

WHO



CATALOGUE

WHO

INTERNATIONAL CHEMICAL REFERENCE SUBSTANCES (ICRS)

List No. 01

May 10

I. TERMS OF SUPPLY

All items listed in this catalogue are supplied strictly on the basis of these Terms of Supply, whose provisions shall have effect notwithstanding any inconsistent provision contained in any document received from a purchaser.

1. QUALITY AND PURPOSE OF ITEMS SUPPLIED

International Chemical Reference Substances are established on the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied for use in physical and chemical tests and assays described in the specifications for quality control of drugs published in The International Pharmacopoeia.

All chemical substances listed in this catalogue are supplied exclusively as International Chemical Reference Substances, (ICRS) for use as reference standards in tests and assays carried out in accordance with the official methods of the International Pharmacopoeia (Ph.Int.) and for no other purpose.

The Council of Europe accordingly 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 of use as a ICRS in tests and assays carried out in accordance with the official methods of the Ph.Int. by professional persons having technical skill and at their own discretion and risk. It is for the purchasers of any such item who are responsible for persons in a workplace to determine independently the risks associated with the item according to the conditions of use and to take appropriate safety measures, including provision of appropriate information to persons working with the substance. Any liability of the Council of Europe 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 law; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

2. PRICES

2.1. PRICE LIST

The price of each substance is 70 Euros per vial.

However, please note that prices and package sizes are subject to change without notice.

The Council of Europe - European Directorate for the Quality of Medicines & HealthCare (EDQM) does not operate a discount policy.

VAT

Prices are exclusive of duties and taxes and are given in Euros. It is the responsibility of the buyer (or the recipient of the delivery if different from the buyer) to contact the national fiscal or customs authorities to pay the duties and taxes. In no event shall the said duties and taxes be paid by the Council of Europe (EDQM).

In the European Union (EU), there is no VAT identification number for organisations with diplomatic status. The Council of Europe (EDQM) therefore has no VAT identification number and is not subject to duties and taxes.

The goods remain the property of the Council of Europe (EDQM) until the invoice has been paid in full.

2.2. DELIVERY AND RELATED COSTS

The goods are shipped to the buyer on a DDU (Incoterms 2000) basis, namely, delivered duty unpaid insurance included. Where the shipment is identified below as airport consignment (see section Delivery charges), the goods are shipped to the buyer on a CIP (Incoterms 2000) basis, namely carriage and insurance included. In all cases:

- the Council of Europe (EDQM) delivers the goods to the buyer not cleared for import and not unloaded by any means of transport;
- the Council of Europe (EDQM) bears the cost and risks of packing, transport to the delivery site and insurance;
- in no event shall the Council of Europe (EDQM) be held responsible for any deterioration of the goods due to their delayed delivery by the carrier;
- the buyer is responsible for the cost of import customs clearance, for paying the duties and taxes required in the country of import and for unloading the goods;
- the buyer shall be entirely responsible if the goods are held up at customs at the time of import into the buyer's country; in no event shall the Council of Europe (EDQM) be able to provide any assistance.

DELIVERY CHARGES

Only the Council of Europe (EDQM) has the right to choose the shipping service used to dispatch reference standards:

- buyers will not be able to choose the shipping company nor will they be able to pick up the order directly;
- buyers will not be able to provide their shipping import account number to pay shipping charges;
- buyers will not be able to request other shipping conditions;
- buyers will not be able to request delivery to countries other than the country indicated in the invoice address (except for the delivery inside the European Union).

The geographical zones are:

- zone 1: member states of the European Pharmacopoeia Convention;
- zone 2: other European countries, Canada and USA;
- zone 3: the rest of the world.

Extra charges are added to each shipment. A shipment is considered to consist only of the reference standards that can be shipped under the same conditions.

Therefore, items requiring special packaging (ice, dry ice), dangerous goods and controlled substances will be billed separately from the rest of the order, and extra charges will be added. Since an order may cover several shipments, the Council of Europe (EDQM) advises its users to group their orders according to the type of shipment; this will make it easier for them to track the complete order and will save shipping costs.

The extra charges are described in the table in the appendix.

