

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing

Standard Terms and Conditions of Sale and Delivery (STSD)

1. Offer and Order

- 1.1. Our deliveries, works and services, and other contractual performances are exclusively based on these STSD, to the exclusion of any third party standard terms and conditions (STC). This also applies, if we unconditionally perform any contract in full knowledge of deviating STC of our contract partners.
- 1.2. Our STSD apply also for future transactions with our contract partners up to the date on which we change the STSD.
- 1.3. The STSD apply only if the purchaser is a merchant (Section 14 German Civil Code), a legal person governed by public law, or a separate estate under public law.
- 1.4. We reserve title to and copyright for catalogues, technical documentations, product specifications, pictures, drawings, calculations, and other information of any kind. These shall not be made available to any third party. This also applies without specific written reference to special confidentiality. Before passing on any corresponding information, the purchaser shall at any time obtain our express written consent.

1.1. Conclusion of the Contract

- 1.1.1. Our offers are subject to confirmation. Our order confirmation is exclusively authoritative for the content of the contract, unless the purchaser has objected thereto with legal valid effect. We can confirm any order in writing, by fax, or orally.
- 1.1.2. We are entitled to accept the order within two (2) calendar weeks of our receipt thereof. If acceptance takes place after expiry of the aforementioned period, and if the purchaser therefore no longer deems itself bound by its order, the purchaser shall notify us accordingly in writing without undue delay; otherwise, the contract is deemed concluded.

1.2. Production Dates

Production dates are agreed with the purchaser in order to reserve the corresponding capacities for provision as at the agreed time.

1.3. Prices, Terms of Payment, Default, Lack of Production Capacity

- 1.3.1. Our prices as valid at the time of the respective conclusion of contract shall apply. Our prices are strictly net, ex works (Lich); any possibly applicable value added tax in the respective statutory amount is added thereto.
- 1.3.2. Any possibly imposed customs duties, fees, taxes, and other public charges shall be borne by the purchaser. Transport packaging and all other packaging subject to the German Packaging Regulation [*Verpackungsverordnung*] is not taken back and passes to the ownership of the purchaser; this does not apply to reusable pallets, which are excluded therefrom.
- 1.3.3. The purchaser is obliged to agree to a reasonable change of price if owing to increasing prices of raw materials and/or energy, costs change by more than 5% between the date of the order confirmation and the delivery date. The same applies to corresponding wage cost increases based on collective bargaining agreements or internal wage and salary agreements between the order confirmation date and the delivery date. Profits may not be increased or extended upon such price adjustment.
- 1.3.4. Unless otherwise agreed, the purchase price shall be due within 14 days of the date of invoice without deduction, receipt on account. Payments shall be made in EUR. Upon expiry of the foregoing payment period, the purchaser shall be in default without further reminder. As from maturity of the invoiced amounts we are entitled to charge interest in the amount of 5% above the respective applicable base rate of the European Central Bank. The assertion of further

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

- default damage remains expressly reserved. In any case of doubt, payments received shall be allocated according to Sections 366 Para. 2, 367 Para. 1 German Civil Code.
- 1.3.5. If the purchaser is in default of any payment, all other claims shall be immediately due for payment, without separate reminder being required.
 - 1.3.6. For financing purposes, we are entitled to assign any claims from deliveries and services against the purchaser.
 - 1.3.7. Any set-off against our claims shall be excluded, unless the claims are undisputed or non-appealable. Retention rights may be asserted only under the same legal relationship.
 - 1.3.8. If after conclusion of the contract it becomes apparent that our claim for payment of the purchase price is at risk due to lack of capacity on the part of the purchaser (e.g. because of a petition for opening of insolvency proceedings), then we shall be entitled to deny performance in accordance with the statutory regulations and – if necessary after setting of a time period - may rescind the contract (Section 321 German Civil Code). With regard to contracts for the manufacturing of non-fungible items (manufacture to customer's specification) we may declare rescission immediately; the statutory regulations on the dispensability of setting a period remain unaffected.
 - 1.3.9. With regard to deliveries and services to customers abroad, it shall be expressly deemed agreed that all costs of bringing legal action on the part of the supplier in the case of a default in payment of the customer, both in court and out of court, shall be at the expense of the customer.

