

# EDQM reference standards monthly newsletter – February 2025

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*1 new Ph. Eur. reference standard and  
22 replacement batches released in February 2025*

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## See also:

[Content of the Ph. Eur. RS catalogue](#)

[How to place an RS order](#)

[Helping users test \*Pharmeuropa\* draft texts with “qualified samples”](#)

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## New and replacement batches of Ph. Eur. reference standards

The European Directorate for the Quality of Medicines & HealthCare (EDQM) announces the release of:

- o 1 new European Pharmacopoeia (Ph. Eur.) reference standard:

| Catalogue code           | Name   | Unit quantity | Price   |
|--------------------------|--|---------------|---------|
| <a href="#">Y0002487</a> | Dapagliflozin propylene glycol monohydrate CRS | 120 MG        | 100 EUR |

- o 22 replacement batches for Ph. Eur. reference standards:

| Catalogue code           | Name                                     | Batch | Unit quantity | Price  |
|--------------------------|--|-------|---------------|--------|
| <a href="#">G0400006</a> | Glycerol monolinoleate CRS               | 2     | 2000 MG       | 79 EUR |
| <a href="#">Y0001644</a> | Capecitabine impurity B CRS              | 2     | 15 MG         | 79 EUR |
| <a href="#">Y0001301</a> | Norfloxacin for peak identification CRS  | 2     | 15 MG         | 79 EUR |
| <a href="#">Y0001410</a> | Sodium fusidate CRS                      | 2     | 10 MG         | 79 EUR |
| <a href="#">Y0001296</a> | Nortriptyline for system suitability CRS | 2     | 20 MG         | 79 EUR |
| <a href="#">Y0001677</a> | Sulfadimethoxine CRS                     | 2     | 60 MG         | 79 EUR |
| <a href="#">Y0000789</a> | Fexofenadine hydrochloride CRS           | 3     | 110 MG        | 79 EUR |
| <a href="#">Y0001359</a> | Prednisolone for peak identification CRS | 3     | 10 MG         | 79 EUR |
| <a href="#">Y0001534</a> | Amisulpride for system suitability CRS   | 3     | 1.002 MG      | 79 EUR |
| <a href="#">Y0001071</a> | Benserazide impurity C CRS               | 3     | 15 MG         | 79 EUR |
| <a href="#">Y0001446</a> | Celecoxib impurity A CRS                 | 3     | 10 MG         | 79 EUR |
| <a href="#">Y0001839</a> | Hydroxychloroquine sulfate CRS           | 3     | 70 MG         | 79 EUR |
| <a href="#">Y0000299</a> | Fluphenazine sulfoxide CRS               | 3     | 20 MG         | 79 EUR |
| <a href="#">L0750000</a> | Loperamide hydrochloride CRS             | 3     | 50 MG         | 79 EUR |
| <a href="#">Y0001645</a> | Capecitabine impurity D CRS              | 3     | 15 MG         | 79 EUR |
| <a href="#">I0060002</a> | Ifosfamide impurity A CRS                | 5     | 100 MG        | 79 EUR |
| <a href="#">Y0000490</a> | Misoprostol CRS                          | 5     | 100 MG        | 79 EUR |
| <a href="#">C0688000</a> | Cefoxitin sodium CRS                     | 5     | 100 MG        | 79 EUR |
| <a href="#">C0200010</a> | N-acetyl-cys1-calcitonin CRS             | 6     | 20.1 MG       | 79 EUR |
| <a href="#">S2191000</a> | Sulpiride impurity A CRS                 | 6     | 20 MG         | 79 EUR |
| <a href="#">Y0001003</a> | Telmisartan for system suitability CRS   | 7     | 0.26 MG       | 79 EUR |
| <a href="#">Y0000787</a> | Caffeine for system suitability CRS      | 9     | 10 MG         | 79 EUR |

## Distribution quota

*Information on distribution quota for immunoglobulin (anti-A, anti-B antibodies test Negative control) BRP (Y0001689)*

Due to premature depletion of stocks of the Immunoglobulin (anti-A, anti-B antibodies test Negative control) BRP (cat. # Y0001689), we wish to inform users that a tight distribution quota has been established.

This BRP will be distributed to plasma-derived therapeutic product manufacturers and official medicines control laboratories only, with a maximum of 1 unit per quarter. This quota may be adjusted according to availability.

This exceptional measure will remain in place until the next batch of this BRP is established, which is expected by the end of the first quarter 2025.

Distribution of the Immunoglobulin for anti-A, anti-B antibodies limit test BRP (cat. # Y0001153) and the Immunoglobulin (anti-A, anti-B antibodies test Positive control) BRP (cat. # Y0001688) is not affected by this measure.

We apologise for any inconvenience caused and thank you for your understanding.

## Information on reference standards removed from catalogue

### Supplement 11.6

Following the implementation of **Supplement 11.6**, the following standards were officially withdrawn (or replaced) on **1 January 2025**.

| Catalogue code | Name   | Comments  |
|----------------|--|---|
| Y0000289       | Polysorbate 20 - reference spectrum<br>Will be replaced by a CRS   | These standards will nevertheless remain available for sale, subject to sufficient stock, until <b>1 July 2025</b> .<br>Likewise, they will remain in the catalogue for a period of 12 months (i.e. until <b>1 January 2026</b> ) to allow users to print the batch validity statement (BVS).<br>See <a href="#">"Change in the policy for withdrawing reference standards from sale"</a> for more details. |
| Y0000290       | Polysorbate 40 - reference spectrum<br>Will be replaced by a CRS   |   |
| Y0000291       | Polysorbate 60 - reference spectrum<br>Will be replaced by a CRS   |   |
| P0309020       | Pefloxacin impurity B  |   |
| P0309030       | Pefloxacin impurity C  |   |
| N1230010       | Norfloxacin impurity A   |   |
| Y0002319       | Atorvastatin for peak identification A CRS   |   |
| Y0002327       | Ciprofibrate for system suitability A CRS will be replaced by Ciprofibrate for system suitability B CRS (Y0002450) |   |
| Y0002197       | Deferasirox for system suitability will be replaced by Deferasirox for system suitability A (Y0002456)             |   |
| I0600000       | Isoprenaline sulfate   |   |
| P1255100       | Phenylmercuric borate - reference spectrum   |   |

| Catalogue code | Name   | Comments |
|----------------|--|----------|
| Y0001463       | Actaea racemosa HRS  |          |
| Y0001958       | Colchicine for system suitability A will be replaced by Colchicine for system suitability B (Y0002460) |          |

