

## GENERAL TERMS AND CONDITIONS ACCEPTANCE

All transactions are subject to, and expressly conditioned on, these General Terms and Conditions. These Terms and Conditions are binding and any additional or inconsistent terms and conditions in any acknowledgement of receipt, Purchase Order, or acceptance documents requested from or provided by the Purchaser are expressly rejected. The European Directorate for the Quality of Medicines & HealthCare / Council of Europe (herein referred to as "EDQM") reserves the right to make changes to these Terms and Conditions at any time including pricing, dispatch policies, terms and conditions, etc. The Purchase will be subject to the terms and conditions policies in force at the time the Purchaser purchases via the EDQM Website, EDQM Store or Online Events Registration System.

No variation of these Terms and Conditions is binding on the EDQM unless agreed to in writing and signed by the EDQM Director or other authorised representative of the EDQM.

## ACCOUNT

Before Purchase Orders can be accepted, the Purchaser must complete an Account & Credit Application Form. Accounts can be closed at the discretion of the EDQM. Purchasers are responsible for ensuring that the information provided to the EDQM is correct and for inform-

ing the EDQM of any changes. The EDQM cannot be held responsible for any damage or losses caused by, or alleged to be caused by inaccurate, partial or out-of-date information provided by the Purchaser as part of the purchasing process with the EDQM.

## PURCHASE ORDERS

Purchase Orders may be placed by the Purchaser in any commercially acceptable manner that the Purchaser and the EDQM deem appropriate, including online or e-mail, with the exception of telephone. Purchase Orders are subject to acceptance by EDQM and are only deemed to be accepted when the EDQM issues an Order Confirmation e-mail. Any contingencies contained in such Purchase Orders are not binding on EDQM unless agreed to in writing by the Director or other authorised representative of the EDQM.

### Availability

The availability of all EDQM items is shown on the EDQM Store for publications and on the EDQM Website for other items, e.g. Reference Standards, Events, etc. The EDQM shall use reasonable efforts to fill orders with due regard to availability, demand and inventory on hand, but when quantities of items are limited, the EDQM will try to dispatch orders in such a way that as many Purchasers as possible receive at least some of the quantities ordered.

Further information on the availability of items for ship-

ment will be provided via an Order Confirmation e-mail upon processing of the Purchaser's Purchase Order by the EDQM. Any unavailable product (except those available in limited quantities and some exceptional cases) will be placed on backorder and the EDQM will automatically ship any back order that becomes available.

### Duplicate orders

The Purchaser is financially responsible for duplicate orders in the following cases: when confirming orders, not clearly marked as confirming an order already submitted, are sent to the EDQM, or when submitting the same order multiple times (e.g. via fax, e-mail, EDQM Store, or any combination thereof).

### Amendments/cancellations

Amendments/cancellations can only be accepted within 24 hours of the date and time of the Order Confirmation e-mail sent by EDQM and upon the express agreement of the EDQM. After this timeframe, amendments/cancellations are no longer possible. The order will automatically be shipped and/or invoiced and the Purchaser will remain financially responsible for the order.

## SHIPPING/DELIVERY/CUSTOMERS CLEARANCE

A Confirmation of shipment will be provided via a Prior to Dispatch e-mail to the Purchaser before the order is dispatched. A Dispatch Notification e-mail with the tracking details will be sent once the order has been sent.

Only the EDQM has the right to choose the shipping service used to dispatch EDQM items. The Consignee/Purchaser is not permitted to provide their shipping import account number to pay shipping charges nor pick up the order directly. The Incoterms used are listed in the specific Terms and Conditions.

– *Regulatory Procedures and SH/NDP (harmonised system).*

The SH/NDP code added to each item listed in the shipping documentation is a proposal by the EDQM and is not binding. The importer shall be personally responsible for the tariff classification in the country of import and will assume the ensuing regulatory, fiscal, health and safety obligations.

Origin of the goods: Diplomatic, Council of Europe (France) SH/NDP 000009.

This SH/NDP code is strictly limited to the EDQM's export operations out of France.

## PRICES

All prices and product descriptions for goods and order handling charges shall be as those identified on the [EDQM's Website](#) and/or the [EDQM Store](#) at the time the order is processed for dispatch. However, the EDQM will honour all EDQM price quotations up to and including the expiration date on the quotation on condition that the product(s) remain available. Any applicable discounts will be shown on the Order Confirmation.

## VAT & OTHER TAXES

### VAT

All prices on the EDQM Store or EDQM Website are per unit and exclusive of customs duties and taxes and are shown in euros. Transactions with the EDQM (being part of the Council of Europe) within the European Union are exempt from VAT under Article 13 of the Council of the European Union Directive 2006/112/EC on the common system of value-added tax. As an international organisation with diplomatic status, the Council of Europe has no VAT identification number. Customers based in the EU should comply with applicable VAT regulations. Taxable customers should account for VAT via the reverse charge mechanism.

### Import and Customs Charges

Notwithstanding the above, customs duties, VAT and other taxes may be levied on all transactions and shipping outside the EU. These duties and taxes are to be paid by the Purchaser who shall be responsible for both declaration and payment of all applicable import taxes, customs clearance costs, final transport charges (depending on the Incoterm) and other customs duties in the country concerned. In no event shall the said duties and taxes be paid by the EDQM nor should they be deducted from the amount paid to the EDQM.

Applicable taxes, customs clearance costs, final transport charges (depending on the Incoterm) and other customs duties do not entitle the Purchaser to

cancel his/her order, refuse the items or to claim reimbursement or interest from the EDQM.

## INVOICING & PAYMENT

Payment terms will be mentioned on the Order Confirmation e-mail and the invoice. The general payment terms for all items under these Terms and Conditions are thirty (30) days from the end of the month following the date of the invoice issued by the EDQM, based on approval of a credit line by the EDQM's Accounts Receivable Team. However, the EDQM retains the option to modify the payment terms and this will be communicated to the Purchaser before any pending order is processed.

The EDQM accepts payment via the EDQM Store, Bank Transfer or by Credit/Bank Cards (Visa, Eurocard, MasterCard, and American Express). The EDQM store facility for electronic payment by credit card is fully secure. All data transmitted are encrypted, and neither the EDQM nor any third party has access to them.

The EDQM does not accept payment by letter of credit. The Purchaser must ensure that payment is made net of charge for the EDQM and the amount paid must cover the amount invoiced in euros.

### Late Payment

Should the Purchaser fail to comply with the payment terms they will automatically be deemed in default of payment and risk having their line of

credit rescinded. In addition, all outstanding invoices, even if payment is not already due, will require immediate payment in full, and authorised credit terms will be cancelled.

The EDQM reserves the right to apply a penalty charge of 12% of the total amount outstanding after the due payment date. This penalty is based on the number of overdue days and is calculated as follows: [overdue amount x 12 %] x [overdue days /365]. The EDQM also reserves the right to apply a charge for debt recovery costs per invoice as follows:

Invoice amount	Recovery costs
Up to €999.99	€40
Between €1000 and €9999.99	€70
Above €10 000	€100

The EDQM reserves a security interest in the items until payment is collected in full.

## ELECTRONIC COMMUNICATIONS AND DATA

### Electronic Communications

Where possible, the EDQM limits communication with the Purchaser to electronic means. By placing Purchasing Orders with the EDQM, the Purchaser consents to receive electronic communications in respect of the processing and dispatch of their order from the EDQM as well as updates on product safety and price and service changes.

### Personal data processing – Fair Processing Notice (FPN)

The EDQM will use data and other information provided by the Purchaser on the order form and/or the Credit Application

Form for ordering and for invoicing purposes, and to address any issues linked with the quality of the products bought. The EDQM will also use this data for direct marketing via e-mail, provided that the product or service being marketed is similar to one which the Purchaser has bought within the previous twelve months or, in the case of publications, the Purchaser has purchased the previous edition of the item. Each time the EDQM sends a marketing e-mail, the Purchaser will have the option to decline to receive further marketing e-mails by sending an e-mail to [cdu@edqm.eu](mailto:cdu@edqm.eu) with “unsubscribe” in the subject line. If the Purchaser has received a marketing e-mail from the EDQM for a similar product or service during that twelve-month period without objection, the EDQM will consider that the Purchaser’s consent remains valid and will keep using his personal data for direct marketing until the Purchaser expresses his wish to opt out from this marketing communication.

