

## General Terms and Conditions

### **A. General terms**

#### **I. Validity**

These General Terms and Conditions of EVP Pharma GmbH (hereinafter referred to collectively as EVP) apply to all of EVP's deliveries, development activities services and offers. These General Terms and Conditions are part of all agreements that EVP enters into with its contracting partners (hereinafter referred to as the 'Client') regarding deliveries, development activities and services offered by EVP. They shall also apply to future deliveries and services even if these are not yet specifically agreed.

Any contradicting terms and conditions of sale, development activities and supply of the Client do not apply even if EVP does not explicitly object to them in advance. Contradicting terms and conditions of sale, development activities or supply of the Client do also not apply if EVP refers to an offer or other correspondence of the Client containing these terms and conditions; consent is not associated with such reference.

#### **II. Contract conclusion**

Orders awarded to EVP become binding upon EVP's written order confirmation. There shall be no verbal subsidiary agreements.

#### **III. Offer**

1. Offers made by EVP are subject to confirmation, unless otherwise agreed. An obligation to supply or develop does not become binding until EVP has confirmed the order in writing (contract conclusion in accordance with clause II). Any samples attached to the offer are always non-binding approval samples unless otherwise agreed. If the offer also contains the phrase 'as usual', this refers solely to the quality of the goods and not to the price.
2. The scope of the order shall be according to with EVP's written order confirmation.
3. Orders from the Client can be accepted by EVP within 14 days of receipt. The date of the order confirmation's dispatch is decisive.

Offers made by EVP regarding the delivery item (e.g. weight, dimensions, tolerances or technical data) may exhibit usual deviations on delivery; these deviations are acceptable and are not in contradiction to the agreed quality.

#### **IV. Place of delivery and performance**

The place of performance for all obligations shall be where EVP is based, respective the Subsidiary or Affiliate of EVP which is involved in conducting last steps of EVP's performance on behalf of EVP and arranged the readiness for shipment, resp. shipment of EVP's deliveries.

#### **V. Confidentiality and copyright protection**

1. EVP reserves all property and copyrights to all documentation, drawings, plans, sketches, images, samples, calculations. They may not be made available to third parties or replicated without the express written consent of EVP and may only be used for the contractually agreed purpose.
2. The obligation for the non-disclosure and non-usage of information does not apply, insofar as, it was already known (public, state of the art etc.) and is therefore no longer secret or capable of being protected. The obligation for the non-disclosure and non-usage of information does not apply from that time when the information becomes public.
3. The duty to maintain confidentiality continues beyond the termination of the contractual relationship, unless the information becomes public in the meantime. Therefor the burden of proof lies with the Client.
4. From the time when the information becomes public or from the termination of the contract the Client is obliged to return all confidential information which are committed for the execution of the contract, including all copies thereof and to destroy all copies and records to the extent they contain confidential information. EVP is entitled to retain one copy of such confidential Information for the purpose of archiving and proof.

## **VI. Applicable law and place of jurisdiction**

These General Terms and Conditions and the entire legal relationship between the parties are subject to the law applicable at EVP's registered offices, excluding the UN Sales Convention (CISG). The sole place of jurisdiction for all disputes arising from this agreement or in connection with this agreement is at EVP's registered offices, providing the law does not stipulate a different sole place of jurisdiction.

## **VII. Serverability clause**

Should any provision of these terms and conditions or the agreement be ineffective, this shall not affect the effectiveness of the remaining provisions. Instead of the ineffective provision, a provision shall apply which comes as close as possible to the commercial purpose of said ineffective provision. This shall also apply accordingly to any gaps. After the ineffective provision has been recognised or a gap in the agreement has been noticed, the parties shall immediately put into writing what should apply instead.

## **B. Particular provisions for deliveries**

### **I. Prices and payment terms and conditions**

1. The payment terms and conditions as confirmed by EVP in the order confirmation shall apply. The Client shall pay the price quoted in the order confirmation plus statutory VAT in Euros.
2. The prices are without delivery and packaging. Paper bags, corrugated cardboard and cartons are non-returnable.
3. Invoices are due for payment without deduction within 7 days of the invoice date. The Client is automatically in arrears if payment is not made by the due date - no reminder is needed. In respect of payment arrears, default interest at 10 percentage points above the current annual base interest rate shall be paid for the length of the default whereby EVP is free to assert further damage.
4. There is no obligation to accept cashless payment instruments (bills of exchange and cheques). In any event, bills of exchange and cheques are only accepted by EVP on account of performance. The purchase price owed is not settled until the full invoice total has been credited to EVP's account after the cheque or bill of exchange clears. The Client shall pay all the costs incurred through the encashment of bills of exchange and cheques.

