

Comments concerning revised texts published in Supplement 10.1

The following information details the technical modifications that have been made to revised texts adopted by the European Pharmacopoeia Commission at the March 2019 session and published in Supplement 10.1.

When a text has been modified, this is indicated by horizontal or vertical lines in the margin of 10.1. The details given below complete this information, but are not necessarily exhaustive.

The following details can also be consulted in the [Knowledge database](#) under View history.

GENERAL CHAPTERS

2.4.24. Identification and control of residual solvents

Following revision 6 of ICH Q3C (addition of methylisobutylketone in class II), the chromatograms in figures 2 and 4 have been updated. An error in figure 4 has been corrected: the peak labelled “14” actually corresponds to ortho-xylene while pyridine is eluted later ($t_R = 6.1$ min) as a small peak.

5.22. Names of herbal drugs used in traditional Chinese medicine

Table updated to include a new monograph adopted at the 163rd Commission session.

SUTURES FOR HUMAN USE

Sutures for human use: introduction (90004)

Following the replacement of Directive 93/42/EEC by Regulation (EU) 2017/745 in the European legislation on medical devices, the reference has been modified.

Simplification of the text.

HERBAL DRUGS AND HERBAL DRUG PREPARATIONS

Calendula flower (1297)

Identification C: TLC replaced by HPTLC (2.8.25).

Fraxinus chinensis bark (2452)

Identification B: illustration of powdered herbal drug introduced and its legend integrated into text of identification B.

Assay: grade of solvents amended in accordance with Technical Guide (2015).

Hawthorn berries (1220)

Identification: TLC replaced by HPTLC in accordance with general chapter 2.8.25.

Senna leaflet (0206)

Title: updated.

Identification:

- microscopic and macroscopic botanical descriptions updated;
- TLC replaced by HPTLC in accordance with general chapter 2.8.25.

Tests: test for total anthraquinones (aloe emodin and rhein) introduced.

Assay: unspecific absorbance assay replaced by more specific LC assay.

Senna pods (0207)

Based on changes in the botanical classification, the species *Cassia senna* L. and *Cassia angustifolia* Vahl. are now considered as 1 species. Following this change the 2 monographs *Alexandrian senna pods (0207)* and *Tinnevelly senna pods (0208)* are merged into a single monograph on Senna pods. All parts of the monograph have been updated accordingly.

Identification:

- macroscopic botanical descriptions updated;
- TLC replaced by HPTLC in accordance with general chapter 2.8.25.

Tests: test for total anthraquinones (aloe emodin and rhein) introduced.

Assay: unspecific absorbance assay replaced by more specific LC assay.

HOMOEOPATHIC PREPARATIONS

Magnesium fluoratum for homoeopathic preparations (2676)

Solution S: wording changed to state that solution S is to be filtered through ashless filter paper to retain very fine precipitates.

Appearance of solution: updated following the change in preparation of solution S.

MONOGRAPHS

Asparagine monohydrate (2086)

Related substances test: reference solution (d) revised to facilitate the dissolution of impurity C; in the preparation of reference solution (e), the volume is expressed using fewer significant figures due to the qualitative use of this solution.

Atenolol (0703)

Second identification: UV spectrophotometric test deleted as not practicable in pharmacies.

Benzocaine (0011)

Identification: 2nd identification series added as substance is used in pharmacies for extemporaneous preparations; a mixed melting point is described.

Related substances: in the preparation of reference solution (b), volume is expressed using fewer significant figures due to qualitative use of this solution.

Castor oil, hydrogenated (1497)

Definition: revised to allow use of refined castor oil as source material.

Clobetasol propionate (2127)

Related substances: specifications updated to reflect current quality of substances in approved medicinal products on European market; grades of solvents amended in accordance with Technical guide (2015).

Impurities: section updated.

Dimethyl sulfoxide (0763)

Related substances: packed column replaced by capillary column.

Water: semi-micro determination of water replaced by micro determination.

Ergometrine maleate (0223)

Related substances: TLC method replaced by LC, impurities added and limits updated.

Loss on drying: wording revised in accordance with revised general chapter 2.2.32.

Impurities: section added.

Exemestane (2766)

Related substances: additional impurities controlled by the current LC; limit for total of impurities modified accordingly; system suitability criterion updated; grade of solvents amended in accordance with Technical Guide (2015).

Impurities: section updated.

Fluocortolone pivalate (1212)

Content: limits updated.

Identification: TLC from 1st identification series replaced by cross reference to LC for assay; TLC and one colour reaction are sufficiently discriminatory at 2nd identification.

Specific optical rotation: dioxan replaced by less-toxic solvent; limits adjusted accordingly.

Related substances: 2 additional specified impurities introduced; limits updated; explicit criterion for unspecified impurities introduced; section aligned with requirements of general monograph *Substances for pharmaceutical use (2034)*.

Assay: UV absorbance assay replaced with LC for related substances.

Impurities: section updated.

Fluphenazine decanoate (1014)

Identification: retardation factors in test C added.

Related substances: reagent used to describe stationary phase modified.

Loss on drying: milder vacuum conditions introduced.

Fluphenazine enantate (1015)

Identification: retardation factors in test C added.

Related substances: reagent used to describe stationary phase modified.

Loss on drying: milder vacuum conditions introduced.