Without prejudice to the possibility of transmitting to its bank the data required to process orders, the EDQM undertakes not to divulge the Purchaser’s data to third parties with the exception of those contacts provided by the Purchaser on the Account and Credit Application Form and/or during the ordering process.

## DISTRIBUTORS /WHOLESALERS

Although there are a number of companies that offer EDQM items for sale, the EDQM does not appoint authorised distributors of its items. Purchasers are free to purchase directly from the EDQM or from a distributor. The EDQM is not liable for items purchased via a distributor.

## WARRANTIES, LIABILITY & RESPONSIBILITY

### Warranties

The EDQM does not guarantee that the items will meet the Purchaser’s specific expectations. The EDQM only guarantees that the items: (i) are fit for use according to EDQM’s intended use of the product; (ii) were fit for use at the time they were handed over to the carrier responsible for the delivery of the items to the Purchaser with such accessories, including packaging, delivery instructions or other instructions for the item’s delivery and reception, as the Purchaser may expect to receive; (iii) possess qualities and performance capabilities which are normal in goods of the same type and which the Purchaser may expect given the nature of the goods and the information provided on the EDQM’s Website and (iv) were dispatched after both the carrier and the Purchaser received clear and accurate instructions for the item’s delivery and reception. No other guarantees, either explicit or implied, are given by the EDQM. The EDQM does not

guarantee that the purchase or use of the items will not infringe any intellectual property rights, in particular patents.

#### Limitation of Liability

In no event shall the EDQM be liable for any damages due to the use of items, including, but not limited to, loss of business, loss of profit, loss of use, loss of opportunity, costs of procurement of substitute goods, services or systems or for any indirect, special, incidental, punitive or consequential damages, however caused and, whether in contract, tort or under any other theory of liability, whether or not the Purchaser has been advised of the possibility of such damages or costs.

In no event shall the EDQM be held liable for any damages of any kind due to the impossibility of using or accessing its Websites; nor shall the EDQM be held liable for any loss whatever its origins, specifically mentioning loss of profits, connected to the information on its Websites. The EDQM declines all responsibility for any damages of any kind resulting from the fraudulent intrusion of a third party leading to the modification of the information provided therein.

#### Responsibility

The EDQM cannot be held responsible for orders not being fulfilled in the event of items being out of stock or unavailable due to *force majeure*, disturbances or total or partial strike action and flood or fire. Furthermore, the EDQM cannot be

held responsible for the consequences of any delay in delivery due to *force majeure*, such as computer breakdown, disruption or strikes affecting national or private courier services.

#### *– Responsibility for items*

It is the Purchaser's responsibility to check with the local, regional or national authorities and to make sure that the items that they intend to order can be imported or used in that country before ordering. As a result, the EDQM cannot be held responsible for failure to meet any specific requirements of the legislation of the country where the items are delivered.

The Purchaser is solely responsible for the choice of items, their storage from the time of delivery and their use. In no event shall the EDQM be liable for any consequent damage.

#### *– Responsibility for the availability of online facilities and services (EDQM Website, Online Store, CombiStats™ platform and Events Registration System, etc.)*

The EDQM will do its utmost to ensure that availability of the EDQM Website, the EDQM Store, the EDQM Online Events Registration System or the Combistats™ platform is uninterrupted. However, due to the nature of the Internet, this cannot be guaranteed. Also, access may be occasionally suspended or restricted to allow for repairs, maintenance, or the introduction of new facilities or services. The EDQM will attempt to limit the frequency and duration of any

such suspension or restriction.

#### *Purchaser's responsibility*

The Purchaser guarantees the EDQM against all financial or other implications resulting from any breach or infringement of its obligations.

## COMPLAINTS, CLAIMS, RETURNS AND CANCELLATIONS

### Complaints or Claims

All Complaints and claims must be made in writing by the Purchaser. They must be received by fax or e-mail or via the EDQM HelpDesk. Any delays in delivery which cannot reasonably be attributed to the EDQM do not entitle the Purchaser to cancel the Purchase Order, refuse the items or claim damages or interest.

#### *– Faulty or Damaged Goods*

The EDQM is responsible for goods until they are delivered to the Purchaser (or the designated place of delivery) including for any damage *en route* (according to the Incoterms used).

• *Damaged packaging.* The Purchaser's obligation is to evaluate the shipment's outer packaging immediately upon delivery. If the outer packaging is damaged, it is the responsibility of the Purchaser to point this out to the transporter and to undertake a shipment content evaluation in the presence of the transporter. If the content of the shipment is found to be damaged, the Purchaser must ask the transporter to make a note of the damage on the delivery paperwork. The Purchaser must then submit a



complaint about parcel content damages to the EDQM with photographic evidence within 1 working day.

- *Suspected damaged goods.* If, at the time of delivery, the outer packaging is not damaged, but there is a suspicion of damage to the contents of the shipment, the Purchaser must undertake a shipment content evaluation in the presence of the transporter. If the content of the shipment is found to be damaged, the Purchaser must ask the courier to make a note of the damages on the delivery paperwork. The Purchaser must then submit a complaint about parcel content damages to the EDQM, with photographic evidence, within 1 working day.

– *Incorrect goods dispatched / Missing items*

It is the Purchaser's responsibility to inspect delivered goods and make any complaints within 5 working days of delivery. Complaints can be made by the Purchaser only if, upon delivery, the items delivered are not found to correspond quantitatively, or if incorrect items are identified, compared with the Order Confirmation and the Prior-to-Dispatch Notification. The "items delivered" refers to the availability of the product under the conditions laid down in article "Availability".

– *Missing parcel*

Complaints for missing parcels have to be sent to the EDQM within 30 days from the shipping date of the parcel.

– *Rectification for justified complaints*

If a complaint is shown to be justified, the EDQM will discuss with the Purchaser the method of rectification, i.e., either refunding the Purchaser and/or sending a replacement.

Returns

The EDQM has different return policies for each type of EDQM product (see "Specific Terms and Conditions" below). In no event shall the Purchaser return items to the EDQM unless the EDQM has been notified and has given its written consent. If the EDQM gives written consent, the EDQM will decide the most economical method to return the goods.

Cancellations

Cancellations can only be accepted if received within 24 hours from the date and time of the Order Confirmation e-mail.

**ARBITRATION & APPLICABLE LAW**

The aim of the EDQM is to settle any disputes amicably in the framework of these Terms and Conditions. In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the EDQM and the Purchaser as regards the application of these General Terms shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order [No. 481 of the Secretary General](#),

approved by the Committee of Ministers.

This transaction shall be governed by the Council of Europe's relevant regulatory framework, complemented, where necessary, by French national substantive law.

---

**SPECIFIC TERMS AND CONDITIONS: REFERENCE STANDARDS**

General Conditions

Given the nature of the items, the EDQM reserves the right to refuse any order if the Purchaser is unable to provide guarantees of the competencies, import and/or export permits, authorisation or expertise required.

Purchase Orders

– *Addresses*

The invoice and the delivery address must be both within the EU or both outside the EU. The EDQM cannot accept an invoice address within the EU and a delivery address outside the EU or vice versa.

– *Quantities*

Each Reference standard is sold as a "sales unit". Each "sales unit" may include several vials/ampoules. It is the responsibility of the Purchaser to order the number of "sales units" required and not the total number of vials/ampoules. The EDQM's [online database](#) for reference standards should be consulted before ordering. The EDQM cannot be held responsible for the Purchaser incorrectly ordering the number of "sales units" required.

The EDQM reserves the right to change without notice the unit quantity of a reference standard if the monographs has been updated.

#### *– Availability and Restrictions*

When stocks of a given reference standard are low, the EDQM reserves the right to limit the quantities sold to each Purchaser to ensure that as many Purchasers as possible will receive at least some of the quantities available.

Restrictions on quantities are applied at the time the Purchase Order is received.

#### Warranties, Liabilities and Responsibility

##### *– Quality and purpose of items supplied*

Reference standards are supplied by the EDQM as follows:

- All chemical substances, herbal standards or biological preparations listed in our catalogue are supplied exclusively as European Pharmacopoeia Chemical Reference Substances, Herbal Reference Standards Biological Reference Preparations/ Reagents or Reference Spectra (Ph. Eur. CRS, HRS, BRP, BRR or RS) with the primary intention for use in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia (Ph. Eur.).
- All WHO International Chemical Reference Substances (ICRS) are supplied with the primary intention for use in physical and chemical tests and assays described in the specifications published in "The

International Pharmacopoeia" for the quality control of pharmaceutical substances.

