

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group MC3: Medicinal Chemicals

SUMMARY MINUTES

A meeting of this Expert Advisory Group (EAG): Medicinal Chemicals 3 (MC3) was held virtually in on Thursday 29th February 2024.

Present: Mr I Williams (*acting as the temporary Chair*), Mr C Giartosio (*Co Vice-Chair*) Mr C Goddard (*Co Vice-Chair*), Mr M Coxon, Mr P Hampshire, Dr V Ibekwe, Mr J Mehta, Ms D Obaid, Dr R Torano and Mr C Turville.

In attendance: Dr C Swann, Dr M Dmitrieva, Dr B Bahsoun, Ms S Song, Dr S Greatorex (BP Lab) and Ms M Guler (Committee Services Team).

Apologies: Dr K Foster and Dr M Lane.

I 664 General Matters Introductory Remarks

Welcome The Chair welcomed members to MC3. He welcomed the new members to the group, Mr Turville, Mr Coxon. Dr Lane, Mr Giartosio, Mr Mehta, Ms Obaid and welcomed new members of the BP team, Dr Bahsoun and Ms Song to the meeting.

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

Declaration of interests Members were reminded that they are required to inform the BP Secretariat of any changes to their interests throughout the year via email to Ms Guler at committeeserviceteam@mhra.gov.uk.

665 MHRA update MC3(24)01

Mr Williams introduced himself as the new Chairman of MC3 and provided an update on recent personnel changes. Mr. Giartosio was appointed as Vice Chair, and Mr Goddard as Co Vice Chair. He warmly welcomed the five new members.

II 666 MINUTES MC3(24)02

The Minutes and Summary Minutes from the meeting held on 22nd February 2023 were confirmed without amendment.

III

667 MATTERS ARISING FROM THE MINUTES

MC3(24)03

The following matters arising and correspondence items from the meeting held on the 22nd February 2023 were noted.

IV Discussion Topics

668 BP Update

MC3(24)04

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

669 BP Sustainability update

MC3(24)05

An update was provided by Ms Song on the development of an environmental sustainability information pack aimed at encouraging sustainable practices in laboratories and quality control testing. The "Environmental hub" on the BP website, which was under development, would provide this pack for download.

Efforts to improve BP Laboratory practices included the evaluation of two method adjustments to reduce solvent usage in quality control testing. These adjustments involved solvent recirculation and eliminating pre-mixing, as well as combining assay and related substances tests where possible to save time and solvents.

The BP Laboratory aimed to integrate sustainability into monograph development by scaling down column sizes and was demonstrated through Solifenacin Oral Solution and Oral Suspension monographs for BP 2025

V Monographs for BP 2026

670 Ropinirole preparations (New) Ropinirole Tablets Ropinirole Prolonged Release Tablets

MC2(24)06
Annexes 1-6

Mr Hampshire and Mr Mehta declared an interest and were asked to leave the discussion.

Identification Members agreed with the laboratory report that the test was suitable for use as a compendial method.

Dissolution (Tablets) Members agreed the dissolution test in the draft Ropinirole Tablets monograph was found to be suitable as a compendial method. Consensus among members was to not incorporate a resolution requirement into the SST for the dissolution test.

Related substances Members agreed for the laboratory to repeat the analysis with the WMD detector instead of the DAD to improve the S/N ratio sensitivity for Solution 2. Members agreed the Secretariat monitor Ph.Eur. activity regarding this monograph for additional impurities to avoid inconsistencies.

Uniformity of Dosage form Members agreed to maintain the original SST.

Assay Members agreed the procedure with the necessary amendments based on dissolution comments and recommended sending it for public consultation. The Secretariat to correct the misspelling in the title of the monograph.

671	Melatonin preparations (NEW) Melatonin Capsules (NEW) Melatonin Tablets (NEW) Melatonin Prolonged Release Tablets (NEW) Melatonin Oral Solution (NEW)	MC3(24)07 Annexes 1-14
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Mr Hampshire and Mr Coxon declared an interest and were asked to leave the discussion.

Definition (Oral Solution) Members agreed to not include propylene glycol in the monograph definition without further data and strong justification.

Identification (Capsules, Tablets Prolonged Release Tablets) Members agreed to use the HPLC/UV-DAD method and use the same chromatographic conditions and solutions as the Assay test.

Identification (all preparations) Members agreed on employing the HPLC UV-DAD method, using the same chromatographic conditions and solutions as those used in the Assay test.

Content Members endorsed the content limits of 95.0 – 105.0% based on specifications and impurity profiles.

Dissolution (Capsules and Tablets only) Members agreed the laboratory to vary the dissolution profile. Consensus among members agreed the UV method was accepted for use, with a note that significant degradation levels (4-5%) would be unacceptable.

Related Substances (all preparations) Members endorsed incorporating 5-methoxytryptamine, cited as impurity C in the European Pharmacopoeia, into the BP monograph. Members supported changing the limits for secondary peaks and disregard limits, noting that with a disregard limit of 0.1%, solution 6 would have been unnecessary, and solution 2 would have sufficed. Members agreed to further investigate the threshold limit once laboratory work commenced.

Assay (all preparations) Members agreed to investigate the suitability of both HPLC and UPLC methods in the laboratory to determine the most appropriate option. The Secretariat to correct the typographical error in the instruction "*Weight the contents of 20 capsules,*" suggesting it should be corrected to "*20 tablets.*"

VI 672	Issues reported by users Calcipotriol and Betamethasone Cream (Revised)	MC3(24)08
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Related Substances (limit increasing) Members agreed the Secretariat to contact the MAH for further information on the request to increase the impurity limits in the BP monograph and discuss at the next meeting.

Identification Members agreed to correct and change solution (2) to solution (4) in section C for betamethasone identification.

Related Substances (procedure) Members agreed to change the use of Calcipotriol EPCRS for Solution (3) preparation to Calcipotriol for system suitability EPCRS and remove solution (4) of the calcipotriol reference standard.

Assay Members agreed with the proposed corrections from customers queries regarding inconsistency in the concentration of the test solutions and reference solutions in the monographs for Calcipotriol and betamethasone preparations published in the BP 2024.

VII 673	For information European Pharmacopoeia (oral update) The Secretariat provided an update on the European Pharmacopoeia.	MC3(24)09
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VIII 674	MC3 Work Programme	MC3(24)10
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The MC3 Work Programme was presented to members for information.

IX 675	Any Other Business The Secretariat discussed sample preparation for Triamcinolone Acetonide and Oromucosal Paste, citing gel formation during chromatography. Due to limited demand and a single UK manufacturer, further investigation was deemed economically unviable. Members agreed to source donor samples from the US Pharmacopoeia and update the BP with data from the international market.
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676 Members Details

MC3(24)11

Members were reminded to ensure their contact details were up to date with the Committee service team or to directly inform Dr Swann and Dr Dmitrieva of any changes.

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677 Next Meeting

The next meeting will take place in person at Canary Wharf in September. The specific date would be confirmed beforehand.