BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group: Medicinal Chemicals 3

SUMMARY MINUTES

A meeting of this Expert Advisory Group (EAG): Medicinal Chemicals 3 (MC3) was held in an online format (MS Teams) on Thursday 25th September 2025.

Present via MS Teams: Mr I Williams (Temporary Chair), Mr C Giartosio (Co Vice-Chair), Mr C Goddard (Co Vice-Chair), Mr M Coxon, Mr P Hampshire, Dr V Ibekwe, Dr M Lane, Mr J Mehta, Ms D Obaid and Mr C Turvill.

In attendance: Mr M Whaley, Dr C Swann (*absent for item discussed under minutes 714)*, Dr M Dmitriieva, Mr L Magee (BP Lab), and Dr S Greatorex (BP Lab).

Apologies: Ms K Foster, Prof Y Perrie and Dr Ron Torano.

Mr Hampshire and Mr Coxon declared interests in one or more agenda items and appropriate action was taken.

I General Matters

699 Introductory Remarks

Welcome The Chair welcomed members to the MC3 meeting and reminded everyone that the meeting was being recorded for minute-taking purposes.

Conflict of interest Members were reminded that they were required to declare any relevant interests at the start of agenda items.

Expense claims Members were informed that expense claims, and any queries about expenses, should be emailed to the Committee Services Team at the MHRA.

Confidentiality Members were reminded that all papers and minutes were confidential and should not be disclosed outside the BP Commission.

700 MHRA and BP updates MC3(25)19

Members were provided with an update on recent MHRA, BP activities and personnel changes.

II Minutes

701 Minutes MC3(25)20

The Minutes from the meeting held on 26th March 2025 were confirmed without amendment.

III Matters Arising

703 Matters Arising from the Minutes MC3(25)22

The following matters arising and correspondence items from the meeting held on the 26th of March 2025 were noted.

IV Discussion Topics

704 BP Sustainability update MC3(25)23

Members were informed of the updated Environmental Sustainability Information Pack (Environmental sustainability information pack - British Pharmacopoeia) and welcomed the proposal to make sustainability a standing agenda item. They also highlighted opportunities to improve sustainable practices, including through chromatographic optimisation and ongoing Laboratory initiatives.

V Monographs for BP 2027

705 Ropinirole preparations MC3(25)24
Ropinirole Tablets (New)
Ropinirole Prolonged Release Tablets (New)

The draft new monographs would be included in a future BP publication, subject to comments from manufacturers.

706 Melatonin Preparations MC3(25)25
Melatonin Tablets (New)
Melatonin Capsules (Revised monograph)
Melatonin Prolonged Release Tablets (New)
Melatonin Oral Solution (New)

The draft new monographs for Melatonin Tablets, Prolonged Release Tablets and Oral Solution would be included in a future BP publication, subject to comments from manufacturers.

Dissolution (Capsules) The drafted UV method was unsuitable; an HPLC procedure was found appropriate, and all samples complied.

Related substances (Capsules) Members agreed to further investigate the adoption of the Ph. Eur. method.

Uniformity of Content (Capsules) The drafted HPLC method was suitable for all products, with all samples complying.

Assay (Capsules) Members supported harmonising the Assay with the Uniformity of Content method. An updated draft would be circulated for correspondence following receipt of Laboratory data.

707 Brimonidine Tartrate eye drops MC3(25)26

The draft new monographs would be included in a future BP publication, subject to comments from manufacturers.

VI New Monographs

708 Exemestane Tablets (New) MC3(25)27

The draft new monographs would be included in a future BP publication, subject to comments from manufacturers.

709 Rocuronium Bromide Injection (New) MC3(25)28

The draft new monographs would be included in a future BP publication, subject to comments from manufacturers.

VII Major Revisions

710 Clobetasol Scalp Application (Revision) MC3(25)29

Interim editorial updates were approved for a future publication while further laboratory work continued separation of impurity peak and introduction of a BPCRS for clobetasol impurity C in the related substance test.

