



General Terms of Particle Analytical ApS

These General Terms and conditions apply to all services delivered from Particle Analytical (PA), unless otherwise clearly stated in the quotation or other agreements between the parties. The extent of the service and the prices agreed will be described in the quotation from PA.

1. Sample Delivery

Upon order confirmation, the client shall provide PA with clean and intact samples and sufficient sample amount. The PA Sample Submission Form (attached) must be filled. The client will be responsible for delivering samples to PA's premises. Samples can be delivered during normal Danish working days, 9 am – 3 pm. The required information shall be provided with the samples or in advance by email to samples@particle.dk

2. The service

2.1. Quality

PA performs analysis according to Ph. Eur. and USP. PA holds a valid GMP certificate from The Danish Medicine Agency and is registered with the FDA. It is the responsibility of the client to ensure GMP requirements regarding validation and method transfer for GMP analyses is in place, as well as ensuring a quality agreement is in place if required. PA will not perform any release of products to the market. PA will perform analyses as their best effort and according to PAs written quality system. PA has no further responsibility for the analyses than performing analyses according to PAs quality system.

2.2. The deliverables

PA will supply reagents and consumables as required for performing the service

The service includes original CoA and approved print outs from the analysis and will be provided to the customer upon completion of the service to be delivered by regular mail to the customers contact person. The service is regarded as delivered, when mailed by PA. Other services will be invoiced separately according to PA's standard price schedule unless otherwise specific stated in a written agreement between the parties.

2.3. Audits

In case the customer wishes to perform an audit of PA this must be agreed with PA at least one month before the desired audit day. Audits will be invoiced separately according to PA's standard list prices, this also includes audits by regulatory bodies as part of inspectional programs for the customer.

2.4

In case of OOS, which is not a Laboratory error (PA), the customer will be charged with a standard fee for the initial internal laboratory investigation.

3. Timelines

Routine samples will be delivered as ordered by customer as follows:

- Normal delivery - target to be mailed within 10 working days from receipt.
- Priority delivery - target to be mailed within 5 working days from receipt.
- Express delivery - target to be mailed next business day from receipt.
- High priority delivery – targeted to be mailed the same business day from receipt

Priority and express delivery have to be agreed by PA in advance. All delivery time are estimated, and PA bears no responsibility for any delay whatsoever will be the reason for such delay. In no events PA will be responsible for non-delivering due to break down of equipment.

4. Quotation, price and payment conditions

A quotation is valid for 3 months, but no longer as by the end of the running year. The approval of the quotation needs to be sent to: sales@particle.dk Any additional work will require an approval of the additional cost by the customer. All fees will be added in the Quotation. PA will invoice upon completion of services. Invoices will be sent to the customer via email. Payment terms will be 8 days from date of the invoice. Bank transfer fees are agreed to be paid by customer. In case of delayed payment, PA will charge interest rate of 2% per month.



5. Cancellation

In case the customer wants to cancel an ordered service, PA will invoice according to performed work, and not less than 50% of the amount agreed.

6. Limitation of liability

In no case will PA be liable for any loss of profit, consequential loss, or any other indirect loss, which may directly or indirectly have been caused by negligence or delay in performing the agreed services. Particle Analytical shall not be liable for any loss or damages arising from the customer's use of statements or results provided by Particle Analytical. In no event shall Particle Analytical liability exceed the amount paid for the specific service that has caused the liability and shall in no case exceed DKK 50.000. PA will not be liable for any claims made after 30 days from the date of delivery of the service.

7. Force Majeure

PA cannot be held liable for damage or loss due to force majeure, actual or imminent war or similar situations, revolt, civil unrest, natural catastrophe, strike, lockout, boycott or blockades, irrespective of whether said party is a party to a conflict arising and irrespective of whether any conflict arising only affects part of the operations of said affected party. Breakdown of equipment will be regarded as force majeure.

8. Governing law and dispute resolution

These General Terms shall be subject to and be interpreted in accordance with Danish law. If nothing stated in the General Terms, Danish law shall apply. Any dispute or demand arising out of the trade between PA and the customer shall be finally settled by arbitration in accordance with the rules of procedure of the Danish Institute of Arbitration (Voldgiftsinstituttet) in force from time to time. The arbitrators shall be appointed in accordance with the aforementioned rules.

9. Inventions and patents

PA agrees that all data, inventions, discoveries, know-how and works arising from the performance of the services under this agreement (hereinafter, "**Intellectual Property**"), shall be the sole property of the customer and shall become part of customer's confidential information. PA hereby agrees to promptly disclose all Intellectual Property to the customer in writing. Furthermore, PA agrees to provide the customer with proper assistance and documentation, at customer's cost, to enable it to file patents, copyright or other legal protections for the Intellectual Property.

Notwithstanding the foregoing, PA shall own all inventions, discoveries, know-how and works which generally relates to the PA's organization or business and which does not include any of the customer's confidential information.

As far Intellectual Property relates to copyrights of PA which cannot be assigned to the customer, PA hereby grants to the customer and the customer hereby accepts a worldwide, exclusive, timely unlimited, irrevocable and comprehensive license to such copyrights for use and exploitation for all existing and future forms and types of use with or without mentioning of copyrights. Uses are, without limitation, publication, promotion, training and education. The customer is especially authorized to copy, distribute, translate and modify such copyright protected documents.

10. Confidentiality

Parties agree that all information exchanged between both organizations - disclosed during the execution of this agreement, in whatever format - shall be deemed confidential if the nature of the information is confidential and of which the other party reasonably knows or should know that that information is confidential such as, but not limited to, technical, scientific, commercial, financial, organizational, and legal data/ information.

01-July-2024