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THE EUROPEAN PHARMACOPOEIA COMMISSION ENTERS A NEW ERA!
Adoption of the first monograph on a finished product containing a chemically defined active substance

The European Pharmacopoeia (Ph. Eur.) Commission adopted the monograph on Sitagliptin tablets (2927) at its 151st session (March 2015). This is the first time the Ph. Eur. has adopted a monograph on a finished product containing a chemically defined active substance. Until now, individual monographs on finished products have been restricted to a few distinct categories, for instance immunosera, radiopharmaceuticals and some biological preparations such as insulin products and vaccines for humans use and vaccines for veterinary use. This new monograph is a direct result of the decision taken by the Ph. Eur. Commission, in response to calls from its users, to re-consider its general policy on finished product monographs.

The monograph on Sitagliptin tablets, a product still under patent in Europe, was published for public enquiry in the Ph. Eur. online forum Pharmeuropa (Issue 26.3) in 2014 alongside the general principles for finished product monographs that were adopted by the Ph. Eur. Commission at its 148th session (March 2014).

The final Sitagliptin tablets monograph will be published in Ph. Eur. Supplement 8.7. More information on changes made to the Sitagliptin tablets monograph based on the comments received during public enquiry available here.

At the same session, the Ph. Eur. Commission decided to add the elaboration of a finished product monograph on Rosuvastatin tablets (3008) to its work programme. This monograph will be elaborated following the P1 procedure, under which monographs are drafted taking into account products from multiple manufacturers. Interested parties are welcome to take part in the process and are invited to get in touch with the EDQM (via the EDQM HelpDesk) or their National Pharmacopoeia Authority. Interested parties can also participate in the work of the Ph. Eur. by commenting on the draft monograph once it is published in Pharmeuropa.

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Note for the Editor: Further information is available on the internet site www.edqm.eu
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

Useful information:
Procedure 1. Following addition of an item to the Ph. Eur. work programme, the Secretariat circulates information to the public via industry associations, the pharmacopoeia’s contacts in the
pharmaceutical industry, the EDQM web site and Pharmeuropa. Interested parties are invited to contact the Secretariat with a view to providing samples and data and taking part in the work. **Procedure 4.** This procedure is usually applied to substances or products still under patent protection where there is potential for future production of generics. The work is co-ordinated by EDQM and overseen by Group of Experts P4. Data provided by manufacturers is treated in confidence and access is allowed only to EDQM staff and members of Group of Experts P4, which consists of representatives of national pharmacopoeia secretariats or regulatory authorities. General principles for finished product monographs can be found here: [FP monographs: General Principles](#).

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