



DECAHEDRON Ltd, Unit 14, The Spire Green Centre, Merring Way, Harlow, CM19 5TR, United Kingdom
Telephone: +44 (0) 1279 435 591 www.decahedron.com

QUALITY TECHNICAL AGREEMENT

For the Purchase and Transportation of Medicinal Products within GB

between

DECAHEDRON LIMITED

And

(Please delete and enter name of your Company)

Valid for 3 years from the date of signing

(DD/MMM/YYYY)



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This agreement is made between:-

DECAHEDRON LIMITED, of Unit 14, The Spire Green Centre, Merring Way, Harlow, CM19 5TR,
Hereinafter called “Supplier” and

Your Company Name

Of Address

Delivery address if different from above

.....

Hereinafter called “Customer”

1. OBJECT

The object of this agreement is to set out the arrangements and responsibilities between Supplier and Customer, as required under current EU Good Distribution Practice (hereinafter referred to as ‘cGDP’) guidance (2013/C343/01), and as set out in Directive 2001/83/EC, as amended, for the purchase, storage and transportation of pharmaceutical products for parallel distribution within the European Economic Area.

EU GDP Guidance (2013/C343/01), Chapter 9 (Transportation) states, in principle, that ‘it is the responsibility of the Supplying wholesaler to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport’.

It is, however, a generally accepted principle in the pharmaceutical distribution industry that customers purchase goods on an ‘ex-factory’ or ‘ex-works’ basis, that is to say, that all responsibility for the condition of the goods concerned passes immediately they are collected, or loaded for transport by the supplier, (completion of the sale), and that this modifies the nature of the cGDP relationship between supplier and customer. However, Decahedron will supply goods under the minimum of FCA incoterms, i.e. through their approved transportation company at the cost to the customer.

Nevertheless, cGDP places differing burdens of responsibility on both parties in these transactions, and this technical agreement, therefore, addresses the respective responsibilities of the parties in this modified perspective.

2. RESPONSIBILITIES

a) Of the Supplier

- (i) Quality Management: the supplier confirms that they operate the requisite quality system demanded by cGDP. They further confirm that goods provided to the customer have been

placed in free circulation onto the EEA market, and that such sale complies with all relevant national pharmaceutical regulations with regard to their legal sale.

- (ii) **Personnel:** the supplier confirms their observance of cGDP and they employ sufficient competent personnel to carry out the task required, and that the Responsible Person is suitably qualified.
- (iii) **Premises and Equipment:** the supplier confirms that they maintain suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits, in accordance with cGDP.
- (iv) **Documentation:** the supplier confirms that they maintain an adequate documentation system to record all written procedures, instructions, contracts, records and data, in paper or electronic form, and in accordance with cGDP.
- (v) **Operations:** the customer confirms that their operations are in accordance with the requirements of cGDP.
- (vi) **Complaints, Returns, suspected Falsified Medicinal Products and medicinal product Recalls:** the supplier confirms their adherence to the principle and practice of cGDP.
The supplier confirms that they will notify the customer immediately of any recall notice issued in their national market, which affects the medicinal products supplied under this agreement.
- (vii) **Outsourced activities:** the supplier confirms that any activity which is outsourced beyond their immediate company should be correctly defined, agreed and controlled under a written agreement, in accordance with cGDP.
- (viii) **Self-Inspections:** the supplier confirms that self-inspections are undertaken within a defined timeframe in order to monitor implementation and compliance with cGDP principles.
- (ix) **Transportation:** The supplier will notify the Customer of the manufacturers recommended storage conditions for each product. As set out in section 1 of this agreement all responsibilities regarding the condition of the medicinal products pass to the customer after they loaded for transport by the supplier (completion of the sale). The supplier will notify the Customer of the manufacturers recommended storage conditions for each product.
- (x) **Audit:** The supplier accepts the requirements of GDP Chapter 7.

b) Of the Customer:

- (i) **Quality Management:** the customer confirms that they operate the requisite quality system demanded by their National Competent Authority.
- (ii) **Personnel:** the customer confirms their observance of the requirements of their National Competent Authority and they employ sufficient competent personnel to carry out the task required, and that the Responsible Person is suitably qualified.
- (iii) **Premises and Equipment:** the customer confirms that they maintain suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits, in accordance with the requirements of their National Competent Authority.
- (iv) **Documentation:** the customer confirms that they maintain an adequate documentation system to record all written procedures, instructions, contracts, records and data, in paper or electronic form, and in accordance with the requirements of their National Competent Authority.