## Information on reference standards with a future removal from catalogue

### Supplement 11.7

Following the implementation of **Supplement 11.7**, the following standard will be officially withdrawn (or replaced) from **1 April 2025**.

| Catalogue code | Name   | Comments   |
|----------------|--|--|
| Y0000130       | Amiodarone impurity E  | These standards will nevertheless remain available for sale, subject to sufficient stock, until <b>1 October 2025</b> . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until <b>1 April 2026</b> ) to allow users to print the batch validity statement (BVS). See <a href="#">"Change in the policy for withdrawing reference standards from sale"</a> for more details. |
| F0180000       | Fludrocortisone acetate will be replaced by fludrocortisone acetate for ID and assay |  |

### Supplement 11.8

Following the implementation of **Supplement 11.8**, the following standard will be officially withdrawn (or replaced) from **1 July 2025**.

| Catalogue code | Name                  | Comments  |
|----------------|-----------------------|---|
| F0188500       | Flumetasone pivalate  | These standards will nevertheless remain available for sale, subject to sufficient stock, until <b>1 January 2026</b> . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until <b>1 July 2026</b> ) to allow users to print the batch validity statement (BVS). See <a href="#">"Change in the policy for withdrawing reference standards from sale"</a> for more details. |
| Y0000372       | Thiamazole impurity A |   |

## Change of sales units

None

## Information on change of amount per unit

- Capecitabine impurity D CRS (Y0001645) **batch 3** contains 15 mg per unit (10 mg previously)
- Terbinafine hydrochloride CRS (Y0000535) **batch 1** contains 15 mg per unit (10 mg previously)
- N-acetyl-cys1-calcitonin CRS (C0200010) **batch 6** contains 20.1 mg per unit (20 mg previously)
- Norfloxacin for peak identification CRS (Y0001301) **batch 2**: contains 15 mg per unit (10 mg previously)
- Capecitabine impurity B CRS (Y0001644) **batch 2**: contains 15 mg per unit (5 mg previously)
- Amisulpride for system suitability CRS (Y0001534) **batch 3**: contains 1.002 mg per unit (1.0015 mg previously)
- Triclabendazole CRS (Y0001737) **batch 1**: contains 15 mg per unit (10 mg previously)

## Information on change of price

None

## Information on change of EDQM storage/shipping conditions

None

## Information on International Chemical Reference Substances (ICRS) and International Standards for Antibiotics (ISA)

*ICRS*

None

*ISA*

None

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## Content of the European Pharmacopoeia RS catalogue

The EDQM proposes more than [3 100 Ph. Eur. RS](#) including a wide range of highly characterised chemical reference substances (CRS), herbal reference standards (HRS) and biological reference preparations (BRP), as well as reference spectra for the tests

and assays to be carried out in accordance with the official methods prescribed in the Ph. Eur.

The Ph. Eur. RS catalogue is updated on a daily basis and gives access not only to all the Ph. Eur. RS, but also to:

- o batch validity statements (BVSs) for each reference standard;
- o Safety Data Sheets and Safety Data Statements for hazardous biologicals;
- o leaflets (downloadable PDFs).

For your convenience, the Ph. Eur. RS catalogue is published daily and can be downloaded in in [PDF format](#) and in [XML format](#).

When stocks of a given reference standard are low, the EDQM reserves the right to limit the quantities sold to each user to ensure that as many users as possible will receive at least some of the quantities available. Restrictions on quantities are applied at the time the purchase order is received.

Following a request from many users, the quantities allowed in case of sales restrictions now appear in the online catalogue as well as in the catalogue in XML format.

The EDQM is also responsible for the establishment, preparation, storage and distribution of WHO ICRSs and ISAs.

## How to place an RS order

If you wish to place an order, you can send your request to the EDQM either:

- o via the [WebStore](#);
- o or by e-mail to [orders@edqm.eu](mailto:orders@edqm.eu) (in this case, please ensure that your order, on your company letterhead, states both the catalogue code and substance name and is attached to your e-mail).

A [video](#) has been prepared to help users ordering through the RS WebStore.

## Helping users test *Pharmeuropa* draft texts with “qualified samples”

In some cases, “qualified samples” are made available by the EDQM when a new issue of *Pharmeuropa* is released to allow users to check the changes (e.g. to the related substances test) proposed during the public enquiry and best prepare for the implementation of the monograph.

After use, users are kindly requested to share their results with the EDQM.

Where a qualified sample is available, it is described in the briefing note of the *Pharmeuropa* monograph and may be ordered free of charge by making a request via the EDQM [HelpDesk](#).

To place an order via the EDQM [HelpDesk](#), please select “European Pharmacopoeia” and choose the category “Question about General Chapters and Monographs”. For rapid processing, please:

- o provide your full shipping address;

- specify the title of the corresponding Ph. Eur. monograph;
- include “Qualified sample” in the subject of the query.

Consult the [HelpDesk User Manual](#) for more information on how to use the EDQM HelpDesk.