THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

European Pharmacopoeia Reference Standards

Handling, dispatch, where to find useful information and other practicalities

European Pharmacopoeia training webinars
Strasbourg, 30 June 2023

Dr Pierre Leveau
Head of Reference Standards & Logistics Department

TOPICS

- Before ordering
- Ordering
- Labelling
- What is expected from users
- Proving validity
- Shipping & Storing
- Safety
- Other source of information & FAQ

Before ordering

BEFORE ORDERING

Consult the online catalogue.

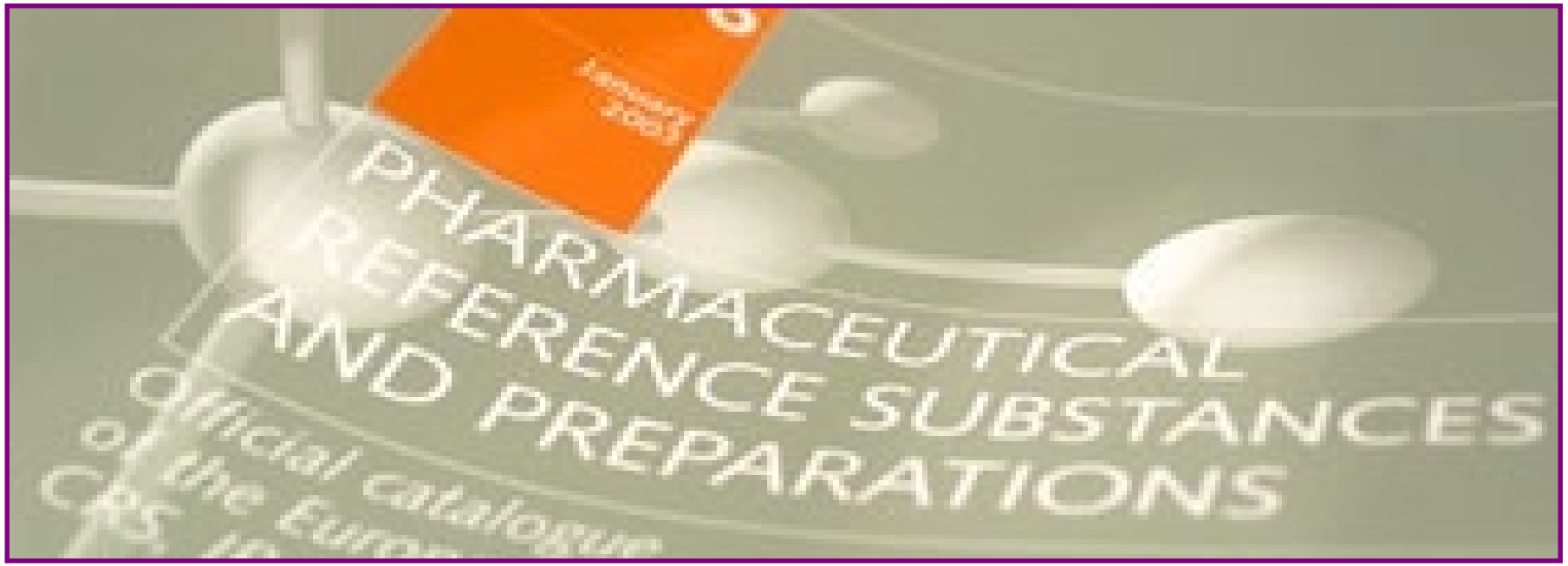
 Specific catalogue for Ph. Eur. / ISA and ICRS (WHO)

BEFORE ORDERING

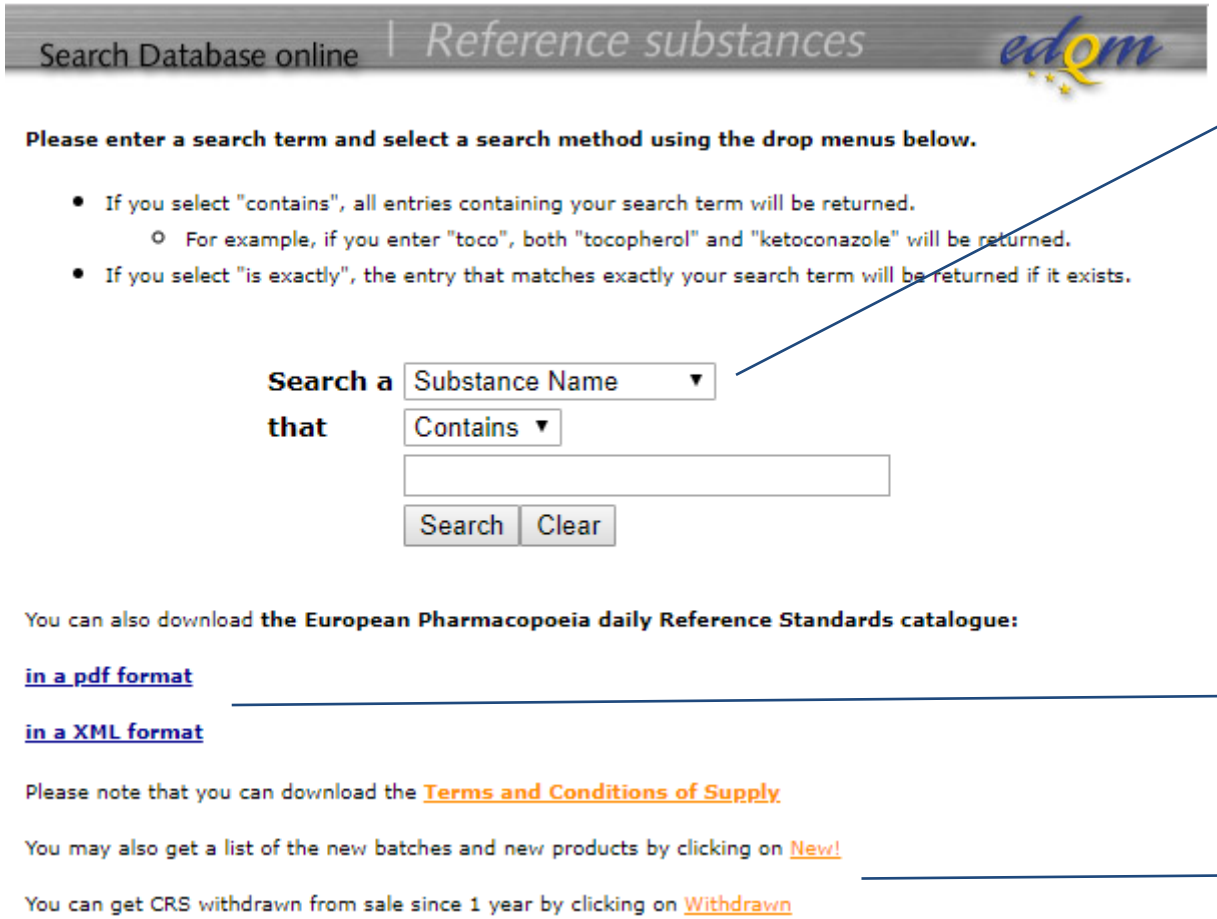
Available online.

Updated daily. English only.

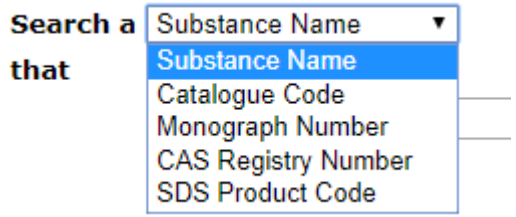
- For searching database: https://crs.edqm.eu



BEFORE ORDERING



Several possibilities to search for a RS:



⚠ CAS are provided for information only and are not independently verified.

