

Certification of Substances Division

FML/CB

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Certification of suitability to the Monographs of the European Pharmacopoeia

Impact of changes to monograph titles to reflect degree of hydration of substances on CEPs

Introduction

In certain circumstances, the European Pharmacopoeia (Ph. Eur.) Commission may decide to change the title of Ph. Eur. monographs, e.g. in the case of a policy change regarding nomenclature. Such changes are listed in the contents list published for the edition or supplement of the Ph. Eur. which contains the change. The change in the title of a monograph is effective 6 months after the publication in the relevant edition or supplement.

The new policy included in the Ph. Eur. style guide of 2014 for monographs states that when a monograph describes a hydrate form there is a need to reflect the degree of hydration in the monograph title, the formulae (molecular and structural) and the chemical name.

Updating monograph titles will happen progressively for monographs requiring clarification of the degree of hydration in line with the new policy (approximately 75 monographs are affected as described in Pharmeuropa 27.2). At its 154th session in March 2016, the Ph. Eur. Commission decided that this change would be made in the context of the next revision of the respective monograph.

There are a number of monographs (25) where the term “anhydrous” will be removed in the 9th edition, effective 1st January 2017. The list of affected monographs is shown in annex 1 and is available on the EDQM website.

This document describes the policy regarding any CEPs for substances where the title of the monograph is changed to either remove the word “anhydrous” or to clarify the degree of hydration.

Implementation Policy

To avoid unnecessary regulatory burden when there is no public health issue, a stepwise approach will be applied to CEPs. The new monograph titles will therefore be applied from the time of publication of the Ph. Eur. edition/supplement for any new CEPs granted, but will be introduced gradually as and when existing CEPs are revised. This means that there will be a neutral effect on the CEP user community of the changes in the monograph titles. .

If there are changes to other aspects of the monographs than just the titles, the normal monograph revision procedures will be followed by EDQM and CEPs will not be revised if the only change to make on the CEPs after completion of the assessment of any CEP revision is to implement the change of substance name due to this change of monograph title.

Impact on CEP applications and CEPs.

After a revised monograph with a new title due to removal of the word anhydrous or due to implementation of the policy on hydrates is published in the European Pharmacopoeia:

All subsequent communication generated by the Certification Division of EDQM will include the new title, this will include any new or revised CEPs issued between the publication and implementation dates of the revised monograph.

As CEPs will not be revised merely to update the substance name, this means that for many CEPs, the currently valid CEPs will contain the “old” substance name for a while. Where this is the only change in a revised monograph, the holders of existing CEPs will not be

individually contacted regarding the change. This document serves as notification of the policy which is being applied.

Annex 1 – Monographs where the word “anhydrous” will be removed in the 9th edition.

Old title	New title	Number
Ampicillin, anhydrous	Ampicillin	0167
Beclometasone dipropionate, anhydrous	Beclometasone dipropionate	0654
Calcipotriol, anhydrous	Calcipotriol	2011
Calcium acetate, anhydrous	Calcium acetate	2128
Calcium hydrogen phosphate, anhydrous	Calcium hydrogen phosphate	0981
Calcium lactate, anhydrous	Calcium lactate	2118
Chlorobutanol, anhydrous	Chlorobutanol	0382
Citric acid, anhydrous	Citric acid	0455
Copper sulfate, anhydrous	Copper sulfate	0893
Disodium phosphate, anhydrous	Disodium phosphate	1509
Docetaxel, anhydrous	Docetaxel	2593
Ephedrine, anhydrous	Ephedrine	0488
Glucose, anhydrous	Glucose	0177
Lactose, anhydrous	Lactose	1061
Lufenuron (anhydrous) for veterinary use	Lufenuron for veterinary use	2177
Magnesium citrate, anhydrous	Magnesium citrate	2339
Nevirapine, anhydrous	Nevirapine	2255
Niclosamide, anhydrous	Niclosamide	0679
Paroxetine hydrochloride, anhydrous	Paroxetine hydrochloride	2283
Phloroglucinol, anhydrous	Phloroglucinol	2301
Sodium carbonate, anhydrous	Sodium carbonate	0773
Sodium sulfite, anhydrous	Sodium sulfite	0775
Theophylline-ethylenediamine, anhydrous	Theophylline-ethylenediamine	0300
Torasemide, anhydrous	Torasemide	2132
Valaciclovir hydrochloride, anhydrous	Valaciclovir hydrochloride	1768