2. Development Works

Based on special agreement, we perform the development works required for performing specific tasks within the scope of our offer range. These works can for example include, without being limited thereto, laboratory tests, examinations of material, sample productions, sample sterilisations, developments of packaging, shelf-life tests, process developments, preparations of production and testing instructions, validations, translations from foreign languages, and similar works which aim at the implementation of a product idea into suitable, cost-effective and competitive production or marketing. Unexpected development costs that are not foreseeable upon issue of the offer will be charged to the purchaser according to time and expense.

3. Pilot Batches, Risk of Pilot Manufacture

In a pilot batch, a test batch will be produced in little, under regular operating conditions upon instruction of the purchaser. The size of the batch shall be chosen to the effect that meaningful findings can be established for the course of the subsequent production. The production risk is at the expense of the purchaser. Unexpected costs of pilot manufacture that are not foreseeable upon issue of the offer will be charged according to expense. In-process controls as well as quality controls for pilot manufactures are made and charged upon agreement.

4. Allocation of Responsibility

Responsibilities with regard to the GMP (*Good Manufacturing Practice*) regulations shall be allocated – to the extent necessary – in a separate allocation of responsibility contract (ARC or GMP Agreement). Such agreement shall be entered into before the first regular manufacture.

5. Treatment of Material of the Purchaser, Harmlessness of Substances

5.1. Storage

Starting material, semi-finished products and other substances provided to us by the purchaser for production and/or processing will be labelled and temporarily stored by us. Special storage notes, such as for example keep cool, keep cold, and instructions for inflammable, highly effective, valuable, perishable or otherwise endangered substances must be notified to us separately in writing before the items are being delivered. Also, the containers etc. have to be marked accordingly.

5.2. Health / Environmental Protection

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

The purchaser is responsible for the health- and environment-related harmless-ness of the substances and materials provided by it. Based on its expert competence, the purchaser must notify us of any risks in writing, and give instructions on measures for minimising such risks. If any safety data sheets are available, these must be provided to us in writing before the corresponding substances or materials are delivered to us. The purchaser is liable for any damage arising from culpable non-compliance with these provisions.

5.3. Risk of Production

If agreed that the purchaser provides to us without costs the quantities of active agents required for the manufacturing of the ordered product he shall bear the production risk regarding the provided active agents. Any losses of active agents, for any cause whatsoever, are not at our expense. This also applies to any shortfall in yield. If due to production-related losses of active agents or other losses of active agents or any lower yield of active agents for any cause whatsoever any agreed or planned batch quantities regarding the ordered products cannot be generated, this shall not be at our expense. In the aforementioned cases the purchaser shall not have a claim for subsequent delivery and/or subsequent production of shortfalls, no claim for replacement of the active agent or partial quantities of the active agent, and in addition also no claims against us, in particular no claims for lost profits or futile investments. This does not apply insofar as the loss of active agent is based on grossly negligent or wilful acts within our sphere of control.

5.4. Insurance / Liability

Any material of the purchaser is stored by us without insurance. We do not assume any liability for damage and perishing occurring during production or storage, unless such damage has been caused by us by intent or gross negligence. Upon request of the purchaser we take out a storage insurance against fire, burglary, hail, storm and tap water damage, according to its instructions and at its expense, with coverage sums to be agreed.

6. Batch Samples

Unless otherwise agreed with the purchaser, we retain samples of each production batch, within the scope prescribed by law. Our retention of samples does not release the purchaser from properly holding retention samples according to statutory regulations. After expiry of the statutory retention period – for lack of such period, 5 years from the production date - we will provide the batch samples retained by us to the purchaser for disposal, or upon consultation with the purchaser destroy them.

