

Consultation Dissolution testing in BP finished products monographs for solid oral dosage forms

The British Pharmacopoeia (BP) is consulting on how the current situation with Dissolution testing in BP finished product monographs for solid oral dosage forms could be improved.

It was agreed by the BP Expert Advisory Groups on Pharmacy (EAG PCY) that stakeholders should be consulted on the issue prior to further discussions at the EAG PCY and the BP Commission.

Current situation

There are a number of BP finished product monographs for solid oral dosage forms currently published in the BP.

For BP finished product monographs for conventional release solid oral dosage forms published prior to 2008, the established BP criteria using either the basket or the paddle apparatus specified under 'Monographs of the British Pharmacopoeia' in *Appendix XII B. Dissolution* are currently applicable.

For BP finished product monographs for conventional-release solid oral dosage forms published after 2008, the harmonised "Q" acceptance criteria are currently applicable, where Q = 75% of label claim in 45 minutes.

A large number of BP finished product monographs for solid oral conventional release dosage forms do not refer to the Q acceptance criteria within the monograph.

For BP finished product monographs for prolonged-release solid oral dosage forms, a Production statement is currently included rather than including a dissolution test in the monograph.

Your comments are welcomed on the following questions:

- What are your general comments on the current situation in the BP outlined above and how could it be improved?
- For monographs requiring Dissolution testing, what methods would be useful to include to enable users to carry out the test?
- Should multiple Dissolution tests be included in the BP to reflect the methods used for available products?
- Do you believe that Dissolution tests and acceptance criteria should be included in BP monographs for prolonged-release preparations? If yes, please indicate what tests and criteria you would propose including in the monograph.
- Should Q acceptance criteria be included in the BP for solid oral dosage forms in future new monographs or included as part of a revision for current monographs?
- In your opinion, how could Q values be set to ensure that they are appropriate for the preparation? For example, current BP policy is a default Q = 75% at 45 minutes. However such default values may not be appropriate in practice.
- What criteria are important to consider in a compendial quality standard when setting the acceptance criteria in dissolution testing?

The deadline for comments is 21st April 2017. To comment, please send an email with 'Dissolution consultation' as the subject to bpcom@mhra.gsi.gov.uk. Please circulate this webpage to other parties who you feel may have an interest in this consultation.