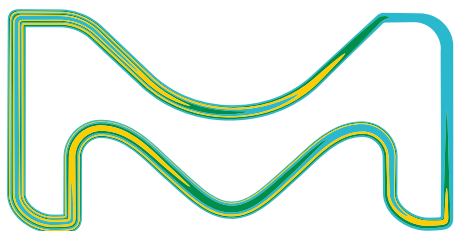


pharmaceutical secondary standards



The life science
business of Merck
operates as
MilliporeSigma in
the U.S. and Canada.

Supelco®
Analytical Products



pharmaceutical secondary standards

The Supelco® range of pharmaceutical secondary standards provide pharmaceutical laboratories and manufacturers with a convenient and cost effective alternative to making in-house working standards.

The US Food and Drug Administration (FDA), United States Pharmacopeia (USP) and European Pharmacopoeia (EP) all recognize the use of secondary standards, or working standards, which are established with reference to the corresponding primary standard (references available on request). Using these commercially available secondary standards allows you to focus on core business activities, rather than consuming time and resources preparing internal working standards. In addition, our secondary standards provide larger quantities at less expense.

The most important product features are:

- **Traceability** to United States Pharmacopeia (USP) and also to European Pharmacopoeia (EP) and British Pharmacopoeia (BP) standards where available.
- Analysis is performed using **instruments validated according to GMP** using pharmacopeia monograph methods
- **Certified purity value** according to ISO Guide 17034 and ISO/IEC 17025 using mass balance approach
- **Comprehensive certificate** according to ISO Guide 31

Our secondary standards are offered as certified reference materials (CRMs) produced in an ISO/IEC 17025 and ISO Guide 17034 accredited facility. Their comprehensive certificates supply values for the shipped material demonstrating traceability to USP, EP and BP primary standards (occurring when a corresponding primary CRS (certified reference substance) is available).

In addition, an independent certified purity value is given. This allows the secondary standards to be used as reference materials for quantitative uses.

Now also available

Primary Pharmaceutical Standards

We also provide a stress-free, time-saving and efficient route to procuring USP, EP and BP standards. Following full compliance checks, these are available for easy ordering either through the web or following your usual B2B purchasing routes.

A large number of these reference materials are currently held in stock in our warehouses, and Merck has a major program to increase this week on week. Our web pages provide live stock levels and those not in stock will generally be delivered in 3–4 weeks.

Use of Primary Pharmaceutical Standards

The use of primary reference standards is prescribed by the issuing pharmacopeia.

USP Reference Standards are intended only for use in analytical or laboratory applications as specified in USP compendia.

EP Materials are supplied exclusively as European Pharmacopoeia Chemical Reference Substances, Biological Reference Preparations or Reference Spectra (Ph. Eur. CRS, BRP or RS) for use as reference standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia (Ph. Eur.) and for no other purpose.

A primary standard in metrology is a standard that is accurate enough that it is not calibrated by or subordinate to other standards. In a pharmaceutical setting, primary standards are produced and supplied by scientific organizations such as the EDQM (European Pharmacopoeia) and the US Pharmacopeia.



View our complete offering of
primary pharmaceutical standards at
SigmaAldrich.com/pharmaceuticalstandards

Comprehensive Certificate

Our certificate of analysis for these pharmaceutical secondary standards consists of up to 8 pages and contains traceability assay results and certified purity as well as information about analytical methods, chromatograms and additional analytical data.

An example of how the pharmacopeia traceable values are reported in the certificate:

Traceability Assay Results

Comparative assay demonstrates direct traceability to Pharmacopeial Standards

- 1 **Specification:** 97.0–103.0% (anhydrous, USP/NF)
98.5–101.0% (dried substance, EP)

Determination Method: HPLC
(ref., Current Compendial Monograph: Ibuprofen)

- 2 **Column:** Ascentis® C18, 4.6 x 250 mm, 5 µm

Mobile Phase: Acetonitrile/Water/Chloroacetic acid (600:400:4)

Column Temperature: 30 °C

Flow Rate: 2 mL/min

- 3 **Injection:** 5 µl

Detector Wavelength: 254 nm

Assay vs. USP Reference Standard (as is basis)

- 5 **Assay Value** 99.5% 4 **vs. USP LOT** R024X0
Labeled Content = 0.998 mg/mg

- 1 Analytical specification
- 2 Reference to Pharmacopeial monograph (if available) used for the certification
- 3 Analytical conditions of the method used
- 4 Reference to the Pharmacopeial lot of the primary standard
- 5 Assay value (traceable to the given Pharmacopeial lot)

Certificate excerpt of traceability assay results (vs. the USP reference standard) for Ibuprofen (PHR1004).

The values on the certificate are always traceable to the **current Pharmacopeial lots**. If a valid Pharmacopeial lot changes, then our **corresponding Pharmaceutical Secondary Standard will be recertified** with traceability to the new lot and a new certificate will be made available online. For this reason, the **valid certificate** always needs to be **downloaded** from the website prior to use of the material.

Please note the following:

The Reference Standards of the Pharmacopeial authorities are for the specified use described in the monograph. The use of the standard beyond that limited scope is not supported by the Pharmacopeia. Other data supplied in the certificate of secondary standards is for informational purposes only and does not support Pharmacopeial use beyond that stated in the corresponding monograph.

The comprehensive certificate contains the following data and information:

- Handling and storage instructions
- Traceability results versus Pharmacopeial primary standards
- Certified purity value by mass balance (according to ISO/IEC 17025)
- Comprehensive additional analytical data



Monthly COA Updates

Customers are notified in advance of any COA changes that may occur due to re-qualification etc. This service helps users ensure that they always have the most current version of a product certificate.

Sign up for these email updates on our website at [SigmaAldrich.com/pharmastandards](https://www.sigmaaldrich.com/pharmastandards)

Sample certificates are also available for free download at this address



Custom Services

Let us partner with your organization to provide manufacturing and packaging services customized to your specifications. Our scopes of accreditation include a broad range of technologies and competencies, ensuring that custom projects can be accommodated and with the highest quality.

Your projects will be processed in a dedicated clean room production facility and under cGMP conditions appropriate to the manufacturing of reference materials.

- We can supply **custom reference materials** based on your specific needs for your required specifications. These materials can be qualified and characterized at our Laramie, Wyoming, USA facility and can be supplied as Certified Reference Materials in accordance with ISO Guide 17034 and ISO/IEC 17025.
- We can supply **packaging services** customized to your specifications. We currently offer packaging services for both **solids and liquids** and have **blister packaging** capabilities.

Capabilities

Powder Dispensing

- Serum vials: multiple sizes, crimp cap, fluoropolymer stoppers
- Glass/plastic bottles
- HEPA filtered cleanroom dispensing cabinets
- Low actinic light control
- Automated powder filling
- Screw cap vials
- Clean room dispensing suites
- Humidity control
- Anaerobic glovebox

Liquid Dispensing

- Automated flame-sealed ampuling
- Inert gas overlay
- Amber or clear ampules: 2, 5, 10, or 20 mL

Packaging

- Solids/Liquids
- Flammable materials
- Oxygen sensitive
- Toxic materials
- Light sensitive
- Hygroscopic materials



Our portfolio of pharmaceutical secondary standards is continually growing



Please visit our website at SigmaAldrich.com/pharmastandards for an up-to-date product listing



Please also have a look at our offering of pharmaceutical impurity standards SigmaAldrich.com/pharmaimpurities



and pharmaceutical proficiency testing materials SigmaAldrich.com/ptpharma

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