7. Scope of Delivery, Delivery Period, Non-availability of Performance

- 7.1. The scope of delivery is subject to our order confirmation. Unless otherwise agreed, we shall be entitled to deliver the quantities which can be manufactured from the substance delivered to us upon proper processing and treatment, according to the order instructions of the purchaser. We will return any residual quantities, or dispose of them at the expense of the purchaser.
- 7.2. The delivery period commences on the day on which we have received all raw substances and materials to be provided by the purchaser, as well as all documents required for production and control, and on which all technical questions have been clarified. The delivery period is individually agreed or stated by us upon confirmation of order. We have complied with the delivery period if the delivery item has left the plant upon its expiry, or if readiness for dispatch has been notified. Upon delay of items to be provided by the purchaser, the purchaser shall notify us without undue delay. The manufacture period shall in such case be newly agreed between the purchaser and us.
- 7.3. Insofar as for reasons for which we are not responsible we cannot comply with binding delivery periods (non-availability of performance), we shall without undue delay inform the purchaser accordingly, and at the same time determine a new delivery period reasonable under the respective given circumstances. If the performance is also not available within the new delivery period, we shall be entitled to withdraw from the contract as a whole or in part; any consideration already given by the purchaser will be reimbursed without undue delay. Non-availability of

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

performance within the meaning of the foregoing shall in particular be the case that we ourselves do not receive timely delivery from our own suppliers if we have entered into a congruent hedging transaction.

- 7.4. Our statutory withdrawal and termination rights, as well as the statutory regulations on the settlement of the contract upon exclusion of the performance obligation (e.g. impossibility or unacceptability of performance and/or subsequent performance) shall remain unaffected. Likewise unaffected are the withdrawal and termination rights of the purchaser according to these STSD.

8. Passing of Risk, Acceptance

- 8.1. The risk of accidental loss or accidental deterioration of the products shall pass to the purchaser at the latest upon handover. In the event of dispatch, however, the risk of accidental loss or accidental deterioration of the products, as well as the risk of delay shall pass already upon delivery of the products to the forwarding agent, the carrier, or to any other person or agency commissioned with the dispatch. Upon request and at the expense of the purchaser we are prepared to take out insurance against the transportation risk. In such case, the purchaser shall instruct us accordingly, stating the value of the products.
- 8.2. Insofar as acceptance is agreed, it shall be authoritative for the passing of risk. In addition, the statutory regulations of the laws on contracts for works and services shall apply to any agreed acceptance. The handover and acceptance is equal to a default of acceptance on the part of the purchaser.

9. Liability for Defects

Upon manufacture of the products we warrant compliance with the agreed processing, treatment, testing and other procedures according to the acknowledged rules of pharmaceutical production technology. We do not assume liability for any defects of the starting substances, active agents or other materials used in the manufacture which have been provided by the purchaser. We also do not assume liability for any defects of the finished product which have been caused by defective starting substances, active agents or other materials provided by the purchaser.

9.1. Quality

- 9.1.1. Our liability for defects is primarily based on the agreement on the quality of the products. An agreement on the quality of the products does not constitute any guarantee on our part. Special guarantees are given only on the basis of a separate agreement regulating the content and scope of the guarantee independent from these STSD and the statutory rights of the purchaser.
- 9.1.2. Insofar as a quality has been agreed, the products shall be free from defects if they show the agreed quality.
- 9.1.3. Insofar as a quality has not been agreed, the products shall be free from defects if they are suitable for the use provided for in the contract. Apart from that, the products shall in addition to the statutory regulations also be free from defects if they show the qualities which the purchaser may expect according to the product specifications given by us. In this respect it shall suffice if the product specifications have been provided to the purchaser after conclusion of the contract (in particular together with the products). Usual production-related losses (filtration losses, residuals in production items, etc.) are accepted by the purchaser and do not constitute a defect of the product.