Isoprenaline hydrochloride (1332)

Related substances: reagent used to describe stationary phase modified; retention time of isoprenaline updated.

Lisinopril dihydrate (1120)

Impurities: section updated to include additional unspecified impurity (impurity J) controlled by test for related substances.

Maize oil, refined (1342)

Definition: it is specified that the expression is mechanical in order to harmonise with Labelling section and general monograph *Vegetable fatty oils (1579)*.

Production: section added containing limits for brassicasterol content (2.4.23) formerly stated in the test for sterols.

Identification: reference to test for composition of fatty acids added as 1st identification since it is more specific than identification of fatty oils by TLC; the latter is maintained in 2nd identification series used in pharmacies.

Composition of fatty acids: clarification of limits.

Sterols: test moved to production section.

Mercaptopurine monohydrate (0096)

Title: modified to reflect that the monograph covers a monohydrate.

Characters: solubility in a lipophilic solvent added.

Related substances: TLC replaced by HPLC.

Impurities: transparency list updated.

Metformin hydrochloride (0931)

Impurity F: grade of solvents amended in accordance with Technical Guide (2015).

Related substances: retention time of metformin and relative retention values of impurity A and impurity D updated.

Mometasone furoate (1449)

Identification: 2nd identification series modified; TLC now harmonised with the *Prednicarbate* (1467) monograph published in Pharmeuropa 30.1.

Related substances: in the preparation of reference solution (a), the volume is expressed using fewer significant figures due to the qualitative use of this solution.

Nomegestrol acetate (1551)

Content: limits updated to reflect revised Assay.

Characters: solubility in lipophilic solvent introduced.

Related substances: additional specified impurity introduced; grades of solvents amended in accordance with Technical guide (2015); reagent used to describe stationary phase modified.

Assay: UV assay replaced with LC from related substances test.

Oxfendazole for veterinary use (1458)

Loss on drying: milder vacuum conditions introduced.

Pentoxifylline (0851)

Related substances: reagent used to describe stationary phase modified; redundant first system suitability test criterion deleted.

Loss on drying: use of diphosphorus pentoxide deleted and milder vacuum conditions introduced.

Perindopril *tert*-butylamine (2019)

Related substances: gradient table updated as the adjustment of conditions with dwell volume is covered now by the general chapter 2.2.46.

Prazosin hydrochloride (0856)

Second identification: UV spectrophotometric test deleted as not practicable in pharmacies.

Prednicarbate (1467)

Identification: 2nd identification series introduced as substance is used in pharmacies; IR is sufficient for the 1st identification and the TLC method has been modified and is used for the 2nd identification.

Related substances: grades of solvents amended in accordance with the Technical Guide (2015); in the preparation of reference solution (a), the volume is expressed using fewer significant figures due to the qualitative use of this solution.

Pyrantel embonate (1680)

Related substances: impurity C quantified in relation to the corresponding CRS.

Pyrimethamine (0288)

Second identification: UV spectrophotometric test deleted as not practicable in pharmacies.

Rosuvastatin calcium (2631)

Impurity L: LC for control of this additional impurity introduced.

Related substances: additional specified impurities introduced.

Impurities: transparency list updated.

Squalane (1630)

Production, Identification: identification test C has been deleted as a Production section has been added requesting the manufacturer to state the origin of the product (vegetable, animal or synthetic).

Assay: reagent used to describe stationary phase modified.

Sulfamethizole (0637)

Identification: 1st identification restricted to IR spectroscopy; TLC for related substances modified to replace chloroform with methylene chloride, moved to 2nd identification series and re-labelled; former identification tests B, C and D deleted as no longer relevant.

Related substances: TLC for related substances replaced by LC capable of detecting and quantifying impurities; limits introduced for a specified impurity, for unspecified impurities and for total impurities based on batch results and in line with the general monograph *Substances for pharmaceutical use (2034)*.

Impurities: section added.

Testosterone (1373)

Content: limits updated to reflect change of assay method.

Impurities D and F: test deleted.

Related substances: new more robust LC method introduced to control additional impurities.

Assay: UV assay replaced by LC for related substances.

Impurities: transparency list updated.

Tiaprofenic acid (1157)

Identification: retardation factors added in test D.

Related substances: in the preparation of reference solution (d), volume is expressed using fewer significant figures due to the qualitative use of this solution; grade of water used in the mobile phase amended in accordance with Technical Guide (2015); identification of impurities section added; retention time of tiaprofenic acid included.

Loss on drying: milder vacuum conditions introduced.

Tranexamic acid (0875)

Identification: description of sample preparation deleted.

Related substances: method optimised and now covers 2 new impurities, limits revised.

Impurities: section updated.

Zanamivir hydrate (2611)

Impurities: the structure for impurity A was updated following recent data.

Zoledronic acid monohydrate (2743)

Impurities E and F: information on the use of self-regenerating anion suppressor introduced.

Related substances: in the preparation of reference solution (a), the volume is expressed using fewer significant figures due to the qualitative use of this solution.

Zolpidem tartrate (1280)

Identification: retardation factors in test B added.

Related substances: reagent used to describe stationary phase modified; run time added; 1 new specified impurity and 4 new unspecified impurities now covered; method updated from being a limit test to a quantitative test.

Impurities: section updated.