- a) Shipment at ambient temperature
- b) Shipment packed in ice (+ 5 °C) in refrigerated shipping containers
- c) Shipment packed in ice (- 20 °C) in refrigerated shipping containers

- d) Shipment packed in dry ice in refrigerated shipping containers
- e) Shipment of dangerous goods packed in ice or dry ice
- f) Dangerous goods at ambient temperature
- g) Dangerous goods in exempted quantities
- h) Dangerous goods shipped only by road
- i) Chemical precursors of narcotics (controlled substances)
 - EU: as these products require special shipping conditions they are billed separately.
 - Mexico: these products cannot be shipped because this is prohibited by the specific legislation for controlled substances in this country.
- j) Psychotropic substances (controlled substances)
 - France: as these products require special shipping conditions they are billed separately.
 - Mexico: these products cannot be shipped because this is prohibited by the specific legislation for controlled substances in this country.
- k) Narcotics (controlled substances)
 - Mexico: these products cannot be shipped because this is prohibited by the specific legislation for controlled substances in this country.

3. HOW DO I ORDER?

3.1. ORDER FORM

DO NOT MIX ORDERS FOR REFERENCE STANDARDS OF THE EUROPEAN PHARMACOPOEIA, WHO ISA REFERENCE STANDARDS AND WHO ICRS REFERENCE STANDARDS ON THE SAME ORDER FORM.

Please submit your order online at: <http://www.edqm.eu/en/WHO-International-Chemical-Reference-Substances-ICRS-1384.html> (this does not require payment online). Alternatively, we accept orders using the ICRS reference standards order form (see the appendix) or your official order form / purchase order. The ICRS reference standard order form may be downloaded from <http://www.edqm.eu> under Products & Services / Reference Standards / WHO International Chemical Reference Substances (ICRS).

You can send the completed order (with any required special documentation (see section 3.3) to us by:

- e-mail: orders@edqm.eu
- fax: +33 (0)3 88 41 27 71 – for the attention of EDQM Sales Section
- post: Council of Europe, European Directorate for the Quality of Medicines & HealthCare, Sales Section, 7 allée Kastner, CS 30026, F-67081 Strasbourg, France

Customers are financially responsible for duplicate orders in the following cases:

- confirmation orders that are not clearly marked as being a confirmation of an order that has already been sent to the Council of Europe (EDQM);
- submission of the same order multiple times (i.e. via fax, e-mail, mail or any combination thereof).

Please note that we do not accept orders by telephone.

If you are using any other documentation other than the official reference standards order form, please ensure you have included:

- details of the invoicing/billing address including name of company, post code, town, country and telephone number;
- details of the delivery/dispatch address (if different) including name of company, post code, town, country (please note STREET ADDRESS ONLY, no P.O. boxes); **reminder:** buyers will no longer be able to request delivery to countries other than the country indicated in the invoice address (except for delivery inside the European Union);
- contact name, telephone number, fax number and e-mail address: an e-mail address is required for order confirmation and shipping notification purposes;
- VAT number (mandatory within the European Union);

- your order reference/purchase order reference;
- item order code;
- official name of the reference standard as set out in this catalogue;
- sales/unit quantity.

If orders are received without the official name of the reference standard and the full item order code (as set out in this catalogue) the EDQM takes no responsibility for an incorrect item being dispatched.

Unfortunately, we will not be able to process any orders received without the above information.

Once you have received your order confirmation by e-mail, you have 24 hours in which to modify or cancel your order. After this time, no modifications or cancellations will be accepted.

3.2. QUANTITIES

It is the policy of the EDQM to limit the purchase quantities of a reference standard where stock levels are low. The EDQM will do everything possible to ensure all orders are dispatched in their entirety, but when quantities of CRSs or BRPs are limited, the EDQM will try to dispatch orders in such a way that as many customers as possible will receive at least some of the limited quantities.

Restrictions on quantities are applied at the time the order is received and are not retroactive.

3.3. SPECIAL DOCUMENTATION

3.3.1. FOR ALL PRODUCTS

It is the **responsibility of the customer** 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 products).

For customers in **China**: an additional form has to be completed and to accompany each reference standard order (see example in the appendix).

For customers in **Brazil**: an additional form has to be completed and to accompany each reference standard order (see example in the appendix).

For customers in the **United States of America**: an additional form has to be completed and to accompany each reference standard order (see example in the appendix).

3.3.2. CONTROLLED DRUGS

— 3.3.2.1. Psychotropic substances and narcotics of the Vienna Convention

As our premises are located in France, the reference to ‘*psy’ and ‘*narc’ given in this catalogue only refers to the French legislation.

