

EDQM reference standards monthly newsletter

– August 2025

*1 new Ph. Eur. reference standards and
17 replacement batches released in August 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”](#)

New and replacement batches of Ph. Eur. reference standards

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

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

Catalogue code	Name	Unit quantity	Price
Y0002520	PALONOSETRON IMPURITY MIXTURE CRS	0.002 MG	100 EUR

- 17 replacement batches for Ph. Eur. reference standards:

Catalogue code	Name	Batch	Unit quantity	Price
Y0001831	IRINOTECAN FOR PEAK IDENTIFICATION CRS	2	1.005 MG	79 EUR
Y0000359	ACEBUTOLOL IMPURITY B CRS	3	15 MG	79 EUR
Y0002146	ROSUVASTATIN FOR IMPURITY L IDENTIFICATION CRS	3	10 MG	79 EUR
M1830000	METOPROLOL TARTRATE CRS	3	60 MG	79 EUR
Y0001040	MESITYL OXIDE CRS	3	110 MG	79 EUR
Y0000486	KETOROLAC TROMETAMOL CRS	3	15 MG	79 EUR
O0290000	OXYMETAZOLINE HYDROCHLORIDE CRS	3	80 MG	79 EUR
Y0001629	FOLLITROPIN CRS	4	0.2 MG	79 EUR
P0850000	PHENIRAMINE MALEATE CRS	4	250 MG	79 EUR
C2269000	CLINDAMYCIN PHOSPHATE CRS	4	250 MG	79 EUR
V0033000	VALPROIC ACID CRS	4	100 MG	79 EUR
Y0002244	ACICLOVIR FOR IMPURITY G IDENTIFICATION CRS	4	0.002 MG	79 EUR
Y0001053	CROSPROVIDONE CRS	5	25 MG	79 EUR
Y0000772	MOXIDECTIN CRS	5	70 MG	79 EUR
R0800000	RIFAMPICIN QUINONE CRS	6	50 MG	79 EUR
F0048035	FENOFIBRATE IMPURITY G CRS	6	25 MG	79 EUR
Y0000683	PHENYLEPHRINE HYDROCHLORIDE FOR PEAK IDENTIFICATION CRS	7	2.004 MG	79 EUR

Information on reference standards removed from catalogue

Supplement 11.7

Following the implementation of **Supplement 11.7**, the following standards were officially withdrawn (or replaced) on **1 April 2025**.

Catalogue code	Name	Comments
Y0000130	AMIODARONE IMPURITY E	These standards will nevertheless remain available for sale, subject to

Catalogue code	Name	Comments
F0180000	FLUDROCORTISONE ACETATE will be replaced by FLUDROCORTISONE ACETATE FOR ID AND ASSAY	sufficient stock, until 1 October 2025 . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 April 2026) to allow users to print the batch validity statement (BVS). See "Change in the policy for withdrawing reference standards from sale" for more details.

Supplement 11.8

Following the implementation of **Supplement 11.8**, the following standards were officially withdrawn (or replaced) on **1 July 2025**.

Catalogue code	Name	Comments
F0188500	FLUMETASONE PIVALATE	These standards will nevertheless remain available for sale, subject to sufficient stock, until 1 January 2026 . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 July 2026) to allow users to print the batch validity statement (BVS). See "Change in the policy for withdrawing reference standards from sale" for more details.
Y0000372	THIAMAZOLE IMPURITY A	

Information on reference standards with a future removal from catalogue

Supplement 12.1

Following the implementation of **Supplement 12.1**, the following standards will be officially withdrawn (or replaced) from **1 January 2026**.

Catalogue code	Name	Comments
D0738000	DEXTRAN 40 FOR PERFORMANCE TEST CRS replaced by DEXTRAN 40 FOR SYSTEM SUITABILITY	These standards will nevertheless remain available for sale, subject to sufficient stock, until 1 July 2026 . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 January 2027) to allow users to print the batch validity statement (BVS). See "Change in the policy for withdrawing reference standards from sale" for more details.
D0739000	DEXTRAN 60/70 FOR PERFORMANCE TEST CRS replaced by DEXTRAN 60/70 FOR SYSTEM SUITABILITY	

Change of sales units

- o None.

Information on change of amount per unit

- o MESITYL OXIDE CRS (Y0001040) **batch 3** contains 110 mg per unit (100 mg previously)
- o KETOROLAC TROMETAMOL CRS (Y0000486) **batch 3** contains 15 mg per unit (10 mg previously)
- o IRINOTECAN FOR PEAK IDENTIFICATION CRS (Y0001831) **batch 2** contains 1.005 mg per unit (1 mg previously)

Information on change of price

- o Please note the price change for batch **2.1** of HUMAN TETANUS IMMUNOGLOBULIN BRP (H1110000) to €180 per sales unit.

Information on change of EDQM storage/shipping conditions

Erratum: Please note that storage condition for SAW PALMETTO EXTRACT HRS (Y0001483) **Batch 2** will finally remain unchanged and information given in the previous Newsletter will not be effective. Therefor storage condition remains at ambient temperature as well as shipping temperature.

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

ICRS

None

ISA

None

Gradual rollout of a new primary label for European Pharmacopoeia reference standards

We would like to inform you that the EDQM will gradually introduce a **new primary label** for European Pharmacopoeia reference standards.

This introduction will take place in several stages and will affect new reference standards (batch 1) placed on the market from the end of July 2025 onwards. It will then be gradually rolled out to all other reference standards during 2026.

This new label has been designed to meet the requirements of Regulation (EC) No 1272/2008 (CLP). It will allow additional information to be included, such as:

- the CAS number of the substance (if available),
- the chemical name,
- safety pictograms (if any).

Other key information will of course remain, but in a clearer and more harmonised visual format.

Standards labelled before this date will not be relabeled, so two labels' layouts will coexist for a certain period of time.

[Our team](#) remains at your disposal should you have any questions.



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:

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

For your convenience, the Ph. Eur. RS catalogue is published daily and can be downloaded 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 (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;
- o specify the title of the corresponding Ph. Eur. monograph;
- o include “Qualified sample” in the subject of the query.

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