711 Citalopram Preparations: MC3(25)30

Citalopram Tablets
Citalopram Oral Drops

An impurity section was included, and statements would be adjusted to reflect each formulation. Minor editorial updates would be included in a future publication

VIII Issues reported by users

712 Morphine Preparations (Revision) MC3(25)31

Morphine Sulphate Injection
Morphine Suppositories
Morphine Tablets
Morphine Prolonged-Release Tablets
Morphine Capsules
Morphine Prolonged-Release Capsules
Morphine Oral Solution
Morphine Granules for Oral Suspension

Related substances – Morphine Sulphate Injection Members agreed with the request from an MHRA assessor to revise the limit for Impurity B from not more than 0.4% to not more than 1.0% and the Experts were satisfied that there were no quality or safety concerns. Subject to consultation, the revision would be made in a future publication.

Acidity The formation of Pseudomorphine (Ph. Eur. impurity B), the main morphine degradant is promoted by oxygen and higher pH. To prevent the impurity formation at higher pH the Secretariat suggested introducing a lower pH limit. Members discussed the option but did not support this, noting that the widening the existing pH specifications wouldn't act as an appropriate control.

Assay content Members agreed to adjusting the content limit to 95.0-105.0% for all Morphine dosage forms. These revisions would be made for a future publication.

713 Dexamethasone Sodium Phosphate Injection (Revision) MC3(25)32

The draft of the revised monograph would be included in a future BP publication, subject to comments from manufacturers.

Appearance Members acknowledged the variation in the appearance of available products and endorsed the proposed change to the appearance description in the monograph.

Identification It was agreed to develop an IR identification test and replace the TLC method.

Alkalinity Members agreed to extend the range to 7.0-8.5 to accommodate all UK authorised products.

Related Substances Members agreed to the laboratory investigation of the inclusion of two new impurities in the monograph.

Assay Members agreed not to make changes to the assay method which would be investigated at the laboratory.

BPCRS Requirements The group considered options for reference substances to support the revised method, including establishing a new BPCRS containing the impurities. The group would await the laboratory results before deciding

714 Lorazepam Tablets (Revision) MC3(25)33

The draft of the revised monograph would be included in a future BP publication, subject to comments from manufacturers.

Members supported revising system suitability criteria, subject to further laboratory confirmation. The adjustments would also have applied to the Injection monograph, with no expected impact on other dosage forms.

715 Vitamins B & C Injection (Revision) MC3(25)34

The draft of the revised monograph would be included in a future BP publication, subject to comments from manufacturers.

Members agreed to revise the content limit to 90.0-105.0%. Broader issues relating to scope, method structure, and differences between authorised formulations were identified for future review. Members agreed to publish the restyled monograph with amended limits in a future edition.

716 Nitrazepam Tablets (Revision) MC3(25)35

An enquiry had been received from a manufacturer of a Nitrazepam Tablets product who had suggested that Impurity B in the BP monograph for Nitrazepam Tablets should include a correction factor.

The current related substances test had been introduced into the BP monograph for Nitrazepam Tablets by means of the BP 2017. The lab work conducted to support the introduction of this method had not included any linearity assessment on impurities B or A.

The validation data provided by the manufacturer using the BP method highlighted that a correction factor of 1.8 would be needed for Impurity B.

It was noted that the same chromatographic conditions were used in the Related substances test in the monograph for Nitrazepam Oral Suspension and therefore the same correction factor may also be needed in this monograph.

Members agreed to introduce this revision and other revisions in the Related substances method subject to public consultation in a future edition.

717 Ursodeoxycholic Acid Capsules (Revision) MC3(25)36

Members supported a request to modify a solvent used in the Assay in the monograph. Members agreed the update could be published in a future addition without further laboratory work.

IX For Information

718 European Pharmacopoeia MC3(25)37

The Secretariat provided an update on European Pharmacopoeia activities and thanked members for their support and contributions to Pharmeuropa 37.2 and 37.3.

X

719 MC3 work programme MC3(25)38

The MC3 Work Programme was presented to members for informational purposes.

XI

720 BPCRS update MC3(25)39

The Secretariat presented an update on two out of stock BPCRS.

XII Any Other Business

721 Alkyl Sulfonate Ester Impurities MC3(25)40

Members were presented with a paper challenging the scientific basis for current BP and Ph. Eur. guidance on alkyl sulfonate ester impurities and were asked to provide feedback on whether existing requirements remain appropriate.

XIII Next meeting

712 Members were informed that the next meeting would take place in person at Canary Wharf in March 2026.