- All WHO International Standards for Antibiotics (ISA) are generally intended for the establishment of regional or national secondary standards subsequently used in routine laboratory tests and assays.

##### *– Safety*

In the event of any safety concerns or for any other information about a product, the Purchaser must read carefully the safety data sheets or safety data statements available for hazard identified products. It is up to Purchasers to determine independently the risks associated with the items according to the information leaflet and safety data sheet for each item listed on the EDQM's reference standards online database and to take appropriate safety measures, including the provision of appropriate information, equipment and training to those persons coming into contact with the item.

##### *– Warranties*

Except for the use of Reference Standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and by professionals with the necessary technical skills and at their own discretion and risk, the EDQM makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for

any particular purpose except that as described above.

##### *– Liability*

Any liability of the EDQM for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted by internationally accepted commercial standards; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

#### Shipment/Delivery/Customs Clearance

##### *– Incoterms*

EDQM items are shipped to the Purchaser on either a:

- DAP (Delivered at Place + destination name),
- CIP (Carriage and Insurance Paid to + destination name),
- or CPT (Carriage Paid To + destination name) basis (only for certain countries or for shipments of EUR 500 or less).

Details will be provided to the Consignee on the Dispatch Notification e-mail. The information is also available on the Website in document [Order and dispatch of EDQM products](#).

##### *– Specific documentation for shipment*

It is the responsibility of the Purchaser to check if a special permit is needed in the importing country for the given product or if, for the given product, no importation at all is allowed. All necessary documentation has to be provided with the order (especially as regards biological items). The Purchaser must provide one import licence per

controlled item. The EDQM reserves the right to refuse an import document which would mention several controlled items. For details related to specific countries the Purchaser should check the EDQM Website and the Order Confirmation e-mail.

#### Prices

##### *– Order Handling charges*

The EDQM will charge EUR 2.50 order handling charge per sales unit, regardless of geographical zone or type of product ordered. This handling charge does not apply to reference spectra.

##### *– Discount*

No discounts are granted on our reference standards.

#### Complaints, Claims and Returns

The EDQM only accepts complaints related to faulty, damaged or the incorrect goods dispatched or missing items.

##### *– Returns*

For quality reasons, the EDQM cannot take back any item which has been sent.

---

## **SPECIFIC TERMS AND CONDITIONS: PROFICIENCY TESTING STUDIES (PTS)**

---

In addition to the EDQM's General Terms and Conditions, participation in PTS schemes is also bound by specific conditions pertaining to the programme and the related Registration Form PTS and prices as found on the EDQM Website.

#### Purchase Orders

Purchasers are requested to complete a Registration Form PTS identifying the studies in which they wish to participate.

Each registration will be confirmed after the registration deadline.

Purchasers must inform the EDQM if they no longer wish to participate otherwise the items of the study will be shipped and the Purchaser will be liable for payment.

#### Shipment/Delivery

##### *– Incoterms*

EDQM items are shipped to the Purchaser on a DAP (Delivered at Place + destination name) basis. However, the EDQM reserves the right to ship on a CIP (Carriage and Insurance Paid to + destination name) basis or CPT (Carriage Paid To + destination name) basis. Details will be provided to the Purchaser on the Dispatch Notification e-mail.

#### Prices

Details can be found on the EDQM Website:

[Chemical and Biological PTS](#)

[Blood PTS](#)

[Complaints, Claims and Returns](#)

The EDQM only accepts complaints related to faulty, damaged or incorrect goods dispatched or missing items.

The EDQM does not accept claims related to unwanted or cancelled items more than 24 hours from the date and time of the Order Confirmation e-mail.

##### *– Returns*

For quality reasons, the EDQM cannot take back any item which has been sent.

---

## **SPECIFIC TERMS AND CONDITIONS: PUBLICATIONS**

---

##### *– Free EDQM Publications*

A number of EDQM publications are provided free of charge by the EDQM. The free EDQM publications are identified on the EDQM Store, EDQM Website and/or the EDQM [Free Publications site](#). The Purchaser shall provide an e-mail address to download a free publication. The Purchaser, by acquiring a free publication, shall obtain the non-exclusive right from the EDQM to install and use the publication. To allow the EDQM to understand how many times the publication is being read the Purchaser agrees not to redistribute or resell the publication.

#### Prices

*– Order handling charges (not applicable for orders placed via the store)*

**9<sup>th</sup> Edition:** the EDQM will charge EUR 9 per print issue and EUR 27 per print subscription of the 9<sup>th</sup> Edition regardless of geographical zone of delivery.

**All other publications (10<sup>th</sup> Edition, Guides, etc.):** the EDQM will charge EUR 20 per print issue and EUR 60 per print subscription regardless of geographical zone of delivery.

##### *– Bookseller Discount*

Booksellers may receive discounts from the EDQM for their publication-related purchases. Details of any discounts are listed when the account is set up and reviewed every 3 years.

#### Invoicing & Payment

Invoices may be established before the goods are shipped. Payment must be received by the EDQM within the payment

terms identified on the invoice within the limits of the general payment policy outlined under the General Terms and Conditions herein.

#### Shipment/Delivery/Customs Clearance

##### *– Incoterms*

EDQM publications are shipped to the Purchaser on a DAP (Delivered at Place + destination name) basis only.

##### *– Bookseller Shipment*

EDQM publications are sent directly to the bookseller and not to the end user.

#### Complaints

The EDQM only accepts complaints related to faulty, damaged or the incorrect goods dispatched or missing items.

#### Returns, cancellations and exchanges

In no event shall the Purchaser return publications to the EDQM unless the EDQM has been notified and has given its written consent. Please be aware that the EDQM will not reimburse the post & packaging charges unless specifically agreed in advance, and in writing, by the EDQM.

##### *– Print format of the European Pharmacopoeia*

Returns, cancellations and exchanges requests within the EU are considered on a case-by-case basis, e.g. if the product remains unopened and in its original packaging and only if the request is received within 10 days from receipt of the product. Unfortunately due to issues with reimportation from outside the European Union (EU), returns, cancellations and exchanges

from outside the EU are not permitted.

##### *– Downloadable and USB formats of the European Pharmacopoeia*

Cancellation and exchanges are not permitted.

##### *– Online formats of the European Pharmacopoeia*

Cancellations and exchanges are considered on a case-by-case basis.

##### *– Other print formats*

Cancellation and exchanges are not permitted.

In addition to the EDQM's General Terms and Conditions and these specific conditions, subscriptions to the Online or Offline version of the European Pharmacopoeia are also bound by the relevant Licence agreement (see below).

---

#### **SPECIFIC TERMS AND CONDITIONS: COMBISTATS™**

---

In addition to the EDQM's General Terms and Conditions, a CombiStats™ subscription is also bound by a Licence agreement for the use of CombiStats™ (see underneath).

---

#### **SPECIFIC TERMS AND CONDITIONS: CERTIFICATION (CEP)**

---

In addition to the EDQM's General Terms and Conditions, the submission of an application for a CEP is also bound by specific conditions pertaining to the Certification Procedure, the related application form and prices as found on the EDQM Website.

#### Invoicing & Payment

Upon receipt, the application is checked for completeness and, if appropriate, listed for assessment. Once the application has been listed, an invoice will be established.

Payment must be received by the EDQM, in compliance with the payment terms stated on the invoice, irrespective of the outcome of the assessment. The invoice also remains liable for payment even if the Purchaser withdraws their application during the assessment period or if the EDQM decides to definitively close the application as a result of insufficient information being received (after such information has been requested in writing and a deficiency letter has been sent in the event that the Purchaser fails to provide the information in a timely fashion). Failure to settle the invoice by the due date will result in the Certification Procedure being suspended or stopped, and this process will similarly affect the assessment of other ongoing or future applications, until payment is received.

---

#### **SPECIFIC TERMS AND CONDITIONS: EDQM EVENTS (CONFERENCES, TRAINING COURSES AND WEBINARS)**

---

For EDQM events the terms Purchaser and Registrant are interchangeable.

#### Prices

##### *– Registration Fees*

Fees vary for each event and according to the registration method used (i.e. paper format



or the EDQM Online Events Registration System) and the status of the registrant. The registration fees (in EUR) for each event are published on the EDQM Website ([www.edqm.eu](http://www.edqm.eu)) and/or on the Event Registration Form. If the registration form is received by fax, e-mail or via the EDQM HelpDesk, it is not considered as online registration.