Possibility to print the entire catalogue (interface with IT system in xml)

See next slide

BEFORE ORDERING

Catalogue Code	Y0001984
Name	Codeine for system suitability - * narc CRS
Current batch number	2
Unit quantity per vial	10 mg
Number of vials per sales unit	1
Used in monograph(s)	0074, 0075, 0076, 1412
Assigned content	See leaflet
Additional information	An original import permit is required to apply for an export licence from the French authorities (allow 2-3 weeks). Your permit must be valid for at least 3 months. Please state on your purchase order your preferred airport. You should apply for your import permit, per vial: - 9,19 mg of codeine monohydrate - 0,019 mg of thebaine - 0,031mg of norcodeine
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201600233
CAS Registry Number	N/A
Presentation	
Origin	click to download Origin Of Goods.pdf
Proposed Import HS code	293911
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	Not classified
Shipping group	A2A
Price*	79 EUR
Availability	Available
Sales restriction	No

Batches

batch 2 is valid at this date

Print BVS

RS webshop

Prepare for customs and reception in your laboratory

Direct link to Webstore

NEW reduced from 8-10 weeks to 2-3 weeks.
Composition to declare is provided.

SDS

Origin of goods **NEW** – Country of origin
Proposed HS code

EDQM Dispatch and storage conditions

Availability
Sales restriction are provided

BEFORE ORDERING

Necessary documents in some cases:

- For **precursors**, **psychotropic** and **narcotic** substances: an original import permit to be sent to the EDQM
- For ***ODS substances**, a valid LabODS number (EU) or license (outside EU) is required (refer to specific FAQ for further guidance)
- For **biological material**: please check that you have the import permit (e.g. USDA and Australian permits)
- Some specific documents available from website:
  - ✓ Letter replacing CoA
  - ✓ Legal Framework and Diplomatic Status of Reference Standards for Customs Purposes
  - ✓ For UK users: Brexit impact document

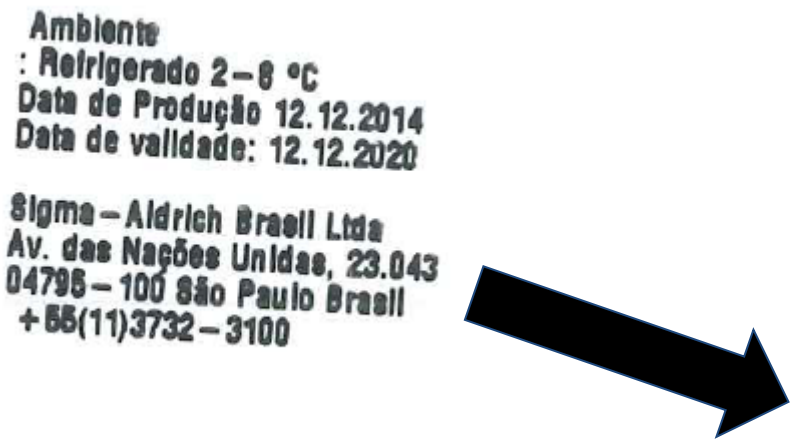
Ordering

ORDERING

- Ph.Eur. RS can be ordered directly from EDQM:

  https://www.edqm.eu/en/ph-eur-reference-standards-orders-catalogue

- Care should be taken when ordering from other sources:



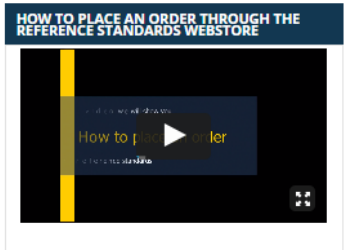
ORDERING

- EDQM does not have authorised distributors.

....but EDQM provides a list of organisations or companies known to re-sell EDQM products.

This list is available through the website.

- A video explaining how to use the webstore is available from the website.



- Reference spectra are mailed as a pdf file since 2021.

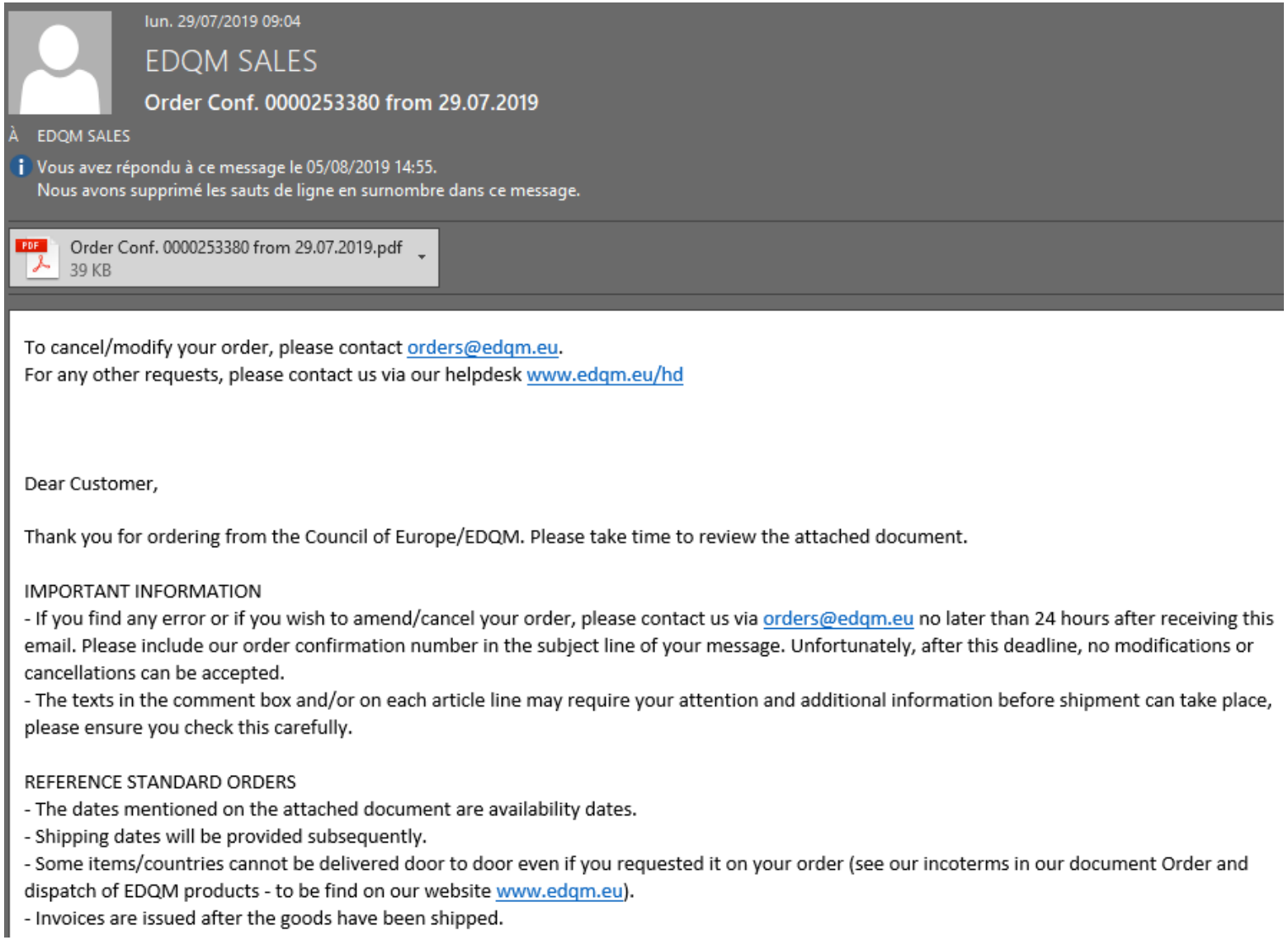
ORDERING

- **NEW:** revised certificates of origin are now online (from the online catalogue).