5. If the payments made are insufficient to cover the Client, interest and costs, the payment shall first be credited to the costs, then for the interest and lastly to the Client service.
6. During the Client's default in payment EVP is entitled to withhold its deliveries and is not obliged to execute these deliveries or to adhere to delivery dates.
7. Any set-off or retention of payment by the Client shall only be permitted with because of undisputed or court-approved counterclaims of the Client.
8. EVP is entitled to retain any pending deliveries upon advanced payment or provision of security by the Client if, after submission of the order confirmation, circumstances become known to EVP which may essentially reduce the Client's credit standing and jeopardise payment for receivables by the Client from the contractual relationship.

### **II. Scope of supply/delivery period/customer provisions**

1. The scope of supply shall be as defined in EVP's order confirmation. EVP is entitled to make partial deliveries unless otherwise agreed. EVP may issue partial invoices for partial deliveries which must be paid on the respective due date.
2. Details of delivery periods in offers made by EVP are generally non-binding unless a binding delivery date has been agreed in the offer. Agreed delivery times and dates for dispatch always refer to handover to the forwarding agent, carrier or any other third party commissioned for dispatch ('Supplier').
3. EVP shall not be liable in respect of failure or delays in the supply of goods or services caused by Force Majeure or other events which were not foreseeable at the time of contract conclusion, particularly disruption of operations of any kind, difficulties arising during procurement of materials or energy, transport delays, strikes, lockouts, lack of labour, energy or raw material shortages, economic sanctions as well as difficulties in procuring any necessary official authorisations or official actions or the absence, incorrect or untimely delivery by the Suppliers for which EVP is not responsible. If such events significantly impair delivery by EVP or render delivery impossible and the hindrance is not of a temporary nature EVP is entitled to withdraw from the sale agreement. If the hindrance is temporary, delivery times and dates shall be extended

accordingly for the period of the hindrance and with the addition of another week from the end of the hindrance. If the Client cannot be expected to accept the delivery due to such a delay, the Client may withdraw from the supply agreement by immediate written notification to EVP.

4. Tools which are either offered, procured or delivered by EVP for the manufacture of the delivered goods or products ('Goods') or their packaging shall remain the property of EVP even where the procurement costs have been paid partially or in full.
5. If the Client provides raw materials or packaging materials for an order (customer provision) EVP, with reference to the order confirmation, will request that the Client delivers these materials at a specified location and time. The delivery shall be made DDP (Incoterms 2010). The Client shall take care that the delivery is correct and timely; EVP shall not be responsible for any delays and damage caused by late or inappropriate delivery. Materials delivered by the Client shall be inspected visually by EVP; the Client shall be liable for any deviations in quality or quantity. The Client shall be liable for any damage and consequential damage to EVP which is the result of the materials provided by the Client being defective and has an impact on EVP's end product or facilities or companies affiliated with EVP for example, production downtime and the resulting additional costs.

If the Client provides raw materials EVP shall guarantee a yield of 90%. For lower yields EVP shall reimburse the costs to the extent of the difference between actual yield and 90% upon written proof and written notice from the Client.

EVP's delivery periods do not start before the Client has duly provided EVP with all raw materials and/or packaging materials agreed for each order.

### **III. Deliveries**

1. Deliveries from EVP are always EXW (Incoterms 2010). Any risk shall pass to the Client when the goods are ready for pick-up according to EXW (incoterms 2010). The place of performance for all obligations shall be depending on where the delivery works is based (A IV).
2. The decision regarding the packaging, as well as, in case other delivery terms than EXW according to the above B.III.1 are agreed, the type of shipping and selecting the

transportation carrier shall be made solely by EVP. The Client shall bear all costs for shipping and delivery.

3. EVP shall not be obliged to take out transport insurance. If the Client wishes EVP to take out insurance it shall declare this to EVP and shall bear all insurance costs. Unless otherwise instructed by the Client, EVP can decide on the type, scope and extent of the agreed transport insurance at its own discretion.
4. If the transfer of the goods is delayed by the Supplier as a result of circumstances outside the Client's area of responsibility, the risk shall pass to the Client as soon as the delivery is ready for dispatch by EVP and EVP informs the Client hereof. At the latest risk shall pass to the Client if the latter falls into default of acceptance. The Client shall bear any storage costs after the risk has been passed over. Storage costs shall be charged at a rate of 0.5% of the order value per week of the additional storage. The contractual parties reserve the right to prove higher or lower storage costs.