### Invoicing & Payment

Payment must be received by the EDQM before the date of the event or the due date on the invoice, whichever is earliest. To benefit from the rates stated, payment must be received in accordance with the payment terms mentioned on the invoice.

#### *– Late Payment*

Failure of the Purchaser/Registrant to comply with the payment terms will mean they are automatically deemed in default of payment and the Registrant may be refused entry to the event.

### Purchase Orders

#### *– Cancellations and “No shows”*

If the Purchaser/Registrant needs to amend or cancel his/her registration, the EDQM shall be informed immediately in writing by post, fax or e-mail via the EDQM HelpDesk. Cancellations are not deemed as receivable by the EDQM until the Purchaser/Registrant has received written confirmation. Refunds will be made as follows:

- Purchasers/Registrants cancelling more than 30 days before the event shall be refunded 80% of the registration fees.

- Purchasers/Registrants cancelling less than 30 days before the event will not be eligible for a refund.

Registration fees outstanding at the time of cancellation are due. If the enrolled Purchaser/Registrant attends the event but the registration fee is still outstanding, the Purchaser/Registrant shall still be liable to pay the due fee during the event. “No-shows”:

- If the invoice has been paid, any registration fees paid will be retained by the EDQM. However, the event package will be sent to the Purchaser/Registrant.
- If the invoice has not yet been paid, it will be treated as an outstanding debt.

#### *– Substitutions*

Substitutions may be made at any time. Substitutions must be received in writing by post, fax or e-mail via the EDQM HelpDesk. The enrolled Purchaser/Registrant must send the registration form of the substitute person to the EDQM at the earliest opportunity. The EDQM will provide the new Registrant with written acknowledgement of receipt of the registration form and with confirmation that he/she has been registered for the event.

The registrations are individual. Sharing of the registration between persons is not permitted.

### Responsibility & Liability

#### *– Event*

The EDQM guarantees that all necessary measures have been taken to ensure that the event

corresponds to the description given in the event’s marketing material and/or on the EDQM Website.

#### *– Changes*

Only the EDQM has the right to choose the services, service providers and premises to be used to deliver the event.

##### *○ Programme Changes*

The EDQM reserves the right to make necessary changes at short notice, arising from, but not limited to, no-shows or cancellations by speakers, panel members, moderators, workshop presenters or any other person or organisation mentioned in the event information. The EDQM will not refund registration fees as a result of changes to the programme.

##### *○ Venue & Time Changes*

It may be necessary for reasons beyond the control of the EDQM to alter the venue (hotel/premises within the same city) or time of the event. The EDQM endeavours to keep the registrant abreast of such changes. If the event is postponed, the EDQM will endeavour to reschedule it and will allow the participant to leave the fee paid as payment towards another event that takes place in the 12 months following the originally booked event or receive a full refund of the registration fee. In the unlikely circumstance of event cancellation, for whatever reason, neither the EDQM, nor the Council of Europe, accepts responsibility for any consequential losses (e.g. travel

and accommodation costs) incurred by Registrants.

#### *– Limitation of Liability*

The EDQM cannot be held liable for any damages of any kind arising from the interpretation or use of the information provided in relation to the event.

The EDQM shall not be held liable for any loss resulting from late arrivals to, or non-attendance at, the event due to delayed or suspended transportation.

The EDQM shall not be held liable for damages or other complications as a result of the Registrant's visa issues. The EDQM shall not be held liable for any loss as a result of the Registrant failing to arrange his/her own insurance.

#### *Electronic Communications and Data*

All personal data submitted within the context of registering for an event is kept in the EDQM's Online Events Registration System and is held in confidence. Processing of Registrants' personal data is needed for efficient event organisation and management and for follow-up activities such as surveys. If necessary, photographs and video/audio recordings may be taken and used to create awareness and publicise the event. A list of the names of all the Registrants and the institutions they represent is included in the event package. Registrants will be asked for their consent before any of this information (including the names of the institutions they

represent) is distributed amongst the event's participants or, if appropriate, published on the EDQM's Website.

---

### **SPECIFIC TERMS AND CONDITIONS: USE OF EDQM STORE AND OF THE REGISTRATION FORM TO EDQM EVENTS**

The EDQM Terms and Conditions of Sale govern the sale of items by the EDQM to Purchasers. Purchasers should read the EDQM's general terms and conditions and all specific conditions before placing an order via the EDQM Store or Online Registration Form. By placing an order via EDQM Store or the Online Registration Form, the Purchaser signals agreement to be bound by these conditions.

#### *Online Electronic Communications*

When the Purchaser uses the EDQM Store or Online Registration Form, or sends information to the EDQM via the HelpDesk, the Purchaser is communicating with the EDQM electronically online. The EDQM will communicate with Purchasers by e-mail or via the HelpDesk. For contractual purposes, Purchasers consent to receive communications from the EDQM electronically in respect of the fulfilment of the order.

#### *Data recorded*

The data recorded by the EDQM constitute the proof of all contractual and financial transactions between the EDQM and its Purchasers.

#### *Payment via the EDQM Store*

The security protocol used (SSL or Secure Socket Layer) ensures that the personal data sent via the Internet remains fully confidential. The EDQM undertakes not to divulge the personal data of its Purchasers to third parties with the exception of its bank to which data must to be transferred for order processing purposes.

#### *Data links*

The EDQM Website, EDQM Store or Online Registration Form may include links to other Internet sites or sources. The EDQM has no control over these external sites and sources and therefore cannot be held responsible or liable for the content, advertising, items, services and any other material made available by or through these external sites and sources.

In addition, the EDQM cannot be held responsible for any damage or losses caused by, alleged to be caused by or arising in connection with the use of, or reliance on, the content, goods or services available on these external sites or sources.

#### *Availability of Online Platforms*

The EDQM will do its utmost to ensure that availability of the EDQM Store will be uninterrupted. However, due to the nature of the Internet, this cannot be guaranteed. Also, access may be occasionally suspended or restricted to allow for repairs, maintenance, or the introduction of new facilities or services. The EDQM will attempt to limit the frequency and duration of any such suspension or restriction.

The EDQM reserves the right to make changes to the EDQM Store or Online Events Registration System policies at any time including pricing, dispatch policies, terms and conditions, etc. The Purchaser will be subject to the terms and conditions policies in force at the time the Purchaser uses the EDQM Store or Online Events Registration System.

#### [Use of the content of the EDQM Store](#)

It is forbidden to copy or download the sites or their contents in whole or in part without the prior express consent of the EDQM.

#### [Orders placed via the EDQM Store](#)

In addition to the general terms and conditions, and any relevant specific terms and conditions, an order placed via the EDQM Store is an offer to the EDQM to buy the product(s) listed in the order. The EDQM will send the Purchaser a Temporary Order Confirmation by e-mail confirming receipt of the order but this does not confirm acceptance of the Purchaser's offer to buy the product(s) ordered.

A Purchaser's order is only confirmed when the EDQM sends the Order Confirmation e-mail.

#### [Discount](#)

Any online discount applicable for purchases made via the EDQM Store will be clearly identified.

---

### **SPECIFIC TERMS AND CONDITIONS: EDQM STORE ACCOUNT**

Ordering via the EDQM Store requires the creation of an ac-

count. Only the EDQM can create and modify an account and therefore Purchasers will have to contact the EDQM to arrange for an account to be created and for a log-in and password to be provided. Purchasers are responsible for ensuring that the details provided to the EDQM are accurate, and are responsible for informing the EDQM of any changes to the information provided.

By requesting the creation of an account for the EDQM Store, the Purchaser agrees to be bound by, and accept, these terms of use and conditions of sale fully and without reservation.

The Purchaser is responsible for the confidentiality of the user name and password and should take all the necessary steps to maintain this confidentiality. Purchasers should inform the EDQM immediately if they have any reason to believe that the password is being or is likely to be used in an unauthorised manner.

---

### **LICENCE AGREEMENT FOR ONLINE ACCESS TO THE COMBISTATS™ STATISTICAL SOFTWARE ONLINE SERVICE:**

**NOTICE: By subscribing to CombiStats™, the Licensee acknowledges that he/she has read and agrees to be bound by the EDQM's General and Specific Terms and Conditions and the following Licence Agreement**

#### **GLOSSARY:**

**GTC:** General EDQM Terms and Conditions and the Terms and the Licence Agreement for online access to **CombiStats™**.

**COMBISTATS™:** Statistical analysis software developed by the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (herein referred to as "EDQM"), based on the statistical chapter 5.3 of the European Pharmacopoeia.