BUT

Be aware that the EDQM is not in a position to release **EUR.1 movement certificate** (also known as **EUR.1 certificate**, or **EUR.1**).

ORDERING



lun. 29/07/2019 09:04

EDQM SALES

Order Conf. 0000253380 from 29.07.2019

À EDQM SALES

Vous avez répondu à ce message le 05/08/2019 14:55.
Nous avons supprimé les sauts de ligne en surnombre dans ce message.

Order Conf. 0000253380 from 29.07.2019.pdf
39 KB

To cancel/modify your order, please contact orders@edqm.eu.
For any other requests, please contact us via our helpdesk www.edqm.eu/hd

Dear Customer,

Thank you for ordering from the Council of Europe/EDQM. Please take time to review the attached document.

IMPORTANT INFORMATION
- If you find any error or if you wish to amend/cancel your order, please contact us via orders@edqm.eu no later than 24 hours after receiving this email. Please include our order confirmation number in the subject line of your message. Unfortunately, after this deadline, no modifications or cancellations can be accepted.
- The texts in the comment box and/or on each article line may require your attention and additional information before shipment can take place, please ensure you check this carefully.

REFERENCE STANDARD ORDERS
- The dates mentioned on the attached document are availability dates.
- Shipping dates will be provided subsequently.
- Some items/countries cannot be delivered door to door even if you requested it on your order (see our incoterms in our document Order and dispatch of EDQM products - to be find on our website www.edqm.eu).
- Invoices are issued after the goods have been shipped.

- When an order is sent, you have **24 hours** to correct or cancel the order.
- Then, the order is blocked **24 hours** for preparation (no possible change).
- We privilege door-to-door shipment.

ORDERING

Line	Item code	Description	Qty	Unit price	Handling charges	Net value	Estimated shipping date
10	Y0001745	**Glucose monohydrate CRS** 1 vial(s) per sales unit ; 750 mg per vial	18	79,00	45,00	1.467,00	23/05/2022
20	F0400000	**Fosfomycin trometamol CRS** 1 vial(s) per sales unit ; 1500 mg per vial	17	79,00	42,50	1.385,50	23/05/2022
30	Y0000400	**Naltrexone hydrochloride CRS** 1 vial(s) per sales unit ; 50 mg per vial	6	79,00	15,00	489,00	23/05/2022
40	Y0001629	**Follitropin CRS** 1 vial(s) per sales unit ; 0,2 mg per vial	16	79,00	40,00	1.304,00	23/05/2022

Ambient, not controlled nor dangerous (shipping group A1A)
DELIVERY TERMS: DAP [redacted] - Door to door

Item	Item code	Description	Qty	Proposed HS code	Estimated ship. date
10	Y0001745	Glucose monohydrate CRS	18	170230	23/05/2022
20	F0400000	Fosfomycin trometamol CRS	17	294190	23/05/2022
30	Y0000400	Naltrexone hydrochloride CRS	6	293919	23/05/2022
50	Y0001816	Sodium aminosalicylate dihydrate for equipment qualification	4	292250	23/05/2022

Dry-ice, not controlled nor dangerous (shipping group D1A)
DELIVERY TERMS: DAP [redacted] - Door to door

Item	Item code	Description	Qty	Proposed HS code	Estimated ship. date
40	Y0001629	Follitropin CRS	16	293719	23/05/2022

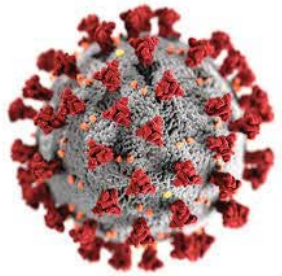
- **Always have a close look to the Acknowledgement of Receipt**

NEW: split per shipping group

- Shipping dates are known at the time of parcel preparation, not before
- Impossible to make door-to-door for some destinations because of shipping companies restrictions (even if requested at order stage!!)
- Ice: delivered at the closest "customs" airport!

- **Chase your broker, if any (especially for ice / dry ice) & ANTICIPATE CUSTOMS ISSUES**

ORDERING



We are still experiencing issues due to Covid pandemic:

- **Flights are subject to last minute change without notice.**
- **Some companies have disappeared (or privilege cargo mode) leading to difficulties to ship to some areas.**
- **Some countries may still block parcels for sanitary reason.**
- **We try to do our best to continue privileging door-to-door shipment or asking for the closest airport but we cannot guarantee that we are successful.**

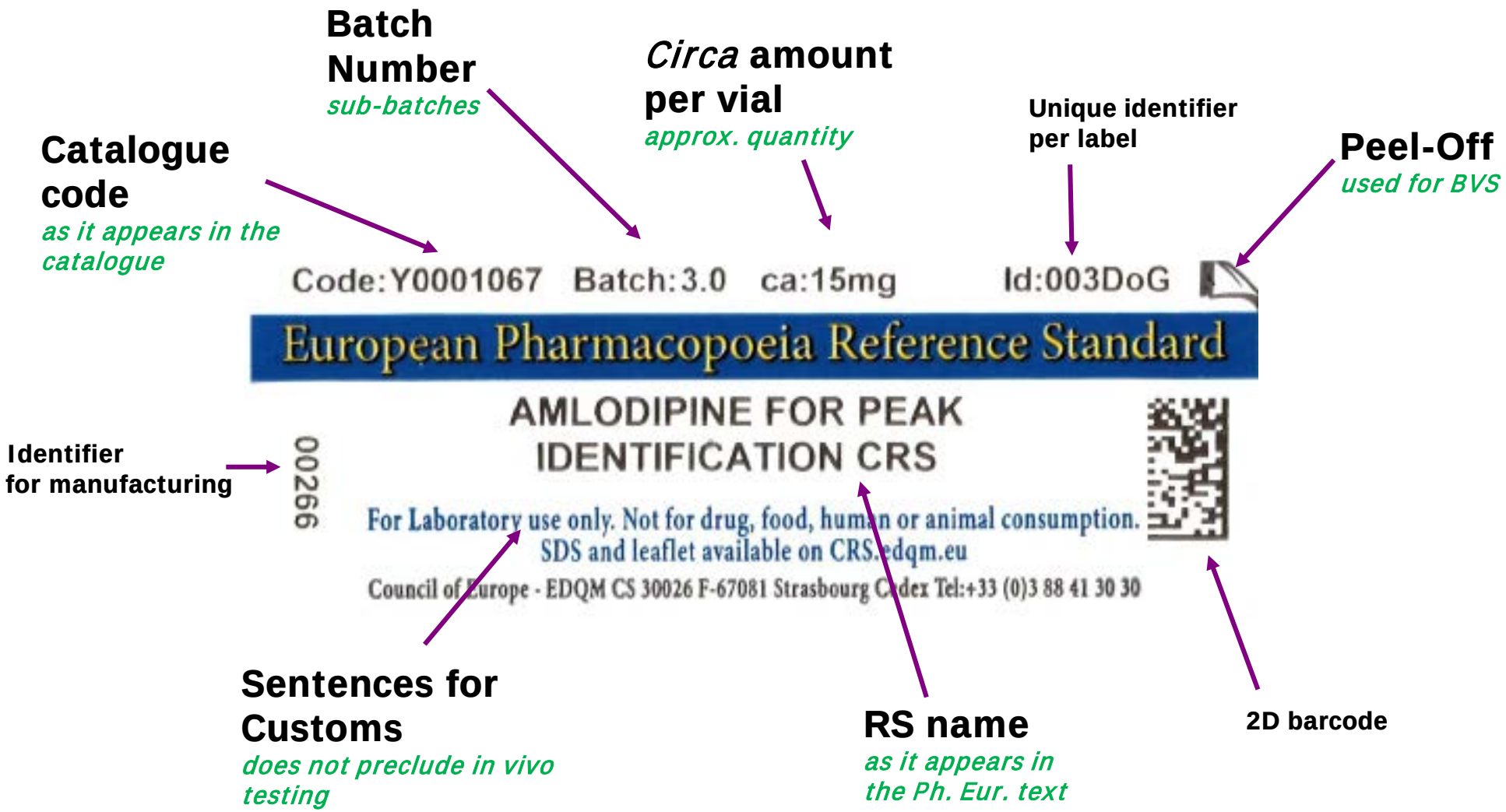
Labelling

LABELLING

Includes:

- Primary label AND the pictogram;
- Secondary label (displaying the pictograms on the outer package);
- Leaflet

LABELLING



LABELLING

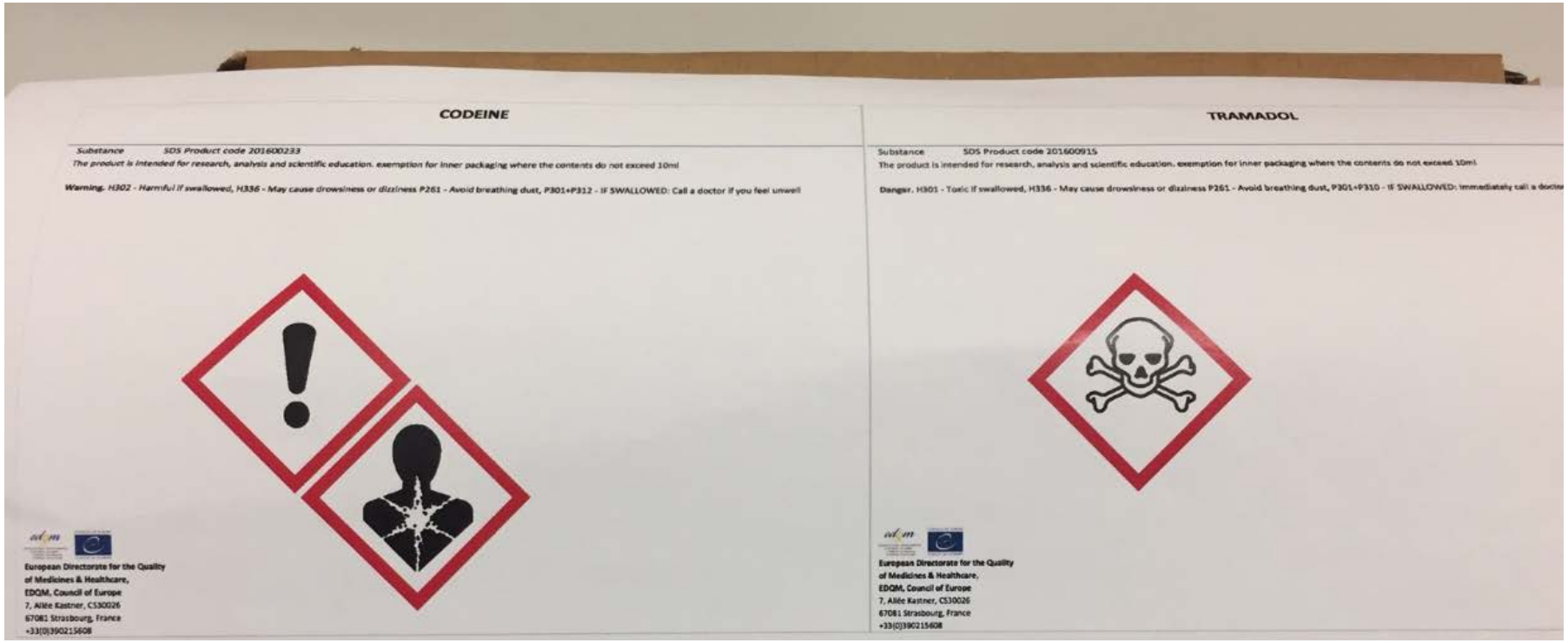
Safety information

Warning tag (if any)

NEW *tags have been recently introduced.*

LABELLING

Safety Information is also provided on the external secondary package: pictograms and warnings (in the language of the country).



LABELLING

Additional information is provided in the information leaflet:

* if used as an assay standard the following information is also given:

- the assigned percentage content;
- or, the content in mg or mL of the chemical entity in the container;
- or, the assigned potency (for biological assays or microbiological assays) in units either per mg or per vial.

This is not mentioned on the primary label or in the catalogue!

* type-chromatograms, stoichiometric conversion factor, etc. are also available in the leaflet.

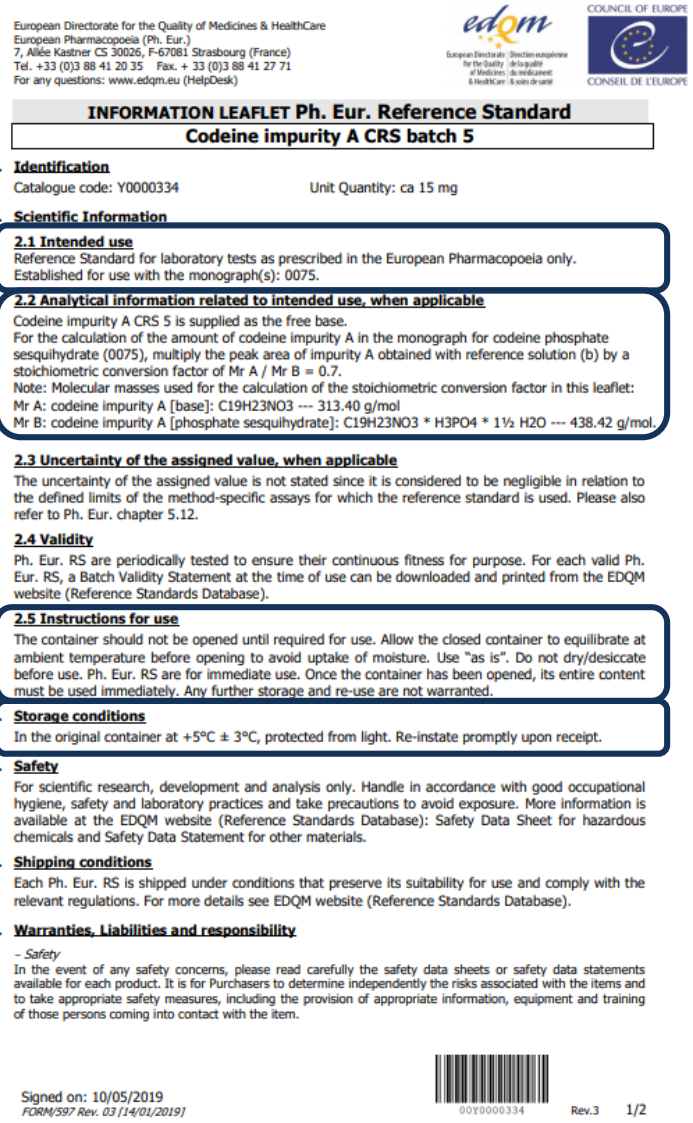
LABELLING

Provides mono number

Analytical information

Specific instruction

EDQM storage conditions



European Directorate for the Quality of Medicines & HealthCare
European Pharmacopoeia (Ph. Eur.)
7, Allée Kastner CS 30026, F-67081 Strasbourg (France)
Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any questions: www.edqm.eu (HelpDesk)

INFORMATION LEAFLET Ph. Eur. Reference Standard

Codeine impurity A CRS batch 5

1. **Identification**

Catalogue code: Y0000334 Unit Quantity: ca 15 mg

2. **Scientific Information**

2.1 Intended use
Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only.
Established for use with the monograph(s): 0075.