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

9.2 Notice of Defects, Liability, Recourse Claims

- 9.2.1. The Purchaser is obliged to inspect the delivered products for obvious defects without undue delay, in particular also with regard to obvious quantity shortfalls or damage, and to notify these to us in writing without undue delay, at the latest however within 2 weeks of receipt of delivery. For observance of the time limit, it shall suffice that the notice of defect be sent in time. In the case of non-obvious (hidden) defects, the purchaser shall be obliged to notify them to us in writing upon detection, at the latest however within the limitation period. The purchaser bears the burden of proof for all requirements, in particular for the existence of the defect, the date of ascertainment of the defect, and the timely notification of the defect. If the purchaser does not notify the defects as set forth above, our liability for defects of the delivered products shall be excluded.
- 9.2.2. If the delivered products are defective, we reserve the right to first remedy the defect at our choice, either through subsequent delivery or subsequent improvement (subsequent performance). In the case of subsequent performance, we shall be obliged to bear all costs required for this purpose, in particular transportation, road tolls, work and material costs, insofar as these are not increased by the fact that the products are delivered to a place other than the destination.
- 9.2.3. If the subsequent performance fails, if it is impossible, if it is seriously and finally denied by us in its entirety, or if it is unacceptable to the purchaser, or if a time period to be fixed by the purchaser for subsequent performance unsuccessfully lapses, or if it is dispensable according to the statutory regulations, then the purchaser shall be entitled, at its own choice, to reduce the purchase price of the defective products (reduction) or to withdraw from the contract for the purchase of the defective products (withdrawal). Upon declaration of withdrawal or request of reduction, the purchaser's claim for delivery of defect-free products under the contract shall lapse. Claims of the purchaser for damages or compensation for futile expenses are granted only within the scope of the following clause 10; apart from that they are excluded.
- 9.2.4. Any liability is excluded with regard to defects which do not or only insubstantially impede the value or the suitability of the products for the use noticeable to us.
- 9.2.5. Our liability is excluded with regard to any damage caused by external impact or incorrect use or storage of the products, in particular such damage caused by incorrect handling and application of the products by the purchaser or third parties, e.g. user or customer. Handling or application is in particular incorrect in those cases where it does not comply with the prescribed instructions of use and with other references or the general rules of medical care. Our liability is also excluded for defects caused by defective quality of the starting materials and packaging material of the purchaser.
- 9.2.6. If newly manufactured products delivered by us to the purchaser are sold to a consumer, the following provisions shall apply in addition to the foregoing clauses 9.2.2 and 9.2.3 with regard to the purchaser's claims based on defects:
- a) The statutory alleviation of the burden of proof in favour of the purchaser regarding the time of the occurrence of the defect (Sections 478 Para. 3, 476 German Civil Code) shall except for the cases regulated by law also not apply in the case that a period of more than six months lies between the passing of the risk to the purchaser and the passing of risk to the purchaser's customer.
 - b) The purchaser's right to subsequent performance according to clause 9.2.2 shall apply subject to the following provision: The purchaser may request the kind of subsequent performance from us which the purchaser owes its customer in consideration of the purchaser's statutory and contractual rights of denial. Our right of choice according to clause 9.2.2. shall insofar not apply. The purchaser is entitled to assign this subsequent performance claim to its customer, but only on account of performance and/or for the purpose of security, i.e. without prejudice of its own continued liability towards its customer. An assignment in lieu of performance is invalid. Our right to deny such subsequent performance according to the statutory requirements shall remain unaffected.
 - c) If we have agreed with the purchaser on an equal compensation within the meaning of Section 478 Para. 4 German Civil Code, the claim for reimbursement of the expenses to be borne by the

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

purchaser under its relationship with its customer (Section 478 Para. 2 German Civil Code) shall be excluded.

