Finished Product Monographs:

General principles

This document is intended to provide additional information to users on how to read and apply future individual FP monographs. It shall be read in conjunction with the Ph. Eur. General Notices, the relevant dosage form monograph and the general monograph on Pharmaceutical Preparations (2619).

Each FP monograph, taken as a whole, should provide a reliable basis for making an independent judgement as to the quality of the medicine in the interest of the protection of public health. FP monographs cover different formulations and strengths (where possible) of the same dosage form unless otherwise indicated, containing the same active substance.

The Ph. Eur. Commission only elaborates monographs on products that have been authorised in at least one of the member states of the Ph. Eur. Convention and that contain an active substance for which a monograph has already been published in the Ph. Eur. or is on the work programme of the Ph. Eur. As with other Ph. Eur. monographs, the elaboration and revision of finished product monographs will be subject to public consultation, and take into account current scientific knowledge and relevant medicinal products authorised at the time.

The Ph. Eur. Commission has decided to start with the elaboration of single-source monographs on products that are potential future generics. However, the Ph. Eur. Commission could also consider elaborating monographs on multi-source products. This would require critical assessment before adding such monographs to the Ph. Eur. work programme, taking the following into consideration:

- the usefulness of having a Ph. Eur. monograph, for examples, when there are known problems with existing products, or when there are other important reasons for harmonisation, and
- the impact on already registered products.

Testing procedures: Since analytical procedures may be affected by the presence of excipients and/or the manufacturing process, it must be demonstrated that the testing procedures described in an FP monograph are suitable. This demonstration has to be documented in the application dossier. The assessment of these data shall be part of the marketing authorisation procedure.
Release vs. Shelf-life specifications: FP monographs provide shelf-life specifications. The applicant may additionally have to propose release specifications in the MAA in line with national or regional legislation.

Additional information on sections of FP monographs:

Related substances Section:
This section is intended to limit the impurities within the finished product. This includes degradation impurities throughout the shelf life of the finished product and impurities that occur due to the manufacturing process. In certain circumstances it is necessary to control impurities of synthesis in the finished product, e.g. when they are detected in the test for related substances at a level greater than the limit for unspecified impurities in the finished product.

However, the Ph. Eur. requirements are not framed to take account of all possible impurities. It is not to be presumed, for example, that an impurity that is not detectable by means of the prescribed tests is tolerated if common sense and good pharmaceutical practice require that it be absent. It is therefore acknowledged that additional controls may be required to monitor degradation products other than those controlled by the Ph. Eur. FP monograph (e.g. degradation products related to different excipients or containers used). It is the responsibility of the marketing authorisation applicant to assess which such impurities shall be monitored. These evaluations shall be part of the marketing authorisation application that will be assessed by the competent authorities.

Dissolution test:
The testing procedure (test conditions, limits and acceptance criteria), if specified in the monograph shall be mandatory unless otherwise justified and authorised. The dissolution test and limits should be sufficiently discriminatory to assure batch to batch consistency and where appropriate consistency with those batches for which satisfactory evidence of efficacy has been demonstrated.

The dissolution test as described in FP monographs is not intended to demonstrate bioequivalence or to compare dissolution profiles and does not replace such a demonstration or comparison versus the reference product in the MAA. The dissolution test as described in FP monographs is indeed provided for quality control (batch-to-batch consistency).

Impurities:
Impurities specific to the finished product are designated by “FP-” followed by a letter of the alphabet; this is to avoid confusion with impurities in the active substance monograph.