### **IV. Inspection and acceptance**

Immediately upon arrival of the goods supplied by EVP, the Client must store said goods appropriately and in suitable premises and inspect them promptly – not later than 7 days after arrival with regard to obvious defects. The Client must notify EVP immediately in writing of any losses, defects and other complaints and before any subsequent delivery to a third party. In the case of hidden defects this period shall apply from the time at which the defect was first recognised by the Client.

### **V. Guarantee and manufacturer regress**

1. If the delivered goods are not up to the agreed quality at the time of the delivery, the Client must immediately inform EVP hereof. The deadlines as specified in clause VII shall apply.
2. In response to the Client's complaint, EVP shall be entitled to render restitution at its own discretion by way of subsequent fulfilment or replacement delivery. If the subsequent fulfilment is unsuccessful (impossible, unreasonable, refused or unduly delayed) then the Client may withdraw from the agreement or demand a reduction of the purchase price.
3. The cost for correcting faults including the return of the goods to their intended destination shall be borne by EVP providing the

subsequent or replacement delivery takes place at the originally agreed destination.

4. Clause VI shall apply to the Client's claims for damages.
5. Claims for defects shall expire 12 months after the transfer of the risk of accidental loss (see. fig. B. III. 1.). This shall not apply if applicable law requires mandatory longer deadlines.
6. The client's rights to recourse against EVP shall only exist if the client has not made any agreements with its buyer exceeding the statutory mandatory claims for defects.

#### **VI. Liability and indemnity**

1. EVP shall only be liable to the Client under the provision of this clause VI for any damages irrespective of the legal reasons and providing it is at fault irregardless of any further legal eligibility requirements.
2. EVP shall not be liable in cases of simple negligence by EVP, its bodies, legal representatives, employees or other vicarious agents, unless essential contractual obligations are violated. Essential contractual violations are obligations, whose infringement jeopardises the attainment of the purpose of the agreement, or the correct execution of the Agreement is only possible if said obligations are fulfilled and the observance of which the parties to the agreement regularly rely on. In this case, EVP's liability shall be limited to the damage which was foreseeable when concluding the contract as a possible consequence of a contract violation or if due care is taken. Indirect and consequential damage which arises from a defective delivery shall only be eligible for replacement if said damage is typically expected with the intended use of the delivered goods.
3. The liability exclusion and liability limitation shall also apply to the bodies, legal representatives, employees and other vicarious agents of EVP.
4. The liability exclusion and liability limitation shall also apply to the internal relationships of the parties if joint liability exists.
5. This liability exclusion and liability limitation shall not apply to deliberate acts, guaranteed qualities and loss of life, physical injury or damage to health or for liability according to fraudulent concealed defects. Mandatory law applicable with regard to Product Liability is thereof unaffected.

#### **VII. Retention of title**

1. EVP shall retain title to all of the goods supplied under the contractual relationship (goods under retention) until payment in full has been made. Goods under retention shall remain the property of EVP until full payment of all secured claims. The Client shall store the goods under retention free of charge for EVP.
2. The Client shall be entitled to sell the goods under retention in the course of ordinary business. Pledges and assignment as security are forbidden.
3. If the Client sells the goods under retention, it shall already at this point transfer all existing claims against the buyer to EVP which shall accept said transfer. The same shall apply to other claims to these goods (e.g. insurance claims, claims from unlawful acts of loss and destruction). EVP shall conferrevocable authorise to the Client to collect claims assigned to EVP in its own name.
4. If the goods under retention are processed with other goods by the Client to make a single item or are inseparably mixed then the Client shall already in advance transfer all existing property rights it gains to EVP. EVP shall accept such transfer.
5. In the case of third party access to goods under retention, particularly through seizure, the Client shall point out EVP's ownership without delay and immediately inform EVP of the access. If on enforcement of EVP's right of ownership, the third party is not able to reimburse EVP for any judicial costs and/or extrajudicial costs arising in this context, the Client shall be liable to EVP for these costs.
6. EVP shall release the goods as well as items or claims that take their place as far as their value exceeds the value of the secured claims by more than 20%. The Client has the choice of the items.
7. If EVP withdraws from the agreement because the Client is in breach of the agreement, then EVP shall be entitled to demand surrender of the goods under retention.