2.2 Analytical information related to intended use, when applicable
Codeine impurity A CRS 5 is supplied as the free base.
For the calculation of the amount of codeine impurity A in the monograph for codeine phosphate sesquihydrate (0075), multiply the peak area of impurity A obtained with reference solution (b) by a stoichiometric conversion factor of Mr A / Mr B = 0.7.
Note: Molecular masses used for the calculation of the stoichiometric conversion factor in this leaflet:
Mr A: codeine impurity A [base]: C19H23NO3 --- 313.40 g/mol
Mr B: codeine impurity A [phosphate sesquihydrate]: C19H23NO3 * H3PO4 * 1½ H2O --- 438.42 g/mol

2.3 Uncertainty of the assigned value, when applicable
The uncertainty of the assigned value is not stated since it is considered to be negligible in relation to the defined limits of the method-specific assays for which the reference standard is used. Please also refer to Ph. Eur. chapter 5.12.

2.4 Validity
Ph. Eur. RS are periodically tested to ensure their continuous fitness for purpose. For each valid Ph. Eur. RS, a Batch Validity Statement at the time of use can be downloaded and printed from the EDQM website (Reference Standards Database).

2.5 Instructions for use
The container should not be opened until required for use. Allow the closed container to equilibrate at ambient temperature before opening to avoid uptake of moisture. Use "as is". Do not dry/desiccate before use. Ph. Eur. RS are for immediate use. Once the container has been opened, its entire content must be used immediately. Any further storage and re-use are not warranted.

3. **Storage conditions**
In the original container at +5°C ± 3°C, protected from light. Re-instate promptly upon receipt.

4. **Safety**
For scientific research, development and analysis only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure. More information is available at the EDQM website (Reference Standards Database): Safety Data Sheet for hazardous chemicals and Safety Data Statement for other materials.

5. **Shipping conditions**
Each Ph. Eur. RS is shipped under conditions that preserve its suitability for use and comply with the relevant regulations. For more details see EDQM website (Reference Standards Database).

6. **Warranties, Liabilities and responsibility**

– Safety
In the event of any safety concerns, please read carefully the safety data sheets or safety data statements available for each product. It is for Purchasers to determine independently the risks associated with the items and to take appropriate safety measures, including the provision of appropriate information, equipment and training of those persons coming into contact with the item.

Signed on: 10/05/2019
FORM/597 Rev. 03 [14/01/2019]
00Y0000334
Rev.3 1/2

– 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.

The EDQM does not guarantee that the items will meet the Purchaser's specific expectations. The EDQM only guarantees that the items (i) were fit for use according to EDQM's intended use of the product ;(ii) were fit for use at the moment that they were handed over to the carrier being 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; and (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) the carrier and the Purchaser received clear and accurate instructions for the item's delivery and reception. No other guarantees, whether explicitly 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, included, 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.
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 internationally accepted commercial standards; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

7. **Arbitration & Applicable Law**
The aim of the EDQM is to settle any disputes amicably in the framework of its 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.

8. **Citation**
Users shall ensure that any reference made to an EDQM Reference Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the exact name, and catalogue code of the Reference Standard and the exact name and address of EDQM as given on the first page of this information leaflet.

9. **Adoption**
The suitability for intended use has been officially adopted by the European Pharmacopoeia Commission.

10. **Signature**
This document is approved by:

Ms Caroline Offerlé
Head of the Quality and Risk Management Section

Signed on: 10/05/2019 Cat. Code: Y0000334 Rev. 3 2/2
FORM/597 Rev. 03 [14/01/2019]

What is expected from the user

WHAT IS EXPECTED FROM THE USER

Immediately before using a Ph. Eur. Reference Standard, the following shall be checked:

- that the reference standard batch number is current at the time of use. Print the real-time batch validity statement (BVS) available online;
- that the container/closure system integrity is maintained, i.e. absence of visible defects originating from shipping;
- that the reference standard after receipt has been stored at the conditions prescribed in the Ph. Eur. RS catalogue (or according to your specifications, if any).

WHAT IS EXPECTED FROM THE USER

Moreover, allow the RS to equilibrate to lab temperature before opening.
Use “as is” unless indicated in the leaflet.

Depending on the quantity in the vial, two main glass vials may be used:

- for filling weights > 15 mg

Brown glass vials (type 7 mL)

NB: also used for evaporation

- for filling weights < 15 mg

V-vials facilitating the recovery of the powder

Proving validity

PROVING VALIDITY

No expiry date nor retest date is stated on the label or leaflet

Use BVS!

PROVING VALIDITY

To get the BVS, go the detailed view of the catalogue

Catalogue Code	Y0001380
Name	Olanzapine for system suitability CRS
Current batch number	3
Unit quantity per vial	10 mg
Number of vials per sales unit	1
Used in monograph(s)	2258, 3047
Assigned content	See leaflet
Additional information	
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201600655
CAS Registry Number	132539-06-1
Presentation	
Origin	click to download Origin Of Goods.pdf
Proposed Import HS code	293499
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	2811
Shipping group	A1A
Price*	79 EUR
Availability	Available
Sales restriction	No

Batches

batch 3 is valid at this date

Print BVS

RS webshop

New Search

PROVING VALIDITY

Olanzapine FSS CRS batch number = **3** => Check online BVS

BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
This Batch Validity Statement has to be used in conjunction with Ph. Eur. general chapter 51200 Reference Standards.

European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet: http://www.edqm.eu

Name	Olanzapine for system suitability CRS
Catalogue code	Y0001380
Batch number*	3
Assigned value	n/a
Validity	Batch 3 is valid at the printing date: 2023-6-19
Additional information	
Storage conditions	Recommended EDQM storage conditions for unopened containers : +5°C+/-3°C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, click to download the leaflet
Origin	Click on the hyperlink to download the origin to check if import permit is required in your country, n/a

Batch 3 is official at the time of printing

* This BVS also includes sub-batches.

This statement is valid at the date of printing : 2023-6-19

Also valid at the date of printing for sub-batches (e.g. 3.1; 3.2, etc.)

PROVING VALIDITY

BUT: batch **2** is still valid until 30/11/2023 => Check online BVS

Catalogue Code	Y0001380
Name	Olanzapine for system suitability CRS
Current batch number	3
Unit quantity per vial	10 mg
Number of vials per sales unit	1
Used in monograph(s)	2258, 3047
Assigned content	See leaflet
Additional information	
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201600655
CAS Registry Number	132539-06-1
Presentation	
Origin	click to download Origin Of Goods.pdf
Proposed Import HS code	293499
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	2811
Shipping group	A1A
Price*	79 EUR
Availability	Available
Sales restriction	No

Batches

batch 3 is valid at this date

batch 3 is valid at this date

batch 2 : validity until 30 November 2023

RS webshop

New Search

PROVING VALIDITY

BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
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European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet: http://www.edqm.eu

