ADDITIONAL INFORMATION
Monograph on Sitagliptin tablets (2927)

During its 151st session in March and following public consultation of the draft text, the European Pharmacopoeia Commission adopted the first monograph to be established following the P4 procedure applicable for substances still under patent protection where there is potential for future production of generics, with the following changes:

- The title of the monograph has been changed from “Sitagliptin phosphate monohydrate tablets” to “Sitagliptin tablets”.
- An alternative identification test by infrared absorption spectrometry using a direct instrumental approach has been introduced. The cross-reference to the assay in the identification test carried out using a diode array detector was originally introduced to simplify the work of the analyst. The decision was taken to add an alternative test for use by labs that do not employ DADs. The new IR identification is performed directly on a powdered tablet and tests for specific bands of the active substance relative to a chemical reference substance. This test was elaborated in close cooperation with the USP.
- Reference solution (c) (which is used for the system suitability test):
  - Tablets containing the active substance and sodium stearyl fumarate can now be used as an alternative to the CRS and sodium stearyl fumarate.
  - The description of the solution preparation has been simplified.
  - The heating time for the in-situ degradation (also reference solution (c)) has been changed from “20-48 h” to “about 30 h”.
- A Disintegration test (5 min in water) has replaced the originally-proposed dissolution test unless otherwise justified and authorised. In view of the specific properties of the active substance, the additional data provided, the approved method in Europe for current products, ICH Q6A and prospective harmonisation with the USP, the decision was taken to switch from the proposed dissolution test to a disintegration test with the limit of maximum 5 minutes. The disintegration test proved to be more discriminatory than a dissolution test for finished products containing this highly soluble active ingredient.
  It is the responsibility of individual marketing authorisation applicants both to prove to the competent authority that the disintegration test is also appropriate for the quality control of their products and to provide a complete dossier.