**LICENSEE:** the person or entity named in the Online Order Form or the person registered on the CombiStats™ Website.

**AUTHORISED USER:** Employees, faculty, staff and students officially affiliated with the Licensee accessing CombiStats™ from either an authorised IP address or EPID code or via an authorisation by the licensee.

---

### **§ 1 SUBJECT MATTER AND CONTENTS OF AGREEMENT**

1. The EDQM shall use all reasonable efforts to make CombiStats™ available to the Licensee via the Internet.
2. The type and extent of the online access services offered by the EDQM are based on the currently prevailing technical, legal, and commercial umbrella conditions of the networks used. The place of transfer of the Software and data is the interface between the server hosting CombiStats™ and the Internet. The responsibility of the EDQM for the data transmission shall end at this point.
3. The present GTC shall apply exclusively. Other terms and

conditions shall not become part of the GTC, even if the EDQM does not expressly object to them. Amendments and modifications of the GTC shall only become effective if they have been agreed between the EDQM and the Licensee in writing.

## § 2 ACCESS AUTHORISATION

1. By acquiring the CombiStats™ software, the Licensee shall obtain from the EDQM the non-exclusive licence conferring the right to install and use the Software on one (1) computer, solely in accordance with the present GTC. If the Licensee wishes to install and use CombiStats™ on more than one (1) computer, a separate licence must be acquired for each computer.
2. The Licensee shall receive a user ID from the EDQM and a password.
3. The Licensee shall register with the EDQM a single-user licence.
4. The Licensee is not allowed to install and/or access any of the functions of the Software in a network configuration. Notwithstanding the forgoing, the Licensee is not licensed to use the Software in order to provide services of any nature to third parties.
5. The Licensee, in order to receive domain access, shall ensure that access from the Licensee's domain is only available from the Licensee's institution.

## § 3 TECHNICAL REQUIREMENTS AND SUPPORT

1. The EDQM shall provide CombiStats™ in data formats that are supported by current, usual IT equipment (hard- and software). The Licensee shall provide the technical requirements for the use of the Software at his/her expense and risk. Information on technical requirements (minimum system requirements) shall be provided on the EDQM (CombiStats™) Internet site, which shall be continuously updated.
2. The EDQM reserves the right to change the technical requirements of new/updated versions of the Software. The EDQM shall attempt to minimise technical changes.
3. Installation: For a period of 60 days from the date of acquisition of the Software by the Licensee, the EDQM will use all reasonable efforts to provide technical support to help solve specific problems concerning installation of the Software. Such technical support shall be in the form of limited consultation via the EDQM HelpDesk. The EDQM does not guarantee that it will solve every problem or correct every bug or error, or that the Software will meet the Licensee's requirements, or that the operation of the Software will be uninterrupted or error-free. The EDQM does not provide any support of an experimental/statistical/mathematical/computational nature to help the Authorised Users use the Software.

## § 4 RIGHTS

1. The Licensee acknowledges that all copyrights and other intellectual property rights, in particular, rights to the use of CombiStats™ as well as of parts thereof (individual texts, articles, excerpts thereof, in particular abstracts, figures, and tables, etc.) are the sole and exclusive property of the EDQM and that the GTC does not convey to the Licensee any right, title, or interest therein except for the right to use CombiStats™ in accordance with the present GTC. The Licensee shall notify the EDQM promptly of the facts and circumstances surrounding any unauthorised possession or use of CombiStats™ or any portion thereof.
2. The Licensee shall receive the following rights to the CombiStats™ information service and the parts thereof:
 

*Single user licence:*

  - (i) The Licensee is authorised to download CombiStats™ in order to conduct statistical analysis for his/herself and for his/her employer in accordance with the rules defined in the GTC and to copy a selection of the licensed Software into his/her computer's RAM.
  - (ii) The Licensee may, only for his/her own use, permanently store the licensed Software mentioned in paragraph (i) and make hard copies thereof (downloading and printout). The transfer



of the licensed data in whole or in part – regardless of whether by electronic data carrier, remote data transmission or in the form of hard copies – as well as granting access to the stored data to third parties, the feeding of the data into an intranet and commercial information brokerage, as well as any use of the licensed data for commercial purposes, are not permitted.

3. Translations, editing, arrangement, and other changes – such as (a) disassembling, decompiling or otherwise deriving source code from the Software, (b) reverse engineering the Software, (c) modifying or preparing derivative works of the Software, (d) copying the Software, except to make a single copy for archiving purposes only, (e) renting or leasing the Software, (f) using the Software in an online system, (g) using the Software in any manner that infringes on the intellectual property or other rights of another party, (h) transferring the Software or any copy thereof to another party, (i) remotely accessing the Software from a computer or workstation in a network configuration, or (j) continuing to use the Software after the licence has been terminated – to the licensed Software and the public communication, representation or performance thereof are prohibited.
4. The EDQM reserves the right to investigate occurrences of sus-

pected unauthorised use or other contract violations and to take appropriate action or to deny the Licensee or individual users access to the service. The EDQM reserves the right to terminate this Agreement for cause and/or to claim damages.

## § 5 SERVICE CHANGES

1. If the technical, legal and commercial umbrella conditions for use of the networks used change and if thereby the provision of contract services by EDQM is materially impaired, the EDQM may change or discontinue the offered services.
2. The EDQM shall immediately inform the Licensee by e-mail or letter if, due to the above reason(s), parts of the services in their present form can no longer be offered from a certain date, and shall propose a partial reimbursement based on the “unavailable” portion of the subscription agreement.

## § 6 THE LICENSEE'S DUTIES

1. The Licensee shall only use CombiStats™ for his/her proper purposes. The Licensee shall in particular:
  - not abuse the access to the Software, in particular in violation of § 4, and the Licensee shall omit illegal acts;
  - comply with the recognised principles of data security for the purpose of data protection;
  - immediately inform the EDQM of any indications of illegal use.

2. The Licensee shall within his/her possibilities ensure the proper implementation of the access to the licensed data.
3. The Licensee shall hold the EDQM harmless from and against all claims, suits, proceedings, losses, liabilities and damages which the EDQM incurs on account of contract violations by the Licensee or the Authorised Users or due to third party claims arising from contract violations of the Licensee or the Authorised Users. The Licensee shall, at the EDQM's option, either defend the EDQM against the claims or satisfy the claims or support the EDQM in the enforcement of its rights and pay the costs of legal action.

## § 7 LIABILITY

The Software is licensed on an "as is" basis without any warranty of any nature. The Software is not an official extension of the texts adopted by the European Pharmacopoeia Commission and no rights can be derived from the output of the Software. In particular, the EDQM cannot guarantee that the Software will always be in agreement with future revisions of official texts in the European Pharmacopoeia. SAVE AS PROVIDED IN § 8 BELOW, THE EDQM DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE (E.G. THE RELEASE OF

MEDICINES). THE EDQM SHALL NOT BE LIABLE FOR ANY DAMAGE OR LOSS OF ANY KIND ARISING OUT OF OR RESULTING FROM THE LICENSEE'S POSSESSION OR USE OF, OR INABILITY TO USE COMBISTATS™ (INCLUDING, WITHOUT LIMITATION, DATA LOSS OR CORRUPTION, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING FROM ITS USE OR INABILITY TO USE THE SOFTWARE, EVEN IF THE EDQM HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), SAVE FOR CASES WHERE SUCH LIABILITY IS BASED ON A VIOLATION BY THE EDQM OF ONE OF ITS UNDERTAKINGS UNDER THE PRESENT AGREEMENT.

UNDER NO CIRCUMSTANCE SHALL THE EDQM'S LIABILITY TO THE LICENSEE ARISING OUT OF ANY KIND OF CLAIM IN ANY WAY CONNECTED WITH THE USE OR INABILITY TO USE COMBISTATS™ EXCEED THE AMOUNT OF THE LICENCE FEES PAID BY THE LICENSEE FOR COMBISTATS™. THE REMEDIES AVAILABLE TO THE LICENSEE AGAINST THE EDQM UNDER THIS AGREEMENT ARE EXCLUSIVE.

## § 8 THIRD PARTY RIGHTS

Notwithstanding the limitation of liability in § 7 above and without prejudice to its privileges and immunities, the EDQM warrants that the transfer and use of the licensed data in accordance with the GTC does not violate any third party rights. In the case that third parties allege

any claims against the Licensee which arise out of any act or omission by the EDQM that constitutes a breach of the EDQM's warranties hereunder, the EDQM shall at its option either defend the Licensee against the claims or indemnify the Licensee.

