

Certification of Substances Department

April 2020

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A list of substances for which draft revised monographs of the European Pharmacopoeia (Ph. Eur.) has been published in Pharmeuropa Volume 32 No 2. The table at the end of this announcement indicates for which of the substances impacted by these revisions CEPs have been granted.

Pharmeuropa can be consulted for free on the EDQM website. You can register by following the link: <http://www.edqm.eu/en/pharmeuropa-bio-and-scientific-notes-584.html>.

Although these draft monographs are only published for public consultation at this stage and must therefore not be regarded as official standards, they will, once adopted by the European Pharmacopoeia Commission at a later date, become legally applicable standards for the substances concerned. It is therefore extremely important that manufacturers and users of the substances **provide feedback on these draft monographs before the deadline for comments i.e. before 30/06/2020**. Comments made after adoption of the monograph and/or the publication in the Ph. Eur. would be too late to be considered and manufacturers and users of the substances may then be in a position where their substance is not compliant to the Ph. Eur. monograph which is a legal standard in Europe.

It is in everyone's interest to have monographs in the European Pharmacopoeia which reflect the quality of the substances available in Europe. EDQM would therefore like to take the opportunity to strongly encourage all users of CEPs for which a draft revised monograph has been published to review the draft monographs and to check the compliance of their substance with the revised draft. The way to feedback on a draft monograph depends on where your company is located:

- If your company is located in a member state of the European Pharmacopoeia Convention, please send comments through the **relevant National Pharmacopoeia Authority** (links are available on the EDQM website).
- If your company is located in a country which is not member of the European Pharmacopoeia Convention, please send comments directly to the **EDQM** through the Helpdesk (www.edqm.eu; topic 04-European Pharmacopoeia & International Harmonisation).

More information available [here](#).

Comments on draft monographs should **NOT** be sent directly to the Certification of Substances Department.

We would like to stress again that only comments sent before the deadline, which is **30/06/2020**, will be taken into account.

Please note that in the context of the current Covid-19 pandemic, the CEP holders concerned will not be contacted individually.;

Draft Monographs for comment

Aluminium stearate - 1663
Cholecalciferol concentrate (oily form) - 575
Flurbiprofen - 1519
Fosinopril sodium - 1751
Miconazole - 935
Miconazole nitrate - 513
Oxytetracycline hydrochloride - 198
Riboflavin sodium phosphate hydrate - 786
Sodium stearate - 2058
Terazosin hydrochloride dihydrate - 2021
Tetra-O-acetyl-mannose triflate for radiopharmaceutical preparations - 2294
Tigecycline - 2825