

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

- a. **Fine Particle Dose** Test methods within individual monographs should not be included and a production statement should be included instead. The test is mandated as a Critical Quality Attribute requirement outlined in the Ph. Eur. General Monograph Preparations for Inhalation included Fine particle dose. Preparations for Nebulisation are excluded from this requirement.
- 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. **Uniformity requirements for nebuliser preparations** Appropriate Uniformity of content tests should be included in BP finished product monographs for preparations intended for nebulisation, to harmonise with the specifications of available products.

d. Assay 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. Where the average of the results of the Uniformity of delivered dose are used as an Assay, the content limits should be aligned with the Preparations for Inhalation general monograph to harmonise with the specifications of licensed products.

3. Preparations for Inhalation of the British Pharmacopoeia This general monograph will be omitted for the BP 2018 publication and suitable validated alternative methodology for the Content of active ingredient on actuation of the Valve test will be established for existing product monographs when available. The Content of active ingredient on actuation of the valve test methodology from this general monograph will be moved to Appendix XII C.10 and a cross-reference to this Appendix will be included in finished product monographs until alternative Assay methodology becomes available.

4. Water A requirement to determine water content should be included in a Production statement in specific finished inhaled product monographs, which are not intended for nebulisation, if control of water content has been shown to be important during product development, to harmonise with the methodology and specifications used for established products.

5. Labelling With the exception of nebuliser preparations, where appropriate, Labelling statements should be added to BP monographs for finished inhaled products to reflect the label claim of the licensed products in terms of either the pre-metered dose, the metered dose or the delivered dose, as appropriate.

6. All BP specific finished inhaled product monographs will be reviewed and revised according to this policy by the individual EAGs.

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