- (v) Operations: the customer confirms that their operations are in accordance with the requirements of their National Competent Authority. The customer agrees that all exported products, that are covered by a marketing authorisation granted by the EU, or by a Member State, are not allowed back into the EU either directly or via a third party.
- (vi) Complaints, Returns, suspected Falsified Medicinal Products and medicinal product recalls: the customer confirms their adherence to the principle and practice of the requirements of their National Competent Authority.
- (vii) Outsourced activities: the customer confirms that any activity which is outsourced beyond their immediate company should be correctly defined, agreed and controlled under a written agreement, in accordance with National Competent Authority.
- (viii) Self-Inspections: the customer confirms that self-inspections are undertaken within a defined timeframe in order to monitor implementation and compliance within the requirements of their National Competent Authority principles.
- (ix) Transportation: The customer confirms the use of supplier transport operation i.e. DHL medical, and that all products will be transported within the storage conditions recommended by the manufacturers. As set out in section 1 of this agreement that all responsibilities regarding the condition of the medicinal products pass to the customer after they have been loaded for transport by the supplier (completion of the sale).
- (x) Audit: The customer accepts the requirements of GDP Chapter 7.
- (xi) Consignee: The Customer confirms that, as the consignee, they are authorized or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of their competent authority. Products purchased from the Supplier will only be delivered to Customers licensed premises.
- (xii) Documentation: Proof of safe delivery to Customers address will be provided to Supplier; and, for export sales, customs documentation to include Bill of Lading, CMR consignment notes, C88/Single Administrative Documents (SAD) etc will be completed, fully and legibly, and provided to the supplier.

Approval by Customer

Company Name:

Print Name:

Title:

Signature:

Date:

Approval by Decahedron Limited

Name:

Title:

Signature:

Date:



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DECAHEDRON STANDARD TERMS AND CONDITIONS FOR THE SALE OF GOODS

1. Interpretation

1.1 In these Conditions:

"Buyer" means the person or persons, firm or company who accepts a written quotation from the Company for the sale of the Goods or his order for the Goods is accepted by the Company.

"Goods" means the Goods (including any installment of the Goods) which the Company is to supply in accordance with these Conditions. "Company" means Decahedron Ltd (Company Registration Number 7732039) whose registered office is at Unit 11, The Spire Green Centre, Merring Way, Harlow, CM19 5TR, United Kingdom.

"Conditions" means the standard terms and conditions of sale set out in this document and (unless the context otherwise requires) includes any special terms and conditions agreed in writing between the Buyer and the Company.

1.2 Any reference in these Conditions to any provision of a statute shall be construed as a reference to that provision as amended, re-enacted or extended at the relevant time.

2 Basis of the Sale

2.1 The Company shall sell and the Buyer shall purchase the Goods in accordance with any quotation of the Company which is accepted by the Buyer in writing or any order of the Buyer which is accepted by the Company subject in either case to these Conditions, which will govern the Contract to the exclusion of any other terms and conditions.

2.2 No variation of these Conditions shall be binding unless agreed in writing between the authorised representatives of the Buyer and the Company.

3 Orders and Specifications

3.1 No order submitted by the Buyer shall be deemed to be accepted by the Company unless and until confirmed in writing by the Company's authorised representative.

3.2 The Buyer shall be responsible to the Company for ensuring the accuracy of the terms of any order, including the relevant specification submitted by the Buyer and for giving the Company any necessary information relating to the Goods within a sufficient time to enable the Company to perform the Contract in accordance with its terms.

3.3 No order which has been accepted by the Company may be cancelled by the Buyer except with the agreement in writing of the Company and on terms that the Buyer shall indemnify the Company in full against all loss (including loss of profit), costs, damages, charges and expenses incurred by the Company as a result of cancellation.



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4. Price of the Goods

- 4.1 The price of the Goods shall be the Company's quoted price and is exclusive of any applicable value added tax, which the Buyer shall be additionally liable to pay to the Company should value added tax in fact be payable.
- 4.2 The Company reserves the right, by giving notice to the Buyer at any time before delivery, to increase the price of the Goods to reflect any reasonable increase in the cost to the Company which is due to any factor beyond the control of the Company, any change in delivery date, quantities or specifications for the Goods which is requested by the Buyer or any delay caused by any instructions of the buyer.
- 4.3 Where carriage, insurance, packaging, storage or other charges are shown separately from the price of the Goods they are nevertheless payable by the Buyer at the same time as if they form part of the price and shall be treated as such for the purpose of these Conditions.

5. Payment

- 5.1 Until an approved Credit Account is established the company reserves the right to request the Buyer to make payment against a pro-forma invoice and the goods will only be purchased on receipt of the funds.
- 5.2 Where goods are delivered in installments the Company may invoice each installment separately and the customer shall pay such invoices in accordance with these Terms and Conditions.
- 5.3 Payment shall be made by the Buyer in the currency of the invoice, in full, within 30 days of the invoice date without set-off or counterclaims.
- 5.4 If the Buyer fails to make any payment on the due date than, without prejudice to any other right or remedy available to the Company. the Company shall be entitled to:
- a. Cancel the contract or suspend any further deliveries to the Buyer,
 - b. appropriate any payment made by the Buyer to such of the Goods (or Goods supplied under any other contract) as the Company thinks fit.
 - c. charge the Buyer interest (both before and after any judgment) on the amount unpaid at the rate of 5% per annum above Barclays Bank Plc base rate from time to time, until payment in full is made (a part of a month being treated as a full month for the purpose of calculating interest).

6. Delivery

- 6.1 Delivery of the goods shall be deemed to have occurred at the point determined by the Incoterms ® agreed between Decahedron and the buyer.