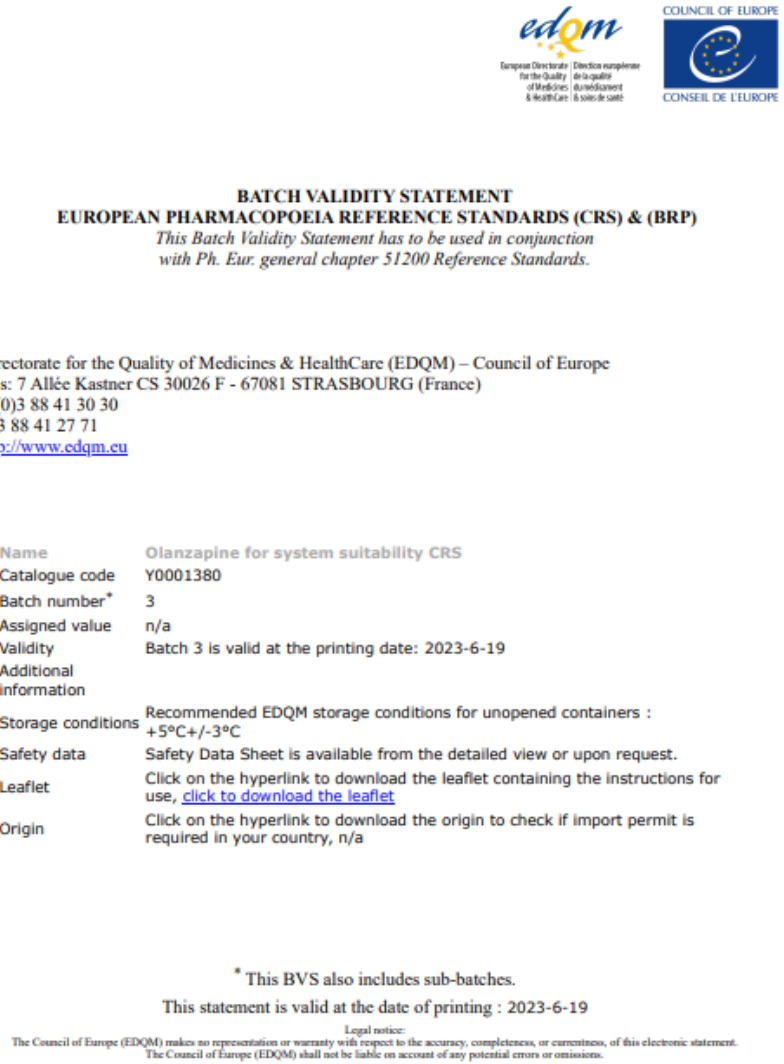
Batch 2 is still official at the time of printing (19/06/2023)

Name	Olanzapine for system suitability CRS
Catalogue code	Y0001380
Batch number*	2
Assigned value	n/a
Validity	Batch 2 is valid until 2023-11-30
Additional information	
Storage conditions	Recommended EDQM storage conditions for unopened containers : +5°C+/-3°C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, click to download the leaflet
Origin	Click on the hyperlink to download the origin to check if import permit is required in your country, n/a

* This BVS also includes sub-batches.

This statement is valid at the date of printing : 2023-6-19

PROVING VALIDITY



BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
This Batch Validity Statement has to be used in conjunction with Ph. Eur. general chapter 51200 Reference Standards.

European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet: http://www.edqm.eu

Name	Olanzapine for system suitability CRS
Catalogue code	Y0001380
Batch number*	3
Assigned value	n/a
Validity	Batch 3 is valid at the printing date: 2023-6-19
Additional information	
Storage conditions	Recommended EDQM storage conditions for unopened containers : +5°C+/-3°C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, click to download the leaflet
Origin	Click on the hyperlink to download the origin to check if import permit is required in your country, n/a

* This BVS also includes sub-batches.

This statement is valid at the date of printing : 2023-6-19

Legal notice:
The Council of Europe (EDQM) makes no representation or warranty with respect to the accuracy, completeness, or currentness, of this electronic statement.
The Council of Europe (EDQM) shall not be liable on account of any potential errors or omissions.

At the time of analysis:

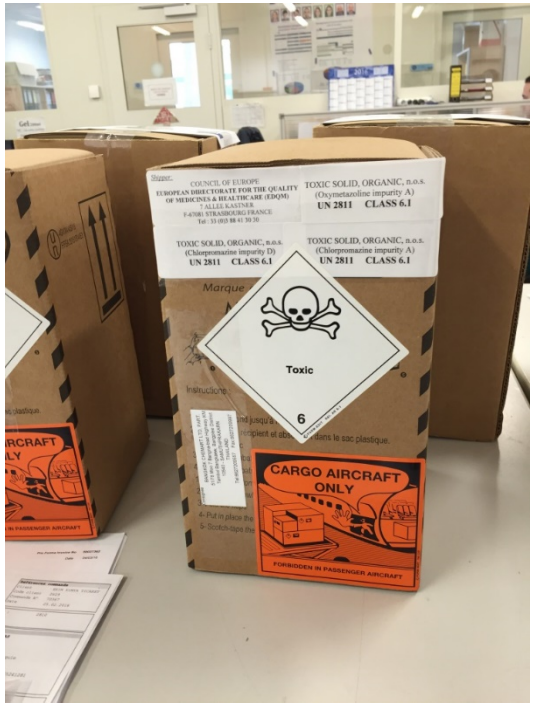
- Print out the BVS and
- Stick the peel-off label.

This ensure that you have used the official CRS at the time of use

Shipping and storing

SHIPPING & STORING

Packing materials (carton, boxes) are selected to minimise the risk of damage during transport and are compliant to the transport regulation prescription when applicable (IATA, ADR, IMDG).



SHIPPING & STORING

Packing materials should ensure respect of T° for three days.

Specifications

+5°C => +1°C / +8°C

-20°C => -15°C / -25°C

Dry ice => -70°C / -50°C

SHIPPING & STORING

Dispatching conditions:

✓Ambient temperature
✓Under ice
✓Under dry ice

Recommended storage conditions:

- ✓ +5°C or -20°C
- ✓ +5°C or -20°c
- ✓ -20°C or -80°C or Liq N_2

Dispatch at ambient temperature – short excursions from the long-term storage temperature during shipping do not impact the quality of the reference standard.

SHIPPING & STORING

EDQM storage conditions are established for **long-term** storage.

They are based on:

- Stability data,
- Data received from supplier of the bulk material,
- Monitoring,
- Literature,
- Ph. Eur. information.

User is free to adopt other storage conditions, under its own responsibility.

SHIPPING & STORING

For optimal stability, storage temperature one level below monograph prescription, if any.

- Room temperature -> +5°C
- +2 to 8°C -> -20°C (if possible, liquids...)
- Under -15°C -> -20°C
- -20°C -> -80°C (if possible)
- -50°C -> -80°C
- -80°C -> liquid nitrogen

SHIPPING & STORING

In case new data is generated and has an impact, an information is published in the RS News published on the EDQM website usually the month before the change is implemented.

Information on change of EDQM storage/shipping conditions

Based on new stability information, storage and shipping conditions have been changed on **15 June 2023** for the following reference standard:

- Cladribine impurity C (Y0000610) CRS **batch 1** is stored at +5°C (previously -20°C) and shipped at ambient temperature (previously on ice at -20°C)

We also try to inform users in advance in other cases (e.g. change in sales unit / prices / amount per unit).

Information on change of sales units / price

- The sales unit of **H1100000 Human rabies Ig BRP** will be changed from 3 to 1 unit and the price will change from 90€ to 79€ from 15/06/2023. The quantity is sufficient to perform the test mentioned in Ph. Eur. monograph 0723. The sales restriction will also be lifted on 15/06/2023.