France: to order a psychotropic substance, the form has to be sent exclusively by mail, with the **appropriate licence to hold such a substance**.

Other countries: to order a psychotropic substance, the form has to be sent exclusively by mail. These substances are subject to import and export control in certain countries. It is the responsibility of the customer to obtain **any necessary documents** to comply with the laws of the importing country.

An import permit (in English or French or with a certified English or French translation attached) must be valid for at least 6 months from the date of its receipt by the Council of Europe (EDQM).

— 3.3.2.2. Chemical precursors of narcotics

Countries from the EU: the order of a substance(s) frequently used for the illegal production of narcotics and psychotropic substances (reference ‘*Drug precursor’ in the catalogue) has to be accompanied by the **end user declaration form** stating the use(s) of the substance(s) in line with the current European form (see example in the appendix).

Other countries: it is the responsibility of the customer to obtain **any necessary documents** to comply with the laws of the importing country.

An import permit (in English or French or with a certified English or French translation attached) must be valid for at least 6 months from the date of its receipt by the Council of Europe (EDQM).

Special charges are required.

Export permits for psychotropic drugs and precursors are required before the goods can be dispatched.

— 3.3.2.3. 'Biotox' substances

As our premises are located in France, the reference to '*Biotox' given in this catalogue only refers to the French legislation.

France: to order a 'Biotox' substance, the form has to be sent exclusively by mail, with the appropriate licence to hold such a substance.

Other countries: an export permit issued by the French authorities is required for the shipment of these substances.

3.4. ORDER PROCESSING AND INVOICING

On receiving the complete order, the EDQM aims to invoice and dispatch all orders within 3-4 working days with the exception of:

- orders for controlled drugs;
- shipments to be made under ice (dispatched only on Mondays and Tuesdays) or dry ice (dispatched only on Mondays);
- orders where pre-payment is required.

Please note :

- all psychotropic drugs and precursors will be invoiced separately from the rest of your order and in all cases extra charges will be incurred;
- for all customers from the EU, all orders for precursors need to be accompanied by the valid End User Declaration; the End User Declaration for precursors is included in the appendix.

Delays in shipping will occur if all documentation is not available when your order is placed. **For this reason we ask customers kindly to order controlled drugs separately from other reference standards.**

4. PAYMENT

You can pay an invoice you have already received by:

CREDIT CARD. We accept payment by Carte Bleue, Visa, Eurocard, MasterCard, American Express, JCB.

— Online: credit cards may be used for online payment of invoices through our website <http://www.edqm.eu/store>, under 'E-payment invoices'; please quote your invoice number when you pay.

— Other cases: you can also provide your credit card details at the bottom of the invoice and send it back to us; please note that we do not accept credit card numbers by telephone.

BANK TRANSFER to our bank:

Société Générale, 255, route de Mittelhausbergen, 67200 Strasbourg, France

IBAN Account Number for International Transfers:

(FR 76) 30003 02360 00550034256 76

SWIFT: SOGEFRPP

CHEQUE. Send your cheques made payable to 'Council of Europe-EDQM' to the EDQM address (see 3.1).

Always quote your invoice number when you pay.

In all cases, the payment should be *net of charge* for the Council of Europe.

Payment by letter of credit is not accepted.

CREDIT TERMS

We do not normally require payment in advance. Our normal payment terms require full payment of the invoice within 30 days of the date of the invoice. **Any other fees, such as customs duties, taxes or tariffs, are also the responsibility of the customer.** Client accounts will be blocked for the purchase of all EDQM products if an invoice remains unpaid.

In addition, for certain countries, especially those with strict monetary regulations, for new clients and for large orders, we reserve the right to ask for pre-payment and will issue a pro forma invoice.

In case of doubt, please contact us via the EDQM Helpdesk (<http://www.edqm.eu/hd>).

5. REGULATORY PROCEDURES AND SH/NDP (HARMONISED SYSTEM – NOMENCLATURE FOR CUSTOMS CLEARANCE OF GOODS)

In the event of special requirements in the buyer's country, the buyer shall obtain the import authorisations and resolve any regulatory matters before the goods are ordered and shipped. The buyer shall be entirely responsible if the goods are held up at customs at the time of import into the buyer's country. In no event shall the Council of Europe (EDQM) be able to provide any assistance.

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

The SH/NDP is strictly limited to export operations out of France.