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6.2 Where the Goods are to be delivered in installments, each delivery shall constitute a separate contract and failure by the Company to deliver any one or more of the instalments in accordance with these Conditions or any claim by the Buyer in respect of any or more instalments shall not entitle the Buyer to treat the Contract as a whole as repudiated.

7. Risk and Property

7.1 Risk of damage to or loss of the Goods shall pass to the Buyer upon collection of the goods from the sellers Premises.

7.2 Notwithstanding delivery and the passing of risk in the Goods, or any other provision of these Conditions, the legal and beneficial title in the Goods shall not pass to the Buyer until the Company has received in cash or cleared funds payment in full of the price of the Goods and all other Goods agreed to be sold by the Company to the Buyer for which payment is then due.

7.3 Until such time as the legal and beneficial title in the Goods passes to the Buyer (and Provided the Goods are still in existence and have not been resold), the Company shall be entitled at any time to require the Buyer to deliver the Goods to the Company and if the Buyer fails to do so forthwith, to enter upon any premises of the Buyer or any third party where the Goods are stored and repossess the Goods.

8. Warranties and Liability

8.1 Subject as expressly provided in these Conditions, all warranties, conditions or other terms implied by statute or common law are excluded to the fullest extent permitted by law.

8.2 Any claim by the Buyer which is based on any defect in the quality or condition of the Goods or their failure to correspond with specification shall be notified to the Company within 3 days from the date of delivery or within a reasonable times discovery of the defect or failure.

8.3 Where any valid claim is notified to the Company in terms of Condition 8.2 above, the Company shall be entitled to replace the Goods free of charge or at the Company's sole discretion, refund to the Buyer the price of the Goods but the Company shall have no further Liability to the Buyer.

8.4 Except in respect of death or personal injury caused by the Company's negligence, the Company shall not be liable to the Buyer by reason of any representation. or any implied warranty, condition or other term, or any duty at common law, or under the express terms of the Contract, for any consequential loss or damage (whether less of profit or otherwise), costs, expenses or other claims for consequential compensation whatsoever which arise out of or in connection with the supply of the Goods or their use or resale by the Buyer except as expressly provided in these Conditions.



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- 8.5 The Company shall not be liable to the Buyer or be deemed to be in breach of the Contract by reason of any delay in performing, or any failure to perform, any of the Company's obligations in relation to the Goods, if the delay or failure was due to any cause beyond the Company's reasonable control (including prohibitions or measures of any kind in the part of any Governmental, or local authority import or export regulations or embargoes, strikes, lock-outs or other industrial action or trade disputes, difficulties in obtaining raw materials, labour fuel, pans and machinery, power failure or breakdown of machinery).

9. Insolvency of Buyer

- 9.1 This Clause applies if:
- a. the Buyer makes any voluntary arrangement with its creditors or becomes subject to an administration order or (being an individual or firm) become bankrupt or (being a company) goes into liquidation (otherwise than for the purposes of amalgamation or reconstruction); or
 - b. an encumbrancer takes possession. or a receiver is appointed, of any of the property or assets of the Buyer: or
 - c. an encumbrancer takes possession or receiver is appointed of any of the property or assets of the buyer; or
 - d. the Buyer ceases, or threaten to cease to carry on business; or
 - e. the Company reasonably apprehends that any of the events mentioned above is about to occur in relation bathe Buyer and notifies the Buyer accordingly
- 9.2 If this Clause applies, without prejudice to any other right or remedy available to the Company, the Company shall be entitled to cancel the Contract or suspend any further deliveries under the Contract without any liability to the Buyer and If the Goods have been delivered but not paid for the price shall become immediately due and payable notwithstanding any previous agreement or arrangement to the contrary.

10. General

- 10.1 Any notice required or permitted to be given by either party to the other under these Conditions shall be in writing addressed to that other party at its registered office or such other address as may at the relevant time have been notified pursuant to this provision to the party giving the notice.
- 10.2 No waiver by the Company of any breach of the Contract by the Buyer shall be considered as a waiver of any subsequent breach of the same or any other provisions.
- 10.3 If any provision of these Conditions is held by any competent authority tribe invalid or unenforceable in whole or in part the validity of the other provisions of these Conditions and the remainder of the prevision in question shall not be affected thereby.
- 10.4 The contract shall be governed by the law of England and the parties submit to the exclusive jurisdiction of the English courts.

Appendix 3 – Standard Letter of Acceptance, see below

We are pleased to welcome you as a new customer of Decahedron. We feel honoured that you have chosen us to fill your business product needs, and we are eager to be of service.

As you know, we carry everything your establishment may need in our specialist area. We have a great variety of products to choose from, all at competitive prices. We would be happy to visit with you at your convenience to discuss your business supply needs. Just call us at the above number, or come by any time between 9:00 a.m. and 5:00 p.m., Monday through Friday.

Thank you again for your choice of Decahedron to fill your business supply needs. We look forward to a long and successful association.

Appendix 4 – Denial Letter, see below

Thank you for submitting your new customer account form. Based upon the information provided, we are currently unable to provide your company with an account. Should your circumstances changes please do contact us again and we will be happy to accept your business.