European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

October 2019

Pharmeuropa Volume 31 No 4, October 2019

A list of substances for which draft revised monographs of the European Pharmacopoeia (Ph. Eur.) have been published in Pharmeuropa Volume 31 No 4. 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 31/12/2019**. 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 **31/12/2019,** will be taken into account.

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Draft Monographs for comment

Alfacalcidol - 1286
Betamethasone sodium phosphate - 0810
Bisacodyl - 0595
Calcium acetate - 2128
Calcium stearate - 0882
Cellulose, microcrystalline - 0316
Clotrimazole - 0757
Croscarmellose sodium - 0985
Cyclophosphamide monohydrate - 0711
Dacarbazine - 1691
Dexamethasone sodium phosphate - 0549
Eucalyptus oil - 0390
Ferrous fumarate - 0902
Ferrous gluconate - 0493
Ferrous sulfate heptahydrate - 0083
Gliclazide - 1524
Glipizide - 0906
Magnesium carbonate, heavy - 0043
Oxybutynin hydrochloride - 1354
Prednisolone sodium phosphate - 0735
Zidovudine - 1059
Zinc stearate - 0306

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