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.

6. COMPLAINTS

Complaints related to delivery

Any delays in delivery do not entitle the buyer to cancel the sale, refuse the goods or claim damages.

Complaints can be made by the buyer upon delivery of goods only if the goods do not correspond quantitatively or qualitatively (if the package containing the goods is badly damaged).

Any complaint must be made to the carrier in writing at the time of delivery.

A copy of the complaint must be sent to the Council of Europe (EDQM) (by e-mail or fax) no later than 12 hours after the complaint was made.

Complaints related to the order

Complaints can be made by the buyer upon delivery of goods only if the goods do not correspond quantitatively with the initial order.

Any complaint should be sent within 48 hours of the time of delivery of the goods in the original package.

For airport deliveries, any complaint should be sent within a week of the time of delivery at the airport.

If the complaint made at the time of delivery is shown to be justified because the package and the goods are badly damaged or because an error has clearly been made, the Council of Europe (EDQM) will be free to choose between issuing a credit note, refunding the customer or making another delivery of similar goods.

In the event of a complaint, shipping costs and other costs (customs) to return goods to the Council of Europe (EDQM) will be borne by the buyer.

In no event shall the customer return goods to the Council of Europe (EDQM) unless the Council of Europe (EDQM) has been notified and has given its written consent.

We will not accept or exchange any returned goods unless the customer complies with the terms and conditions and the above procedure.

Complaints related to quality

Complaints can be made by the buyer via the EDQM Helpdesk (<http://www.edqm.eu/hd>) under the topic "02-Quality, Safety & Environment".

7. RESPONSIBILITY

The Council of Europe (EDQM) cannot be held responsible for failure to meet the requirements of the legislation of the country where the goods are delivered. It is the customer's responsibility to check with the local authorities to make sure that the goods or services that they intend to order can be imported or used in that country.

The customer is solely responsible for the choice of goods, their storage from the time of delivery and their use. In no event shall the Council of Europe (EDQM) be liable for any consequent damage.

The Council of Europe (EDQM) guarantees that the goods have been submitted to the carrier in perfect condition. This is the only guarantee given by the Council of Europe (EDQM). No other guarantees, whether express or implied, are given by the Council of Europe (EDQM). In particular, the Council of Europe (EDQM) does not guarantee that the goods will meet the customer's specific expectations.

The Council of Europe (EDQM) cannot be held responsible for the contract not being fulfilled in the event of goods being out of stock or unavailable, force majeure, disturbances or total or partial strike action affecting in particular postal services and means of transport, and flood or fire.

8. DISPUTES

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 Council of Europe (EDQM) and the customer as regards the application of this contract 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.

Answers to Your Questions

Reference Standards - *Questions about orders, billing, and shipping information.*

Helpdesk: <http://www.edqm.eu/hd>

Fax: +33 (0)3 88 41 27 71

Flight details - *Questions about dispatch of ICRS orders only.*

Helpdesk: <http://www.edqm.eu/hd>

E-mail: RSdispatch@edqm.eu

Fax: +33 (0)3 88 41 27 71

Monographs - *Questions about monographs*

Helpdesk: <http://www.edqm.eu/hd>

Fax: +33 (0)3 88 41 27 71

II. EDQM LONG-TERM STORAGE CONDITIONS

See the relevant column in the list starting on page 1.

The temperature ranges for the EDQM long-term storage conditions are:

- for +5 °C: 2 °C to 8 °C;
- for -20 °C: -25 °C to -15 °C;
- for -80 °C: -85 °C to -75 °C.

III. USE OF INTERNATIONAL CHEMICAL REFERENCE SUBSTANCES

The International Chemical Reference Substances are established and distributed following the general principle of ISO Guide 34.

The specificity of pharmacopoeial reference standards has been officially recognised by ISO (ISO Guide 34 *General requirements for the competence of reference material producers* and ISO Guide 35 *Reference materials - General and statistical principles for certification*): “the uncertainties of the assigned values are not stated since they are considered to be negligible in relation to the defined limits of the method-specific assays for which they are used.”

The reference standards are specially selected and verified batches, suitable for use as prescribed in the International Pharmacopoeia.

Suitability for purposes other than those prescribed in the International Pharmacopoeia monographs is left up to the user or to the pharmacopoeia commission or authority that has prescribed the use. Each vial supplied contains a quantity sufficient for the prescribed use.

