EDQM reference standards monthly newsletter – September 2025

14 new Ph. Eur. reference standard and 17 replacement batches released in September 2025

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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:

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

Catalogue code	Name	Unit quantity	Price
Y0002529	CARBOPROST FOR SYSTEM SUITABILITY CRS	5 MG	300 EUR
Y0002531	HYDROXYZINE FOR SYSTEM SUITABILITY CRS	0.6 MG	79 EUR
Y0002530	HYDROXYZINE IMPURITY E CRS	15 MG	79 EUR
Y0002508	MACROGOL POLY(VINYL ACETATE)-POLY(VINYLCAPROLACTAM) GRAFTED COPOLYMER CRS	20 MG	79 EUR
Y0002538	TESTOSTERONE ENANTATE IMPURITY A CRS	91 MG	79 EUR
Y0002539	TESTOSTERONE ENANTATE IMPURITY K CRS	0.02 MG	79 EUR
Y0002513	PALONOSETRON HYDROCHLORIDE CRS	80 MG	100 EUR
Y0002545	OXALIC ACID DIHYDRATE CRS	20 MG	79 EUR
Y0002533	POLYSILOXANE D4 CRS	50 MG	79 EUR
Y0002534	POLYSILOXANE D5 CRS	50 MG	79 EUR
Y0002535	POLYSILOXANE D6 CRS	50 MG	79 EUR
Y0002541	PROCAINE FOR SYSTEM SUITABILITY CRS	1.01 MG	79 EUR
Y0002526	PROCAINE HYDROCHLORIDE FOR ID AND ASSAY CRS	120 MG	79 EUR
Y0002163	TESTOSTERONE FOR ID AND ASSAY CRS	90 MG	79 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
Y0001983	HYOSCINE BUTYLBROMIDE FOR SYSTEM SUITABILITY CRS	2	15 MG	79 EUR
Y0001655	VALACICLOVIR IMPURITY S CRS	2	15 MG	79 EUR
Y0001365	ETOPOSIDE FOR SYSTEM SUITABILITY CRS	2	10 MG	79 EUR
Y0000527	ROCURONIUM FOR PEAK IDENTIFICATION CRS	3	10 MG	79 EUR
Y0000128	ACEBUTOLOL IMPURITY I CRS	3	0.004 MG	79 EUR
Y0001346	ONDANSETRON IMPURITY G CRS	4	15 MG	79 EUR
Y0002367	FLUNARIZINE FOR SYSTEM SUITABILITY CRS	4	20 MG	79 EUR
I8000010	IVERMECTIN CRS	4	150 MG	79 EUR
Y0001018	CISPLATIN IMPURITY A CRS	4	15 MG	79 EUR
Y0002218	LATANOPROST CRS	4	100 MG	1000 EUR
Y0000320	CLARITHROMYCIN CRS	5	170 MG	79 EUR
A0350040	ALLOPURINOL IMPURITY D CRS	5	15 MG	79 EUR
Y0000087	METRONIDAZOLE IMPURITY A CRS	5	15 MG	79 EUR
I0150020	INDAPAMIDE IMPURITY B CRS	6	15 MG	79 EUR
F0400000	FOSFOMYCIN TROMETAMOL CRS	7	1500 MG	79 EUR

L0700000	LIOTHYRONINE SODIUM CRS	10	60 MG	79 EUR
D0650000	DESMOPRESSIN CRS	13	1 MG	79 EUR

For your information we are currently on **batch 3** of P2152015 PIVMECILLINAM IMPURITY C CRS. The use of **batch 3** is valid for monograph **04/2023:1359.**

In January 2026, a new version of this monograph will be implemented: **01/2026:1359**. To perform the test of this new version of the monograph **ONLY batch 4** of P2152015 PIVMECILLINAM IMPURITY C CRS will be valid. Please note that batch 4 will be available, at the latest, the 1st of December 2025.

Information on reference standards removed from catalogue

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 remplaced 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 code	Name	Comments
D0739000	DEXTRAN 60/70 FOR PERFORMANCE TEST CRS remplaced by DEXTRAN 60/70 FOR SYSTEM SUITABILITY	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.
Y0002249	FLUTICASONE PROPIONATE FOR SYSTEM SUITABILITY CRS replaced by FLUTICASONE PROPIONATE FOR SYSTEM SUITABILITY A CRS	

Change of sales units

- None.

Information on change of amount per unit

- None.

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

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 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:

- via the WebStore;
- 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:

- 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.