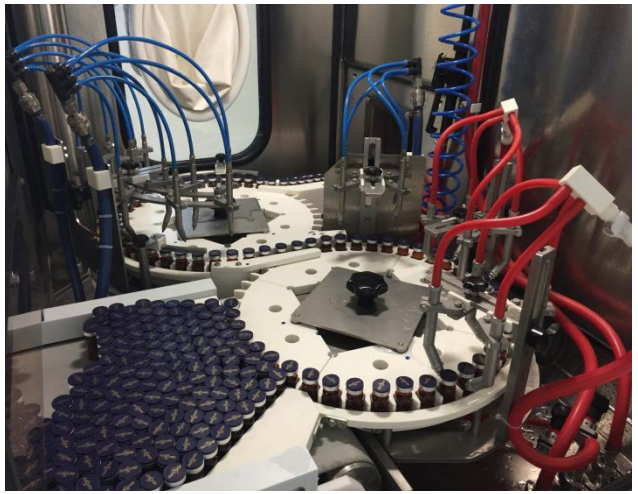
Information on change of amount per unit

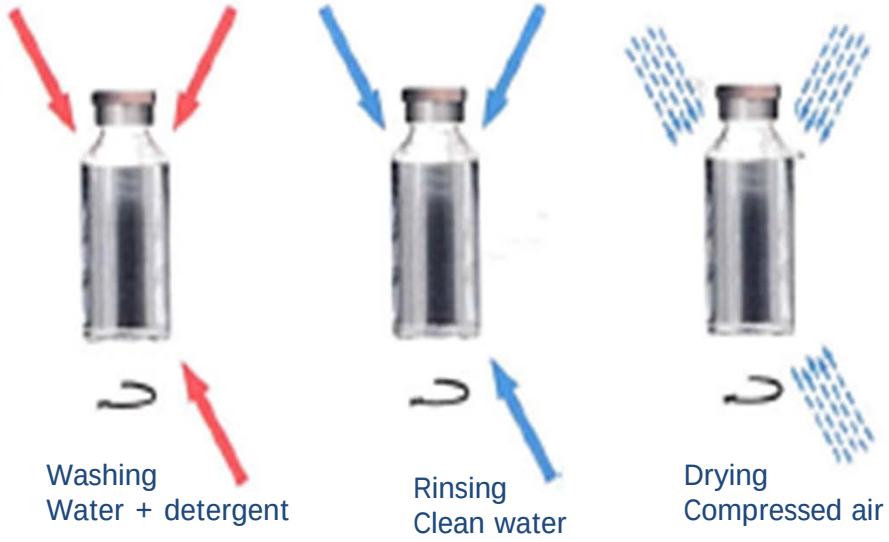
- Sodium aminosalicylate dihydrate (Y0001669) CRS **batch 1.1** contains 20 mg per unit (previously 10 mg)
- Mepyramine impurity C CRS **batch 2** contains 15 mg per unit (previously 10 mg)
- Progesterone for impurity H identification CRS **batch 4** contains 25 mg per unit (previously 20 mg)

Safety

SAFETY

The external part of the vials containing Substances of Very High Concern is washed after manufacturing in order to protect staff using CRS.





SAFETY

How to access the SDS

SDS can be accessed via the European Pharmacopoeia RS database:

Search Ph. Eur. RS

And the WHO RS databases:

Search ISA RS

Search ICRS RS

Safety Data Sheet (chemicals) and Safety Data Statement (bio) are available from website.

NOTES:

- **Hazardous Chemicals**: the EDQM complies with UNECE globally harmonised system for classification and labelling of chemicals; as enacted in the EU.

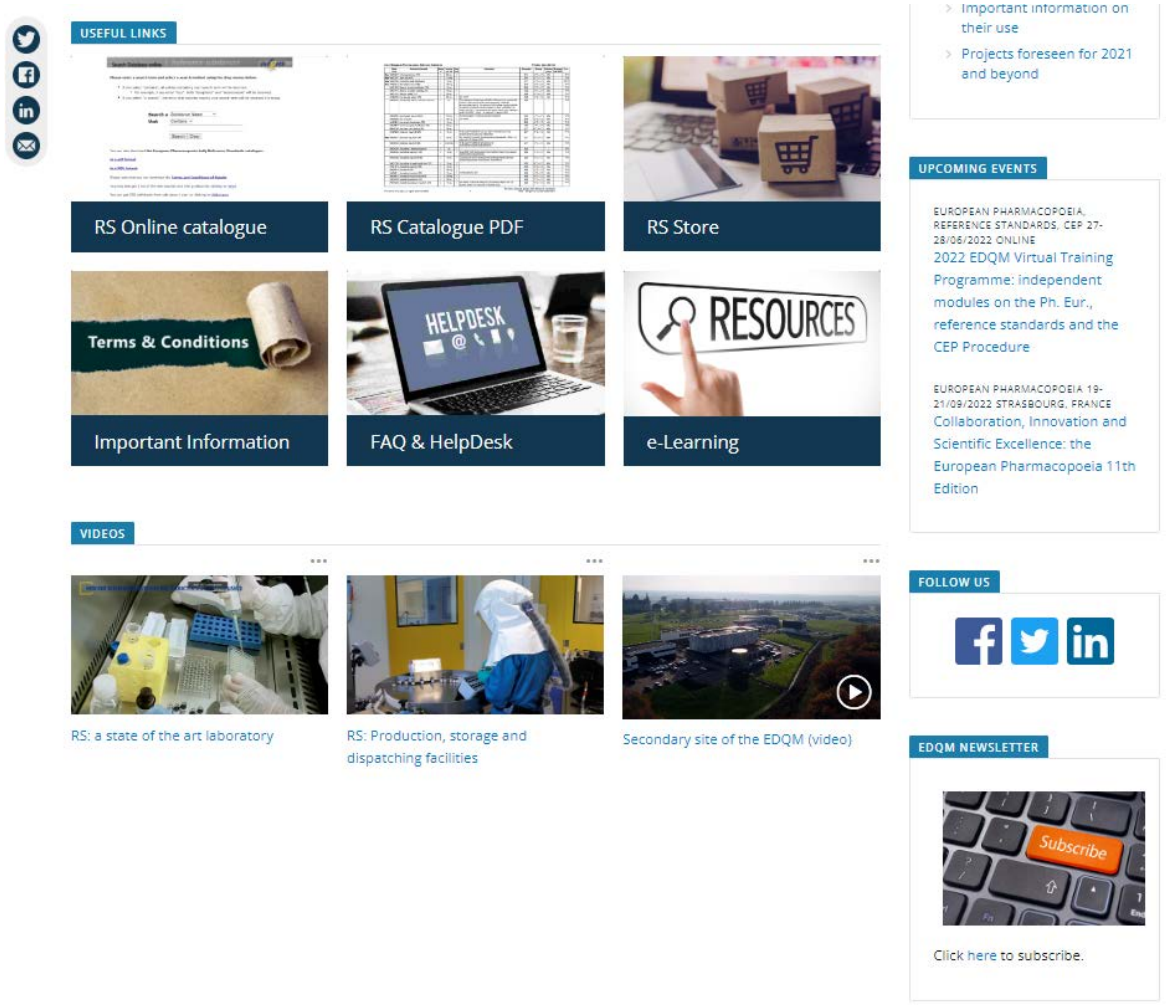
SDSs are not provided for materials for which no hazard has been identified. In such cases, the hazard status of the material is available in the database and is also published on the shipping documents (with the text: ”Hazard: none identified”).

- **Biologicals**: Directive 2000/54/EC applies. EDQM issues Safety Data Statements if a hazard has been identified.
- Safety documentation is provided for occupational health only and is not part of quality standards.
- You may also find which SDS have been updated in a compiled document published on the website.

Other sources of information & FAQ

OTHER SOURCE OF INFORMATION & FAQ

EDQM issues a monthly news & a monthly newsletter.



You can subscribe!