A vial or ampoule is considered as an ‘immediate use’ reference standard. It is recommended that the vial or ampoule is used in the same series of analysis.

It is recommended to purchase only a sufficient amount for immediate use and to use the reference standards as soon as possible.

The stability of the contents of opened vials or ampoules cannot be guaranteed.

In specific cases, for reasons related to filling or labelling, sub-batches 1.1, 1.2, 1.3, etc., are obtained from the same batch of bulk material. However, all necessary precautions are taken in order to guarantee that the quality and the specifications of the sub-batches do not differ from one to another.

The 'Information' column of the catalogue indicates an official date on which the batch is no longer valid as a ICRS for all batches that have just been replaced. Hence "batch 1 valid until 30 June 2010" means that batch 1 is no longer official as of 1 July 2010.

Where no drying conditions are stated, the substance is to be used as received.

For the ICRS with an assigned content, the stated content is expressed on an 'as is' basis.

The reference standards database on our website is updated daily with information on availability. The list of the most recent reference standards (new products and new batches) is available on the website: <http://crs.edqm.eu/> under the link 'new'. Other information available includes details on the origin, assigned value and batch validity.

For reference standards supplied in sealed glass ampoules the following technique is suitable for opening the ampoule: tap the ampoule gently to collect the material at the lower end; score the ampoule with a file; heat a glass rod to white heat and apply firmly to the file mark; if a crack is not produced, deepen and extend the file mark, reheat the glass rod and apply again. A video showing how to open this type of ampoule is available on our website. Warning! To show the operation clearly in this video, the operator was filmed not wearing any hand protection. This in no case should be taken as an example to be followed. Operators must assess the risks associated with the procedure and take any necessary protective measures such as wearing heat resistant gloves, chain mail gloves, etc.

Toxic substances. The potential toxicity of certain reference standards is such that special precautions are needed during use to avoid contact.

Such substances should be manipulated in a glove box, otherwise protective gloves, eye protection and a mask should be worn.

Safety Data Sheets

Safety data sheets are **available on the website** or on request.

Information provided by the EDQM on the safety data sheets is compiled from information provided in the usual way by suppliers or manufacturers of the products and has not been independently verified by EDQM staff. The accuracy of such information cannot therefore be guaranteed.

V. LEAFLET

In all cases, user information leaflet is sent with the product and may be downloadable on the EDQM website, ICRS section.

Extra charge		Zone 1		Zone 2		Zone 3		Exceptions
		Incoterm	Cost	Incoterm	Cost	Incoterm	Cost	
a	Shipment at ambient temperature	DDU	8 €	DDU	30 €	DDU	55 €	for India, Iraq, Turkey, South America and Africa, our shipment is by airport consignment only
b	Shipment under ice (+ 5 °C)	DDU ¹	15 €	CIP	50 €	CIP ²	100 €	¹ for Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the former Yugoslav Republic of Macedonia, Iceland, Malta, Montenegro, Rumania, Serbia and Turkey, our shipment is by airport consignment only ² For Paraguay: cannot be sent
c	Shipment under ice (- 20 °C)							
d	Shipment under dry-ice							
e	Shipment under ice or dry-ice + dangerous goods	CIP	200 €	CIP	250 €	CIP	250 €	
f	Dangerous goods at ambient temperature	CIP	30 €	CIP	70 €	CIP	110 € ⁴	³ for Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the former Yugoslav Republic of Macedonia, Iceland, Malta, Montenegro, Republic of San Marino, Rumania, Serbia and Turkey, our shipment is by airport consignment only ⁴ New cost as from 01/01/10.
g	Dangerous goods in excepted quantities	DDU ³		CIP		CIP		
h	Dangerous goods sent by road	DDU		DDU				
i	Precursors	DDU ⁵	40 €	CIP	80 €	CIP	120 €	⁵ Outside EU, our shipment is by airport consignment only ⁶ France - DDU
j	Psychotropic substances	CIP ⁶		CIP		CIP		
k	Narcotics							
l	Reference spectra	DDU	0 €	DDU	0 €	DDU	0 €	

ZONE 1 Member States of the European Pharmacopoeia Convention (Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, the former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom).

ZONE 2 Other European Countries (Albania, Armenia, Azerbaijan, Georgia, Moldova, Russian Federation and Ukraine), Canada and United States

ZONE 3 Rest of the world