## § 9 CONFIDENTIALITY

The Licensee shall ensure that unauthorised third parties shall not gain access to the access authorisation of CombiStats™, nor to possession of the reproductions of CombiStats™ or portions thereof – regardless of what type – made by the Licensee or Authorised Users. The Licensee shall respect strict confidentiality with regard to the contents of CombiStats™ and shall take the necessary measures to prevent unauthorised third parties from gaining knowledge of the contents of CombiStats™. The Licensee shall inform the Authorised Users in writing of these confidentiality obligations. The GTC is personal to and binding on the parties and neither the GTC nor any of the rights under it may be assigned or sublicensed.

## § 10 TERM OF AGREEMENT

This agreement shall terminate no later than the subscription agreement for CombiStats™.

## LICENCE AGREEMENT FOR ONLINE ACCESS TO THE EUROPEAN PHARMACOPOEIA ONLINE SERVICE (9<sup>TH</sup> EDITION)

**NOTICE:** By subscribing to the European Pharmacopoeia Online Version, the Licensee acknowledges that he/she has read and agrees to be bound by the EDQM's General and Specific Terms and Conditions and the following Licence Agreement.

### GLOSSARY:

**GTC:** General EDQM Terms and Conditions and the Terms and Licence Agreement for online access to the European Pharmacopoeia Online Version.

**EPO:** European Pharmacopoeia Online Version.

**LICENSEE:** The person or entity named in the Online Order Form, or the person registering the product who has subscribed to the EPO for the period of the subscription.

**AUTHORISED USERS:** Employees, faculty, staff and students officially affiliated with the Licensee accessing the EPO from either an authorised IP address or EPID code or via an authorisation by the Licensee.

## § 1 SUBJECT MATTER AND CONTENTS OF AGREEMENT

The type and extent of the online access services offered by the EDQM are based on the currently prevailing technical, legal, and commercial umbrella conditions of the networks used. The place of transfer of the data is the interface between the server

hosting the EPO and the Internet. The responsibility of the EDQM for the data transmission shall end at this point.

## § 2 ACCESS AUTHORISATION

1. The Licensee shall receive a user ID from EDQM and a password for a single-user licence. In justified cases, an access authorisation by other means can be negotiated.
2. In the case of a multiple-user licence, the Licensee shall provide the domain and IP addresses that are registered for them in the Internet; EDQM shall then give the Licensee an access authorisation.
3. The Licensee, in order to receive domain access, shall ensure that access from the Licensee's domain is only available from the Licensee's institution.
4. The Licensee shall register with EDQM a single-user licence or a multiple-user licence.
5. The list of cumulative supplements, for which the Licensee is granted access authorisation, is available on the server. The EDQM will make available the supplement in force on the date of consultation and future supplement(s) to come into force when they are available. Supplements which have been superseded and are no longer legally valid will remain available in the online archives, on the proviso that the Licensee has a valid subscription.

## § 3 TECHNICAL REQUIREMENTS

1. The EDQM shall provide all data in data formats that are supported by the HTTP Internet Protocol. The Licensees shall provide the technical requirements for the use of the service offered at their expense and risk. Information on technical requirements shall be contained on the EDQM Website, which shall be continuously updated.
2. The EDQM reserves the right to change the technical requirements. The EDQM shall attempt to minimise technical changes.

## § 4 RIGHTS

- (i) The Licensee acknowledges that all copyrights and other intellectual property rights, in particular rights to the use of the EPO information service as well as of parts thereof (individual texts, articles, excerpts thereof, in particular abstracts, figures, and tables, etc.) are the sole and exclusive property of the EDQM, and that the Licence Agreement does not convey to the Licensee any right, title, or interest therein except for the right to use the EPO in accordance with the present GTC.
- (ii) The Licensee shall notify EDQM promptly of the facts and circumstances surrounding any unauthorised possession or use of the EPO or any portion thereof.
- (iii) The Licensee shall receive the following rights to the EPO and the parts thereof:

### Single-user licence:

- (i) The Licensee is authorised to access the EPO in order to conduct research for him/herself and to copy a selection of the licensed data into his computer's RAM.
- (ii) The Licensee may, only for his/her own use, permanently store the licensed data mentioned in paragraph (i) and make hard copies thereof (downloading and printout). EDQM reserves the right to limit the extent and the number of copies and printouts in an appropriate manner. The transfer of the licensed data in whole or in part – regardless of whether by electronic data carrier, remote data transmission or in the form of hard copies – as well as granting access to the stored data to third parties, the feeding of the data into an intranet and commercial information brokerage, as well as any use of the licensed data for commercial purposes, are not permitted.
- (iii) Translations, editing, arrangement, and other changes to the licensed data and the public communication, representation or performance thereof are prohibited.

### Multiple-user licence:

In the case of the acquisition of a multiple-user licence, only Authorised Users shall be permitted by the Licensee to access and use the EPO for the purposes and within the limitations included above.

4. The EDQM reserves the right to investigate occurrences of suspected unauthorised use or other contract violations (including non-payment) and to take appropriate action or to deny the Licensee or individual user access to the service. The EDQM reserves the right to terminate this Agreement for cause or to claim damages.

## § 5 SERVICE CHANGES

1. If the technical, legal and commercial umbrella conditions for use of the networks used change and if thereby the provision of contract services by EDQM is materially impaired, the EDQM may change or discontinue the offered services.
2. The EDQM shall immediately inform the Licensee by e-mail or letter if, due to the above reason(s), parts of the services in their present form can no longer be offered from a certain date and propose a partial reimbursement based on the “unavailable” portion of the subscription agreement.

## § 6 THE LICENSEE'S DUTIES

1. The Licensee shall only use the EPO information service for his/her proper purposes. The Licensee shall in particular:
  - not abuse the access to the service, in particular in violation of Section 4, and the Licensee shall omit illegal acts;
  - comply with the recognised principles of data security for the purpose of data protection;
  - immediately inform EDQM of any indications of illegal use.

2. The Licensee shall within his/her possibilities ensure the proper implementation of the access to the licensed data.

3. In the case of a multiple-user licence, the Licensee shall ensure that the Authorised Users comply with the duties set forth in § 4 para. 1 and 2, and in § 7.

## § 7 CONFIDENTIALITY

The Licensee shall ensure that unauthorised third parties shall not gain access to the access authorisation or the EPO, nor to possession of the reproductions of the EPO or portions thereof – regardless of what type – made by the Licensee or Authorised Users. The Licensee shall respect strict confidentiality with regard to the contents of the EPO and shall take the necessary measures to prevent unauthorised third parties from gaining knowledge of the contents of the EPO. The Licensee shall inform the Authorised Users in writing of these confidentiality obligations.

The Licence Agreement is personal to and binding on the parties and neither the Licence Agreement nor any of the rights under it may be assigned or sub-licensed.

## § 9 TERM OF AGREEMENT

The EPO online service Licence Agreement shall terminate no later than the subscription agreement for the EPO.

## TERMS OF USE OF THE TECHNOLOGICAL INTERFACE

### Scope

This appendix presents the terms of use, separately and exhaustively, for Users of the:

- NetIS technological interface (hereafter referred to as “**the technological interface**”) developed by CDISYS (up to the 9<sup>th</sup> Edition).
- PaedffForm developed by EDQM.

### Licence

1. CDISYS vests the user only with a personal right to use the technological interface.
2. The Personal-User Right includes the right to view, save and/or print the information pursuant to the terms of the user authorisation level (hereafter referred to as the “**User Right**”). Other than the User Right, the User does not have and shall not have any rights to the technological interface or any part thereof.
3. The User Right, *inter alia*, does not include any right to create and/or extend an electronic database, printed or otherwise, in a manner based in whole or in part on any of the components of the technological interface.

### Copyright

1. CDISYS owns the copyright and/or the User Rights therein and/or the right to allow the use thereof by the holders of other rights including the holders of the copyright (hereafter referred to as holders of other rights”) in all the technological interface’s components.
2. The User may not duplicate, photocopy, copy, give or trans-



fer to any third party, or translate into another language, including computer language, any of the components of the technological interface other than pursuant to the terms of this licence, without first obtaining CDISYS' written authorisation.

- The User shall not use any of the trademarks included in the technological interface, other than pursuant to the terms of this licence.