OTHER SOURCE OF INFORMATION & FAQ

It contains:

- **New** and **Replacement** batches
- **Removed (and future removal)** items

    Removed RS are kept for an additional 12 months in the catalogue for RA requirements in some countries (6 months for sale -if stock available- and 6 additional months to print documents)

- Change of **sales unit, price, quantity**
- Information on **changes of storage / shipping conditions**

    Unless QA issue, changes are announced in advance (change will occur on the 15th of the next month, if possible)

OTHER SOURCE OF INFORMATION & FAQ

FAQ

Directly available from the website.

TOP 10 Questions

OTHER SOURCE OF INFORMATION & FAQ

- How can I obtain the CoA?

The EDQM does not provide certificate of analysis.

Needed data is available in the information leaflet.

If you want to use the RS for another use, it is done under your responsibility.

OTHER SOURCE OF INFORMATION & FAQ

- I do not find the expiry date

No expiry date is provided. It is down to the user to demonstrate that the CRS/BRP used in an official Ph. Eur. test or assay was current at the time of use. The BVS is used for this purpose. In case of replacement batch, a validity is provided in the online catalogue.

Therefore, it is recommended to purchase only a sufficient amount for analysis and to use the products as soon as possible.

Once the container has been opened, weighing should be carried out immediately. Any further storage and re-use are not warranted.

OTHER SOURCE OF INFORMATION & FAQ

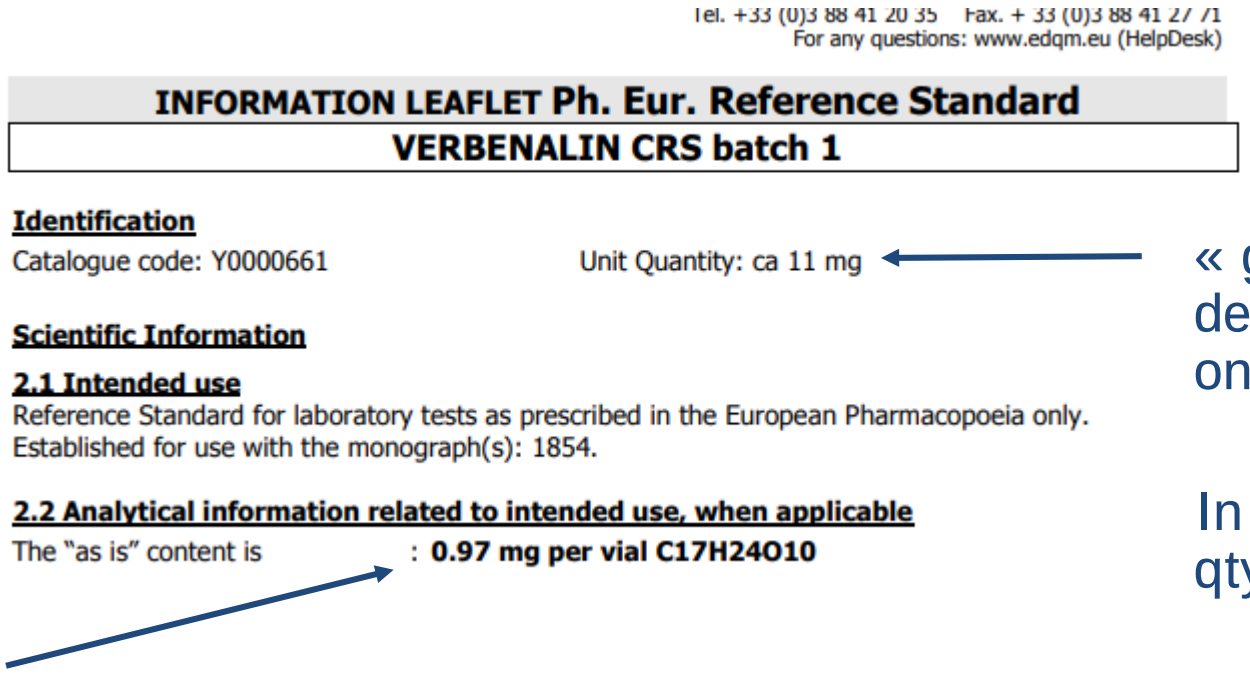
- I do not find the purity

RS are established for a precise intended use. In case the purity / assigned value / activity is not mentioned in the information leaflet, it means that this value is not needed to carry out the test/assay described in the related monograph(s) and therefore it is not provided.

!! it cannot be assumed to be 100%. The only exception is the purity of an impurity CRS, which can be estimated to be 100% for the tests of the monographs, if the EDQM has not stated the purity.

OTHER SOURCE OF INFORMATION & FAQ

- If there are two weights declared: on the label and on the leaflet, which one should I use?



Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any questions: www.edqm.eu (HelpDesk)

INFORMATION LEAFLET Ph. Eur. Reference Standard

VERBENALIN CRS batch 1

1. **Identification**

Catalogue code: Y0000661 Unit Quantity: ca 11 mg

2. **Scientific Information**

2.1 Intended use

Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only.
Established for use with the monograph(s): 1854.

2.2 Analytical information related to intended use, when applicable

The "as is" content is : **0.97 mg per vial C17H24O10**

« gravimetric » weight declared for customs (also on the label) !! ca quantity

In this case: freeze drying qty = (API+excipients)

Declared content to be used for analytical purpose

OTHER SOURCE OF INFORMATION & FAQ

- I cannot recover the quantity from the vial

Each vial or ampoule is individually weighed during manufacturing and therefore contains a quantity sufficient for the prescribed use.

Nevertheless, since there is usually a very low quantity, the product may be distributed between the inner surface and the rubber stopper.
To avoid this problem and recover the full quantity, we usually recommend gently tapping the bottom of the vial several time in order to bring down the product. You can also use an anti-magnetic device to easily collect the powder.

If the test / product allows, you can also work by differential weighing.

OTHER SOURCE OF INFORMATION & FAQ

- The parcel arrived with cool packs thawed, is it suitable for use, may I obtain stability data?

Excursion outside recommended temperature usually does not jeopardise the quality of the RS.

In case of question, the EDQM will analyse the case with available data and will make a recommendation, if possible.

Stability data cannot be shared.

OTHER SOURCE OF INFORMATION & FAQ

- Is there a QMS applied to RS? May I have a copy of the certificate?

The EDQM is ISO 9001 certified for the conduct of laboratory studies and RS production.

The EDQM laboratory is also ISO 17025 accredited for several analytical techniques used in the RS establishment (refer to the annex).

Both certificates are available from the website *(EDQM / About us)*

OTHER SOURCE OF INFORMATION & FAQ

- May I store the RS at different conditions than those stated in the catalogue?

The storage conditions mentioned in the catalogue are intended to preserve the integrity of the CRS during **long-term** storage.

We base our conditions on supplier's information, stability data (when available), monitoring data and bibliography.
Our storage conditions are in most cases more stringent than those given in the monograph.

Provided that you can demonstrate that the RS is fit for use at your chosen T°, nothing prevent you to do so.

OTHER SOURCE OF INFORMATION & FAQ

- I want an old BVS / leaflet

For the leaflet, it can be provided on request.

For the BVS, it is not possible.

OTHER SOURCE OF INFORMATION & FAQ

- I disagree with the CAS number provided in the catalogue

The CAS numbers provided are not independently verified by the EDQM.

They are provided only to help the user and most of the time refer to the CAS number of the parent substance mentioned in the Pharmacopoeia, so it can differ.

If you identify a discrepancy, please contact the EDQM via the Helpdesk.

OTHER SOURCE OF INFORMATION & FAQ

Still a question?

Helpdesk

Directly available from the website with a direct link to FAQs

Thank you for your attention

Stay connected with the EDQM

EDQM Newsletter: **https://go.edqm.eu/Newsletter**
LinkedIn: **https://www.linkedin.com/company/edqm/**
Twitter: **@edqm_news**
Facebook: **@EDQMCouncilofEurope**