Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia Monographs for Inhaled Products

The content and format of BP specific finished inhaled product monographs was reviewed by the former Inhaled Products Working Party, which was disbanded at the end of 2012. The recommendations of the Working Party were summarised in the Inhaled Products Policy Document which was published on the BP website at the time. The aim was to ensure that BP monographs continue to contribute to the safety and efficacy of inhaled products through providing quality specifications in line with current best practices and test methodology. Ensuring that BP monographs are aligned with the methodologies in the Ph. Eur. was a central theme of the recommendations of the former Working Party.

The British Pharmacopoeia Commission's Expert Advisory Group on Pharmacy (EAG PCY) has considered the feedback received from stakeholders and the following recommendations are provided for information. Inhalation vapour preparations have not been included in the review.

The BP Secretariat will prepare revised monographs as appropriate adopting the approach outlined in this document. Development of new monographs will also follow the same approach.

Recommendations

1. Terminology should be aligned with the Ph. Eur. for the naming of specific finished inhaled product monographs and test methods.

a. Specific finished inhaled product monograph titles should use the relevant EDQM full Standard Term for the dosage form, with the BP legacy title included as a subsidiary title for revised monographs.

b. Test method titles should use the relevant Ph. Eur. term in both the monographs and Appendices.

2. Individual specific finished inhaled product monographs should be aligned with the Ph. Eur. 'Preparations for Inhalation' general monograph (0671) and the Pharmaceutical Preparations general monograph (2619).

The following specific points are highlighted to add clarity to specific BP tests that would be affected.

a. Fine Particle Dose The Aerodynamic Particle Size Distribution and Fine Particle Dose should be aligned with the Ph. Eur. General Monograph for Preparations for Inhalation, subject to the approval of the competent authority.

With the exception of preparations for nebulisation, the Fine Particle Dose test and upper and lower limits should be included in a Production statement in specific finished inhaled product monographs as an example of a method and limits that can be used. The test methodology and limits for established products should be included if available. If unavailable, consideration should be given to asking the BP Laboratory to develop a method. The EAG will make recommendations on the limits.

The use of Apparatus D or E is encouraged to determine the Fine Particle Dose, as defined within Appendix XIIC. 7. (Preparations for Inhalation: Aerodynamic Assessment of Fine Particles), in line with the Ph Eur general monograph Preparations for Inhalation.

b. Uniformity of delivered dose The Uniformity of delivered dose test should be aligned with the Ph. Eur. ‘Preparations for Inhalation’ general monograph (0671) and should be included in specific finished inhaled product monographs with the exception of preparations intended for nebulisation.

c. Assay An appropriate Assay (content of active requirement) for all specific finished inhaled product monographs is required. The type of Assay included in the monograph should follow the approach taken by the innovator product and the other established products in order to ensure a consistent approach. This is particularly important for preparations that are not intended for nebulisation.

3. Preparations for Inhalation of the British Pharmacopoeia This general monograph will be reviewed and revised as necessary for a future BP publication, in the event that suitable validated alternative methodology for the Content of Active Ingredient on Actuation of the Valve test is established for existing products. Consideration will also be given to moving the test methodology to an Appendix.

4. Water Tests to determine water content should be included in specific finished inhaled product monographs, which are not intended for nebulisation, as deemed appropriate by the individual EAGs, to harmonise with the methodology and specifications used for established products.

5. All BP specific finished inhaled product monographs will be reviewed and revised according to this policy by the individual EAGs. A BP monograph revision programme is proposed, Table 1.

6. New monographs will be developed in accordance with this policy, by the EAGs responsible for the monographs.

Table 1.

Monograph Title and Expert Advisory Group responsible for the monograph:

Beclometasone Inhalation Powder Expert Advisory Group MC3

Beclometasone Inhalation Powder, pre-dispensed Expert Advisory Group MC3

Beclometasone Pressurised Inhalation Expert Advisory Group MC3

Budesonide Inhalation Powder Expert Advisory Group MC3

Budesonide Inhalation Powder, pre-dispensed Expert Advisory Group MC3

Budesonide Nebuliser Suspension Expert Advisory Group MC3

Budesonide Pressurised Inhalation Expert Advisory Group MC3

Colistimethate Sodium Powder for Nebuliser Solution Expert Advisory Group ABS

Fluticasone Inhalation Powder Expert Advisory Group MC3

Fluticasone Inhalation Powder, pre-dispensed Expert Advisory Group MC3

Fluticasone Pressurised Inhalation Expert Advisory Group MC3

Ipratropium Inhalation Powder, hard capsule Expert Advisory Group MC2

Ipratropium Nebuliser Solution Expert Advisory Group MC2

Ipratropium Pressurised Inhalation Expert Advisory Group MC2

Ribavirin Powder for Nebuliser Solution Expert Advisory Group MC1

Salbutamol Inhalation Powder Expert Advisory Group MC2

Salbutamol Inhalation Powder, pre-dispensed Expert Advisory Group MC2

Salbutamol Nebuliser Solution Expert Advisory Group MC2

Salbutamol Pressurised Inhalation Expert Advisory Group MC2

Sodium Chloride Nebuliser Solution Expert Advisory Group ULM

Sodium Cromoglicate Inhalation Powder, hard capsule Expert Advisory Group MC1