#### **C. Particular provisions for development**

##### **I. Scope of the development activities**

1. In the performance of the development work EVP observes the applicable pharmaceutical and food stuff laws and regulations and the relevant provisions applicable in the individual case as well as the state of scientific and technical progress, as far as this is part of the development offer of EVP. If the Client requests that special regulations or guidelines etc. are to be observed, which are not generally known or recognized, the Client is to point this out to us in writing.
2. EVP prepares a project plan for the development of pharmaceutical products and medical devices in coordination with the Client, which indicates the individual milestones of development and the time which is estimated to be required. For each defined milestone EVP will provide the Client with an intermediate report. For any other products the respective intermediate steps will be separately agreed with the Client.
3. EVP develops the product according to the project plan respectively the individual agreements for and at cost of the Client. The execution of required clinical trials and registration procedures will be in the responsibility of the Client unless it is agreed that the coordination of such activities rests with EVP.
4. EVP will start the performance of the activities for any next milestone determined in the project plan only after the Client has instructed EVP in each case separately and in writing. If the Client withholds such instructions the agreed timelines will be shifted accordingly.
5. EVP shall immediately inform the Client of any delays requiring a shift of the next milestone.
6. Changes of the project plan are only effective in writing and signed by both parties. If the Client requests changes, EVP shall inform the Client within a maximum of 2 (two) weeks after receipt of the inquiry about whether or not the requested change is feasible and about the impact it will have on the development, especially about the alterations with regard to costs, timing and risk of success of the development. If EVP suggest a change, the Client shall inform EVP within a maximum of 2 (two) weeks whether it agrees to the suggested change or not, otherwise the change is deemed to be accepted. EVP will inform the Client accordingly separately.
7. The Client will, for the purpose of the development of a medicinal product, supply EVP with a sufficient quantity of active pharmaceutical ingredients (API) free of charge. The Client is

in charge of the procurement of the API for the medicinal product to be developed. The Client will further qualify and audit the manufacturer of the API and is responsible for the release of the API. The Client will additionally supply EVP with API which has gone lost during the development process or reimburse us any costs incurred through substitution, unless the respective loss is caused by EVP`s gross negligent or willful misconduct.

8. Any raw materials, such as API, provided by the Client shall be delivered to EVP according to DDP (Incoterms 2010). The Client assumes all risk throughout the transport (free ramp) accordingly.
9. After completion of the project, EVP shall provide the client with a final report which contains a summary of the project results.

## **II. Payment and remuneration**

1. For the execution of the development services the Client shall pay EVP the remuneration indicated in the development offer. If not stated otherwise, VAT is excluded and personnel costs and expenses for internal effort are included. This remuneration is made on estimates which are minimums of the workload and hours needed as per our best understanding and experience. EVP preserves the right to invoice the services rendered based on the actual time and effort basis. To the extent possible EVP will give the Client notice on substantial cost alterations and further specifications of costs.
2. The payment of the due amounts will be effected in partial amounts. If not agreed otherwise, the remuneration is due net on receipt of the invoice and to be effected within 30 (thirty) days after receipt of the invoice. The statutory provisions of delay in payment apply.
3. Potential services regarding stability studies will be charged to the Client at least once per calendar year. Services started or terminated in the course of a calendar year will be charged pro rata.

## **III. Acceptance of performance**

Insofar as the character of the contract is a contract of manufacture rather than a contract of service the acceptance of performance follows the individual working steps as set forth under the development offer. Any working step, about which the Client has been informed via intermediate report, is deemed to be accomplished and (physically) accepted as (generally) in accordance with the contract,

either through unconditional acceptance of the intermediate working steps or 4 (four) weeks after receipt of the intermediate report, unless the Client has explicitly issued a notice of defect. The development is deemed to be accepted as completed by unconditional payment, otherwise or 4 (four) weeks after receipt of the final report, unless the Client has explicitly issued a notice of defect. EVP will instruct the Client of the consequences of the expiration of the time limits set forth under the sentences 2 and 3 of this section. Acceptance shall not be withheld by reason of minor defects.

