered products and any goods that replace such products or under reservation of ownership according to this clause shall be referred to as reserved goods within the framework of this clause 9.
- 9.3 If we are liable for the endorsement of a bill or for contingent liabilities arising from the business relationship between ourselves and the Customer, then reservation of ownership shall not expire until we have ceased to be liable for the endorsement of the bill or until the contingent liability has expired.
- 9.4 The Customer shall store reserved goods for us free of charge. This also applies until the time of an agreed return of such goods or until their destruction.



- 9.5 The Customer is entitled to sell reserved goods until their utilisation – see clause 9.11 – in the ordinary course of business. No permission is given for the pledging of the goods or for transfer of ownership as security lien. The Customer shall not resell goods to third parties or use them in any other way unless there is a safeguard whereby the Customer's pecuniary claim towards its customers passes to us under the provisions of clause 9.7.
- 9.6 If reserved goods are processed, then the parties agree that this shall take place on our behalf and on our account as manufacturers and that we shall immediately acquire ownership or – if processing involves materials from several owners or if the value of a processed item exceeds the value of the reserved goods – that we shall immediately acquire co-ownership (i.e. part ownership) of the newly created items at the ratio between the reserved goods and the newly created item. Making provision, by way of security, for the event that we do not enter into ownership, the Customer hereby transfers to us its future ownership or – at the aforementioned ratio – its future co-ownership of the newly created item. If reserved goods are combined with other items into a single item or if they are inextricably mixed and if one of the other items must be seen as the main item and if the main item furthermore belongs to the Customer, then the Customer shall transfer to us the share of the co-owned single item at the ratio specified in the first sentence.
- 9.7 Making provision, by way of security, for the event that the Customer resells reserved goods, the Customer hereby assigns to us the pecuniary claims it holds towards its customers. We hereby accept the assignment. The same applies to any other claims in replacement of the reserved goods or arising in respect of the reserved goods, such as insurance claims or claims arising from unlawful acts in the event of loss or destruction. We authorise the Customer until further notice to collect claims assigned to us on its own behalf but on our account. In the event of utilisation we shall be entitled to recall this authorisation of collection and to collect the relevant claims ourselves.
- 9.8 If third parties take hold on to reserved goods, particularly through a pledge, then the Customer shall immediately draw their attention to our reservation of ownership and notify us accordingly, so that we can assert our rights of ownership.
- 9.9 The Customer gives its assurance that no other anticipation of property has been or is being arranged in respect of the reserved goods where such anticipation might limit our rights on the aforementioned reserved goods.

9.10 Should this be requested, then we shall release the reserved goods or, at our own discretion, the claims that have replaced the goods, provided that their value does not exceed the secured claims by more than 50%.

9.11 If, in response to the Customer's violation of the Agreement – particularly payment arrears – we cancel the same (event of utilisation), then we shall be entitled to the return of the reserved goods.

9.12 If collection authorisation is withdrawn, then the Customer shall provide all the required information concerning the stocks and volumes of reserved goods, notify us of any outstanding claims that have arisen towards its customers through an extended reservation of ownership and assign to us the original documentary proof for the assertion of those claims. In such a case the Customer shall disclose the assignment to its own customers and irrevocably request that they make the relevant payments to us.

#### **Clause 10: Duty of mutual notification**

We and the Customer shall notify each other immediately of any batch recalls and of any complaints in connection with the delivered products and/or their starting materials and/or their packaging materials in cases that concern the other party's sphere of responsibility.

#### **Clause 11: Liability, indemnity and proprietary rights of third parties**

11.1 Subject to the provisions specified in this subclause (11.1), the Customer shall not be entitled to compensation claims for whatever legal reasons or to compensation claims for unnecessary expenses. This exclusion of liability shall not apply to negligent or intentional injuries of life, limb or health or to grossly negligent or intentional damage to other assets. Customer's Compensation claims for violations of important contractual duties (i.e. duties of which the fulfilment is paramount to the compliant implementation of the agreement and where the other party does and can regularly rely on compliance) shall be limited to calculable damage or to loss as per contractual provisions (i.e. damage or loss foreseen by us at the conclusion of the agreement as a possible consequence of contractual violations or damage which was known to us with appreciation of the prevailing circumstances or damage or loss which we should have known or foreseen with due care and attention), unless such claims concern cases of

intent or gross negligence or cases of liability for injury to a person's life, limb or health. This shall not affect compensation claims arising from the provision of a warranty or from regulations detailed in the German Product Liability Act (*Produkthaftungsgesetz*) or in the German Medicines Act (*Arzneimittelgesetz*).

11.2 If the Customer brings delivered products as finished medicinal products into circulation and if a claim occurs which falls under pharmaceutical liability and if we are responsible for such loss or damage, then the Customer shall waive its rights of recourse towards us. The Customer agrees to obtain the consent of its pharmaceutical liability insurance and submit a copy of the same to us upon the conclusion of the agreement.

11.3 If a compensation claim is made on us by a third party and if the Customer is responsible for the damage or loss within the internal relationship with us, then the Customer shall immediately and upon request indemnify us against those compensation claims.

11.4 The Customer gives its assurance that the manufacturing and distribution of the delivered products are legitimate and do not violate third-party proprietary rights. The Customer shall indemnify us against any claims derived by third parties from the violation of third-party proprietary rights as a result of compliant manufactured or delivered products, of the applied manufacturing methods themselves or of their use or application.

## **Clause 12: Insurances**

12.1 Where goods are subject to reservation of ownership (i.e. reserved goods, as specified in clause 9), the Customer shall insure the same appropriately against damage and theft. The Customer shall, upon our request, furnish documentary proof of such insurance.

12.2 Where materials are supplied by the Customer, we shall insure such materials at our own expense against the risk of loss, destruction and damage (i.e. through fire, water damage, burglary and theft) for the period of time when materials are at our disposal.

**Clause 13: Place of performance, place of jurisdiction, applicable law**

13.1 The place of performance for deliveries and payments is the location of our company's registered office.

13.2 The legal relationship between ourselves and our Customer is subject to German law, at the exclusion of international private law and the UN Convention on Contracts for the International Sale of Goods (CISG). The place of jurisdiction is Mannheim. However, the Customer may also, at our discretion, be sued at the Customer's place of business. This provision does not affect mandatory legal provisions concerning exclusive places of jurisdiction.

13.3 Should individual provisions of these Terms and Conditions be or become invalid, null and void or deficient, then this shall not affect the validity of the remaining provisions.

Place: Plankstadt, date: \_\_\_\_\_