#### Limitation of liability

- CDISYS and/or the holders of the other rights have acted to the best of their ability to prevent any defect, fault or mistake and to ensure the accuracy, quality, completeness and cleanliness of the technological interface; however, they shall not be liable for any damage deriving from noncompliance with one or more of the above details.
- Neither CDISYS nor the holders of the other rights shall be howsoever liable, directly or indirectly, for any damage and/or loss, direct or indirect, deriving from the use and/or inability to use the technological interface, for any reason, and/or from any fault, deficiency or unavailability of the service or part of its attributes. Neither CDISYS nor the holders of the other rights in any way guarantee that the technological interface and/or the use thereof meet or shall meet any requirements of the Licensee or Authorised Users.

## LICENCE AGREEMENT FOR ACCESS TO THE EUROPEAN PHARMACOPOEIA ELECTRONIC VERSION (FROM 10<sup>TH</sup> EDITION)

### GLOSSARY:

**GTC:** General EDQM Terms and Conditions and the Terms and Licence Agreement for online access to the European Pharmacopoeia Electronic Version.

**EPEV:** European Pharmacopoeia Electronic Version hosted on the EDQM's Publication Platform comprising an online access via a version accessible from either a desktop application or from a USB stick

**LICENSEE:** The person or entity named in the Order Form, or the person activating the subscription key who has subscribed to the EPEV for the period of the subscription.

**AUTHORISED USERS:** Employees, faculty, staff and students officially affiliated with the Licensee accessing the EPEV from the EDQM's Publication Platform after having been granted access by the Licensee.

## § 1 SUBJECT MATTER AND CONTENTS OF AGREEMENT

The type and extent of the online access services offered by the EDQM are based on the currently prevailing technical, legal, and commercial umbrella conditions of the networks used.

Online version: The place of transfer of the data is the interface between the server hosting the EPEV and the Internet. The responsibility of the EDQM for

the data transmission shall end at this point.

Application/USB version: The EDQM supplies a link for the download of the application and the data and the place of transfer of the data is the interface between the server hosting the EPEV and the Internet. The responsibility of the EDQM for the data transmission shall end at this point.

## § 2 ACCESS AUTHORISATION

- The Licensee shall receive a subscription key to access the EPEV via the EDQM's Publication Platform. The Licensee, in order to activate the subscription key, shall first create an EDQM account, which consists in the licensee's e-mail address and associated password.
- The Licensee shall activate the subscription key on the EDQM's Publication Platform.
- The list of cumulative supplements, for which the Licensee is granted access authorisation, is available on the server. The EDQM will make available the supplement in force on the date of consultation and future supplement(s) to come into force when they are available. Supplements that have been superseded and are no longer legally valid will remain available in the online archives, on the proviso that the Licensee has a valid subscription.

## § 3 TECHNICAL REQUIREMENTS

- The EDQM shall provide all data in data formats that are supported by the HTTP Internet Protocol. The Licensees

shall provide the technical requirements for the use of the service offered at their expense and risk. Information on technical requirements shall be contained on the EDQM Website, and shall be continuously updated.

4. The EDQM reserves the right to change the technical requirements. The EDQM shall attempt to minimise technical changes.

#### § 4 SERVICE CHANGES

3. If the technical, legal and commercial umbrella conditions for use of the networks used change and if thereby the provision of contract services by EDQM is materially impaired, the EDQM may change or discontinue the offered services.
4. The EDQM shall immediately inform the Licensee by e-mail or letter if, for the above reason(s), parts of the services in their present form can no longer be offered from a certain date and shall propose a partial reimbursement based on the “unavailable” portion of the subscription agreement.

#### § 5 RIGHTS

1. The Licensee acknowledges that all copyrights and other intellectual property rights, in particular rights to the use of the EDQM’s Publication Platform and the EPEV as well as of parts thereof (individual texts, articles, excerpts thereof, in particular abstracts, figures, and tables, etc.) are the sole and exclusive property of the EDQM. In addition, the Licence

Agreement does not convey to the Licensee any right, title, or interest therein except for the right to use the EDQM’s Publication Platform and the EPEV in accordance with the present GTC.

2. The Licensee shall notify EDQM promptly of the facts and circumstances surrounding any unauthorised possession or use of the EPEV or any portion thereof.
3. The Licensee shall receive rights to the EPEV and the parts thereof as defined in the [User guide](#) available on the EDQM’s Publication Platform.

#### § 6 CONFIDENTIALITY

4. The Licensee shall ensure that unauthorised third parties shall not gain access to the subscription key or the EPEV, nor to possession of the reproductions of the EPEV or portions thereof – regardless of what type – made by the Licensee or Authorised Users.
5. The Licensee shall respect strict confidentiality with regard to the contents of the EPEV and shall take the necessary measures to prevent unauthorised third parties from gaining knowledge of the contents of the EPEV.
6. The Licensee shall inform the Authorised Users in writing of these confidentiality obligations.
7. The Licence Agreement is personal to and binding on the parties and neither the Licence Agreement nor any of the

rights under it may be assigned or sublicensed.

#### § 7 THE LICENSEE’S DUTIES

1. The Licensee shall only use the EPEV for his/her proper purposes. The Licensee shall in particular:
  - not abuse the access to the service, in particular in violation of Section 5;
  - comply with the recognised principles of data security for the purpose of data protection;
  - not commit illegal acts, and take precautions to prevent any such acts being committed;
  - immediately inform EDQM of any indications of illegal use.
2. The Licensee shall within his/her possibilities ensure the proper implementation of the access to the licensed data.
3. The transfer of the licensed data in whole or in part – regardless of whether by electronic data carrier, remote data transmission or in the form of hard copies – as well as granting access to the stored data to third parties, the feeding of the data into an intranet and commercial information brokerage, as well as any use of the licensed data for commercial purposes, are not permitted.
4. Translations, editing, arrangement, and other changes to the licensed data and the public communication, representation or performance thereof are prohibited.
5. The EDQM reserves the right to investigate occurrences of suspected unauthorised use or

other contract violations (including non-payment) and to take appropriate action or to deny the Licensee or individual user access to the service. The EDQM reserves the right to terminate this Agreement for cause or to claim damages.

6. The Licensee shall ensure that the Authorised Users comply with the duties set forth in § 5 para. 1 and 2, and in § 6.

## § 8 LIABILITY

SAVE AS PROVIDED IN § 9 BELOW, THE EDQM DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE EDQM SHALL NOT BE LIABLE FOR ANY DAMAGE OR LOSS OF ANY KIND ARISING OUT OF OR RESULTING FROM THE LICENSEE'S POSSESSION OR USE OF, OR INABILITY TO USE THE EPEV. UNDER NO CIRCUMSTANCE SHALL THE EDQM'S LIABILITY TO THE LICENSEE ARISING OUT OF ANY KIND OF CLAIM IN ANY WAY CONNECTED WITH THE USE OR INABILITY TO USE THE EPEV EXCEED THE AMOUNT OF THE LICENCE FEES PAID BY THE LICENSEE FOR THE EPEV. THE REMEDIES AVAILABLE TO THE LICENSEE AGAINST THE EDQM UNDER THIS AGREEMENT ARE EXCLUSIVE.

## § 9 THIRD PARTY RIGHTS

Notwithstanding the limitation of liability in § 8 above, the EDQM warrants that the transfer

and use of the licensed data in accordance with the Licence Agreement does not violate any third party rights. In the case that third parties allege any claims against the Licensee which arise out of any act or omission by the EDQM that constitutes a breach of the EDQM's warranties hereunder, the EDQM shall at its option either defend the Licensee against the claims or indemnify him/her.

## § 10 TERM OF AGREEMENT

The EPEV Licence Agreement shall terminate no later than the subscription agreement for the EPEV.

## TERMS OF USE OF THE TECHNOLOGICAL INTERFACE - THE EDQM'S PUBLICATION PLATFORM

### Scope

This appendix presents the terms of use, separately and exhaustively, for Users of the EDQM's Publication Platform (the technological interface).

### Licence

4. The EDQM vests the licensee and Authorised Users a personal right to use the technological interface.
5. The Personal-User Right includes the right to view, save, download and/or print the information pursuant to the terms of the user authorisation level (hereafter referred to as the "**User Right**"). Other than the User Right, the User does not have and shall not have any rights to the technological interface or any part thereof.

6. The User Right, *inter alia*, does not include any right to create and/or extend an electronic database, printed or otherwise, in a manner based in whole or in part on any of the components of the technological interface.