#### **IV. Warranty**

1. The development will be conducted according to the state of the art. EVP does not assume any warranty for the economic usability of the results or for their fitness for the purpose of filing a marketing authorization as medicinal product.
2. EVP shall not be liable in respect of failure or delays in the development of goods or services caused by Force Majeure or other events which were not foreseeable at the time of contract conclusion, particularly disruption of operations of any kind, difficulties arising during procurement of materials or energy, transport delays, strikes, lockouts, lack of labour, energy or raw material shortages, economic sanctions as well as difficulties in procuring any necessary official authorisations or official actions or the absence, incorrect or untimely delivery by the Suppliers for which EVP is not responsible. If such events significantly impair development by EVP or render development impossible and the hindrance is not of a temporary nature EVP is entitled to withdraw from the development agreement. If the hindrance is temporary, development times and dates shall be extended accordingly for the period of the hindrance and with the addition of another week from the end of the hindrance. If the Client cannot be expected to accept the development due to such a delay, the Client may withdraw from the development agreement by immediate written notification to EVP.
3. Clause V shall apply to the Client's claims for damages.
4. Claims for defects shall expire 12 months after acceptance (see C. III.). This shall not apply if applicable law requires mandatory longer deadlines.
5. The client's rights to recourse against EVP shall only exist if the client has not made any

agreements with its buyer exceeding the statutory mandatory claims for defects.

6. The client's claims for defects (subsequent delivery, remedy, withdrawal) shall be excluded if these are due to the fault of the client, especially if
  - 6.1. the underlying formulations, manufacturing instructions, validation instructions or specifications were likely to be misunderstood, incomplete or incorrect or proved to be technically impracticable and if this had been unrecognizable for EVP;
  - 6.2. a starting material, which has been declared unsuitable, was used following explicit instruction of the Client;
  - 6.3. product defects result, either in whole or in part, from inappropriate quality of starting materials purchased by EVP from third party suppliers which had been determined by the Client or which result from starting materials provided by or on behalf of the Client; or
  - 6.4. manufacturing and testing procedures were carried out following the explicit instructions of the Client.

#### **V. Liability and compensation**

1. EVP shall be liable to the client for damages irrespective of whatever cause, in so far as this involves culpability, notwithstanding the other statutory claim prerequisites, alone on the basis of this figure V.
2. In the event of ordinary negligence of EVP, its bodies, legal representatives, employees or other aides, EVP shall not be liable, unless essential contractual obligations have been violated. These essential obligations are those whose infringement jeopardises the attainment of the purpose of the agreement, or the correct execution of the Agreement is only possible if said obligations are fulfilled and the observance of which the parties to the agreement regularly rely on. In such cases, EVP's liability shall however be limited to the foreseeable damage as a consequence of violating the obligation when concluding the agreement, or to the damage foreseeable with due diligence. Indirect damage and consequential damage resulting from poor development shall only be eligible for compensation to the extent to which such damage may typically be expected when the development is used for its intended purpose.

3. The liability exclusion and limitations shall apply equally to bodies, legal representatives, employees and other aides of EVP,
4. In the event of joint liability, the liability exclusion and liability limitations shall also apply in the internal relationship of the parties.
5. In case of third party claims damages against both parties or either of them, the following shall apply:
  - 5.1. If a third party files a claim against one of the parties, the other party shall be obliged to provide best possible support for the defence against the claim.
  - 5.2. The Client shall hold EVP (and their affiliated companies as well as their respective directors, officers, employees and agents harmless upon first request from any liability claims of third parties and if they are attributable to:
    - Marketing, sales and supply of the products and their promoting;
    - Client's breach of the obligations or responsibilities set forth under this contract,
    - violation of developed products against property rights of third parties.
6. Holding EVP harmless shall include but shall not be limited to assume defence, to pay /share our attorney's fees and other defence costs, and to hire our counsel. In any case the Client shall hold EVP harmless upon first request from any liability claims of third parties covered by Client's waiver of rights for indemnification or other legal recourse (see sec. C. VII. 3).
7. EVP shall not acknowledge any third party's claim without Client's prior written approval in writing.
8. This liability exclusion and liability limitation shall not apply to deliberate acts, guaranteed qualities and loss of life, physical injury or damage to health or for liability according to fraudulent concealed defects. Mandatory law applicable with regard to Product Liability is thereof unaffected

registered for said inventions shall solely be made by EVP. EVP shall inform the client about any such registration of industrial property rights.

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## **VI. Right of inventions**

EVP shall exclusively be entitled to all inventions made by employees of EVP during the development phase. The decision as to whether industrial property rights should be