10. Limitation of Liability, Exclusion of Withdrawal

- 10.1. Except for the constituent facts regulated in clause 10.2 below, our liability for damages or reimbursement of futile expenses exceeding the liability for defects according to clause 9 above shall be excluded in the case of a breach of duty, irrespective of the legal nature of the asserted claim. This also applies if and to the extent that breaches of duty occur on the part of our legal representatives or vicarious agents.
- 10.2. The exclusion of liability under clause 10.1 above does not apply in the case of claims of the purchaser based on the Product Liability Act or the German Drug Law. It does also not apply in any case of injury of life, body or health attributable to us, in the case of grossly negligent or intentional breaches of duty, and in the case of a violation of a guarantee or essential contractual obligation, as well as in the case of malice. In those cases, we shall be liable according to the statutory regulations. In the event of a violation of an essential contractual obligation by simple negligence, however, our liability shall in any case be limited to the order value of the batch concerned, without prejudice to the value of the substances provided by the purchaser.
- 10.3. The purchaser may only withdraw from the contract due to a breach of duty not based on a defect of the products, if the circumstance which entitled it to withdraw is based on a fault on our part. In the case of insignificant breach of duty, withdrawal shall be excluded.

11. Statute of Limitations

- 11.1. All claims and rights of the purchaser – based on any legal ground whatsoever – shall be statute-barred 1 year from delivery of the products. If the products have not been delivered, the limitation period commences upon the end of the year in which the claim has arisen. Shorter statutory limitation periods shall take precedence.
- 11.2. In deviation from clause 11.1, the statutory limitation period shall apply in the following cases:
- for claims based on defects, if we fraudulently conceal the defect or if we have assumed a guarantee of quality,
 - for recourse claims of the purchaser within the scope of a delivery chain (clause 9.2.6),
 - for claims for damages or claims for reimbursement of futile expenses resulting from injury of life, body or health,
 - for other claims for damages or claims for reimbursement of futile expenses resulting from any intentional or grossly negligent breach of duty,
 - for claims according to the Product Liability Act or the German Drug Law,
 - for claims for damages or claims for reimbursement of futile expenses resulting from any violation of other essential contractual obligations.

12. Retention of Title

- 12.1. The delivered products remain our property until receipt of full payment of all claims under the business relationship between us and the purchaser (retained products).
- 12.2. The purchaser is entitled to resell the retained products in the course of ordinary business. However, the purchaser is not permitted to pledge the retained products or to assign them by way of security.
- 12.3. The Purchaser is obliged to treat the retained products with care. The purchaser is in particular obliged at its own expense to sufficiently insure them at replacement value against damage through fire, water and theft.
- 12.4. The purchaser already here and now assigns its claims from resale of the retained products. We hereby accept this assignment. Irrespective of the assignment and our collection right, the purchaser is entitled to collection for as long as the purchaser complies with its obligations towards us and does not suffer any deterioration of assets.

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

- 12.5. Insofar as the purchaser takes on refinancing on a factoring basis, it already here and now assigns the claim to which it is entitled thereunder to us, in the amount of the still open balance under the business relationship.
- 12.6. If the retained products are resold together with other products, irrespective of whether without or after processing, combining, mixing or mingling, then the advance assignment agreed above shall apply only in the amount of the invoice values of the retained products sold together with the other products. Upon request, the purchaser shall provide us with details on the assigned claims required for collection, and inform the obligor of the assignment.
- 12.7. The purchaser shall treat or process the retained products without any obligation arising to us therefrom. In the case of processing, combining, mixing or mingling of retained goods with other products which do not belong to us, we shall generally be entitled to the ensuing co-ownership share in the newly created product at a ratio of the invoiced value of the retained goods to the value of the other processed products at the time of processing, combining, mixing or mingling. If the purchaser acquires sole ownership in the new product, the parties agree that the purchaser will grant us co-ownership of the new product at a ratio of the invoiced value of the processed or combined, mixed or mingled retained products, and stores these on our behalf without charge.
- 12.8. With regard to any execution measures of third parties against the retained goods or the claims assigned to us in advance, the purchaser shall without undue delay inform us accordingly, handing over the documents required for an intervention. Any costs of interventions shall be borne by the purchaser.
- 12.9. If the purchaser acts in breach of duty, in particular in the case of non-payment of the due purchase price, we will be entitled to withdraw from the contract on individual call according to the statutory regulations, and request return of the products based on the retention of title and withdrawal. If the purchaser does not pay the due purchase price, we may assert these rights only if we have prior thereto set the purchaser a reasonable period for payment, without success, or if such setting of a period is dispensable according to the statutory regulations. Any exercise of the retention of title by us always simultaneously contains the withdrawal from the contract.
- 12.10. We undertake to release the securities to which we are entitled under the foregoing provisions at our own choice upon request of the purchaser insofar as their value exceeds the claim to be secured by 10% or more.