### Copyright

4. The EDQM owns the copyright and/or the User Rights therein and/or the right to allow the use thereof by the holders of other rights including the holders of the copyright (hereafter referred to as "**holders of other rights**") in all the technological interface's components.
5. The User may not duplicate, photocopy, copy, give or transfer to any third party, or translate into another language, including computer language, any of the components of the technological interface other than pursuant to the terms of this licence.

### Limitation of liability

3. The EDQM has acted to the best of its ability to prevent any defect, fault or mistake and to ensure the accuracy, quality, completeness and cleanliness of the technological interface; however, it shall not be liable for any damage deriving from noncompliance with one or more of the above details.
4. The EDQM will not be liable, directly or indirectly, for any damage and/or loss, direct or indirect, deriving from the use and/or inability to use the technological interface, for any reason, and/or from any fault,

deficiency or unavailability of the service or part of its attributes.

- The EDQM does not in any way guarantee that the technological interface and/or the use thereof meet or shall meet any requirements of the Licensee or Authorised Users.

---

## LICENCE AGREEMENT FOR ACCESS TO THE EUROPEAN PHARMACOPOEIA OFFLINE (USB/DOWNLOAD) SERVICE

**NOTICE: By subscribing to the European Pharmacopoeia Offline Version, the Licensee acknowledges that he/she has read and agrees to be bound by the EDQM's General and Specific Terms and Conditions and the following Licence Agreement**

### GLOSSARY:

**GTC:** General EDQM Terms and Conditions and the Terms and the Licence Agreement for access to the European Pharmacopoeia Offline Version.

**EPOV:** European Pharmacopoeia Offline Version (USB/Download).

**LICENSEE:** The person or entity named in the Order Form, or the person registering the product who has subscribed to the EPOV for the period of the subscription.

### AUTHORISED USERS:

Employees, faculty, staff and students officially affiliated with the Licensee accessing the EPOV.

---

## § 1 SUBJECT MATTER AND CONTENTS OF AGREEMENT

The type and extent of the services offered by the EDQM are based on the currently prevailing technical, legal, and commercial umbrella conditions of the networks used. For the downloadable version, the EDQM supplies a link for the download of the data and the place of transfer of the data is the interface between the server hosting the EPOV and the Internet. The responsibility of the EDQM for the data transmission shall end at this point.

## § 2 ACCESS AUTHORISATION

- The Licensee shall receive the EPOV from the EDQM.
- The Licensee shall register with EDQM each EPOV.

## § 3 TECHNICAL REQUIREMENTS

- The EDQM shall provide all data in data formats that are supported by the HTTP Internet Protocol. The Licensees shall provide the technical requirements for the use of the service offered at their expense and risk. Information on technical requirements shall be contained on the EDQM Website, which shall be continuously updated.
- The EDQM reserves the right to change the technical requirements. The EDQM shall attempt to minimise technical changes.

## § 4 RIGHTS

- The Licensee acknowledges that all copyrights and other intellectual property rights, in particular, rights to the use of

the EPOV information service as well as of parts thereof (individual texts, articles, excerpts thereof, in particular abstracts, figures, and tables etc.), are the sole and exclusive property of the EDQM and that the Licence Agreement does not convey to the Licensee any right, title, or interest therein except for the right to use the EPOV in accordance with the present GTC.

- The Licensee shall notify EDQM promptly of the facts and circumstances surrounding any unauthorised possession or use of the EPOV or any portion thereof.
- The Licensee shall receive the following rights to the EPOV and the parts thereof:
  - The Licensee is authorised to access the EPOV in order to conduct research themselves and to copy a selection of the licensed data into their computer's RAM.
  - The Licensee may, only for his/her own use, permanently store the licensed data mentioned in paragraph (i) and make hard copies thereof. The EDQM reserves the right to limit the extent and the number of copies and printouts in an appropriate manner. The transfer of the licensed data in whole or in part – regardless of whether by electronic data carrier, remote data transmission or in the form of hard copies – as well as granting access to the stored data to third parties, the feeding of the data into an intranet and commercial in-



formation brokerage, as well as any use of the licensed data for commercial purposes, are not permitted.

(iii) Translations, editing, arrangement, and other changes to the licensed data and the public communication, representation or performance thereof are prohibited.

(iv) Only Authorised Users shall be permitted by the Licensee to access and use the EPOV for the purposes and within the limitations set forth in § 4, subparagraph 2 above.

4. The EDQM reserves the right to investigate occurrences of suspected unauthorised use or other contract violations and to take appropriate action or to deny the Licensee, or individual users, access to the service. The EDQM reserves the right to terminate this Agreement for cause or to claim damages.

## § 5 THE LICENSEE'S DUTIES

1. The Licensee shall only use the EPOV information service for his/her proper purposes. The Licensee shall in particular:

- not abuse the access to the service, in particular in violation of Section 4, and the Licensee shall omit illegal acts;
- comply with the recognised principles of data security for the purpose of data protection;
- immediately inform EDQM of any indications of illegal use.

2. The Licensee shall within his/her possibilities ensure the proper implementation of the access to the licensed data.

3. The Licensee shall hold the EDQM harmless from and against all claims, suits, proceedings, losses, liabilities and damages which the EDQM incurs on account of contract violations by the Licensee or the Authorised Users or due to third party claims arising from contract violations of the Licensee or the Authorised Users. The Licensee shall at the EDQM's option either defend the EDQM against the claims or satisfy the claims or support the EDQM in the enforcement of its rights and pay the costs of legal action.

## § 6 LIABILITY

SAVE AS PROVIDED IN § 7 BELOW, THE EDQM DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE EDQM SHALL NOT BE LIABLE FOR ANY DAMAGE OR LOSS OF ANY KIND ARISING OUT OF OR RESULTING FROM THE LICENSEE'S POSSESSION OR USE OF, OR INABILITY TO USE THE EPOV. UNDER NO CIRCUMSTANCE SHALL THE EDQM'S LIABILITY TO THE LICENSEE ARISING OUT OF ANY KIND OF CLAIM IN ANY WAY CONNECTED WITH THE USE OR INABILITY TO USE THE EPOV EXCEED THE AMOUNT OF THE LICENCE FEES PAID BY THE LICENSEE FOR THE EPOV. THE REMEDIES AVAILABLE TO THE LICENSEE AGAINST THE EDQM

UNDER THIS AGREEMENT ARE EXCLUSIVE.

## § 7 THIRD PARTY RIGHTS

Notwithstanding the limitation of liability in § 6 above, the EDQM warrants that the transfer and use of the licensed data in accordance with the Licence Agreement does not violate any third party rights. In the case that third parties allege any claims against the Licensee which arise out of any act or omission by the EDQM that constitutes a breach of the EDQM's warranties hereunder, the EDQM shall at its option either defend the Licensee against the claims or indemnify him/her.

## § 8 CONFIDENTIALITY

The Licensee shall ensure that unauthorised third parties shall not gain access to the access authorisation or the EPOV, nor to possession of the reproductions of the EPOV or portions thereof – regardless of what type – made by the Licensee or Authorised Users.

The Licensee shall respect strict confidentiality with regard to the contents of the EPOV and shall take the necessary measures to prevent unauthorised third parties from gaining knowledge of the contents of the EPOV.

The Licensee shall inform the Authorised Users in writing of these confidentiality obligations. The Licence Agreement is personal to and binding on the parties and neither the Licence Agreement nor any of the rights

under it may be assigned or sub-licensed.

---

## § 9 TERM OF AGREEMENT

The EPOV and the EPEV online service Licence Agreement shall terminate at the end of validity of the edition (for the 9<sup>th</sup> Edition this means 31 December 2019).

## LIMITATION OF LIABILITY

1. CDISYS and/or the holders of the other rights have acted to the best of their ability to prevent any defect, fault or mistake and to ensure the accuracy, quality, completeness and cleanliness of the technological interface; however, they shall not be liable for any damage deriving from noncompliance with one or more of the above details.
2. Neither CDISYS nor the holders of the other rights shall be howsoever liable, directly or indirectly, for any damage and/or loss, direct or indirect, deriving from the use and/or inability to use the technological interface, for any reason, and/or from any fault, deficiency or unavailability of the service or part of its attributes.
3. Neither CDISYS nor the holders of the other rights are howsoever undertaking that the technological interface and/or the use thereof meet or shall meet any requirement of the Licensee or Authorised Users.

## TERMS OF USE OF THE TECHNOLOGICAL INTERFACE

For downloadable version, see appendix for online version.