13. Documents, Descriptions, Processes, Provided Items

Any documents, descriptions, processes we disclose to the purchaser, or items we provide or make available to the purchaser, shall at all times remain our property. They may not be used for any other purposes or made accessible to third parties without our express consent. We can at any time request return of the items, unless the purchaser is obliged by law to retain them. The purchaser warrants that all performances rendered to us are free from rights of third parties and that it can freely dispose of them. The purchaser shall point out any extended retention of title and name the beneficiaries thereunder.

14. Infringement of Proprietary Rights

If claims based on infringements of proprietary rights of any kind or from ownership of third parties are asserted against us on the basis of any performances of the purchaser, the purchaser shall indemnify us from any claims of third parties and defence costs incurred by us which we could consider acceptable and reasonable, and to reimburse our costs. The purchaser is obliged to provide us with any information and documents we consider necessary for the defence against such claims, without undue delay and free of cost. In the event of an assertion of claims by third parties, the maturity of claims of the purchaser shall be suspended until the proceedings for infringements of proprietary rights have been completed by non-appealable judgement.

BAG Health Care GmbH
Pharmaceutical Contract Manufacturing
Standard Terms and Conditions of Sale and Delivery (STSD)

15. Confidentiality

- 15.1. The parties undertake to keep all information on the business operations and/or products received from the other party within the course of the initiation and performance of the respective contract as well as any know how provided and the customer information made available (business secrets) strictly secret during the term and up to 5 years after expiry of the respective contract, in particular not to disclose it and/or make it otherwise available to third parties in any other manner. In addition, they will take all required precautions to comply with this secrecy and confidentiality obligation, in particular impose corresponding secrecy obligations on their own employees. This obligation also applies with regard to the parties' legally or economically affiliated enterprises as well as customers.
- 15.2. This secrecy and confidentiality obligation does not only apply to such confidential information which provably
- is or becomes publicly known by ways other than breach of this contract, or
 - either party makes unrestrictedly available to a third party, or
 - is obtained from either party, after the other party has notified in writing that no further business secrets are requested, or
 - if either party expressly permits the use or passing on by release towards the other party, or
 - is passed on to persons who are obliged to secrecy based on statutory regulations.
- 15.3. The party relying on any of the foregoing exceptions shall bear the burden of proof of the existence of the same.

16. Set-off, Retention

The purchaser shall be entitled to a right to retention of payment or to setting off counter-claims only to the extent that its counter-claims are uncontested, affirmed by non-appealable judgement or acknowledged by us.

17. Place of Jurisdiction, Choice of Law

- 17.1. All legal relationships between us and the purchaser shall be governed by the laws of the Federal Republic of Germany as applicable to the legal relationship between domestic parties.
- 17.2. Place of jurisdiction is the court having jurisdiction for our enterprise. However, we are also entitled to bring action at the head office of the purchaser.

18. Side Agreements, Partial Invalidity

- 18.1. Side agreements, amendments and modifications of these STSD require written form. This also applies to a waiver of this written form requirement.
- 18.2. If any provision or part of a provision of these STSD is or becomes invalid or incomplete, the validity of the remaining provisions of these STSD shall not be effected thereby. Rather, the Parties undertake to replace such invalid provision by such provision, which in its economic effect corresponds with the purpose of the contract. This also applies in the event of a gap in the provisions.

As at December 2010