Gnosis receives CEP certification for Teicoplanin

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The European Directorate for the Quality of Medicines (EDQM) has granted Gnosis a Certificate of Suitability of the European Pharmacopoeia (CEP) for Teicoplanin. The CEP certification provides proof that the quality of the substances used in human medicines is suitably controlled by the relevant monographs of the European Pharmacopoeia.

Teicoplanin is a true fermentation glycopeptide antibiotic produced by Actinoplanes teichomyceticus strains and it is a mixture of glycopeptide components which are currently classified into six main subcomponents known as a specific “Complex”.

The first application for a generic of the reference product was submitted in 2005 through the decentralised procedure (DCP). During Teicoplanin assessment, it was noted that the compositional profile of glycopeptide subcomponents present in the generic version differed significantly compared to the originator.

As the composition of the Teicoplanin subcomponents is dependent upon the strain of microorganism and the fermentation conditions used, these may give rise to significant differences in the composition between the generic and reference product and compliance with the Ph. Eur. (monograph available since January 2009) alone has not been considered sufficient to fulfil the primary condition for a generic application. In order to address the disharmony across the EU in terms of the requirements for generics of Teicoplanin, a procedure was initiated in 2013 to ensure that the active substance is sufficiently characterised, new tests and limits were proposed, in addition to those currently specified in the monograph\textsuperscript{1}.

Gnosis has demonstrated the capability to obtain the same “Complex” profile of the originator, including specific ranges of subcomponents, being the first European company to obtain CEP in compliance with the new tests and limits and having contributed in establishing those limits for the new Ph. Eur. monograph that has not been published yet.
Gnosis Teicoplanin is manufactured in Gnosis Bioresearch site in Pisticci. This site is becoming a center of excellence for the development and production of anti-infective drugs derived from microbial fermentation and semi-synthesis. The site has been also recently approved by FDA for another anti-infective drug (same class of “Complex”) currently in the pre-launch phase.


Gnosis Group

With over 20 years of experience in microbial fermentation and an international manufacturing network dedicated to high-quality and proprietary products Gnosis is specialized in manufacturing and sales of fermentation raw materials and natural finished products used in the pharmaceutical, nutraceutical, and veterinary industries.

The Gnosis Group includes a European manufacturing network made up of three operating divisions and three commercial operations located in Italy, the USA and China. Successful integration between R&D centre and GMP Approved Manufacturing facilities enables the company to constantly work to develop and introduce ground breaking and market leading products to the worldwide market.

For more information contact:
marketing@gnosis-bio.com

Headquarters & Innovation Centre
Gnosis S.p.A.
Via Lavoratori Autobianchi, 1
20832 Desio (MB) - Italy

Operations
Gnosis Bioresearch S.A.
Via Lischedi, 4
6592 Sant’Antonino – Switzerland

Gnosis Bioresearch S.r.l.
Via Pomarico, 75010 Pisticci Scalo
Pisticci (MT) - Italy

Branch Offices
Gnosis USA Inc.
169 N. Main Street
Doylestown, PA 18901 - USA

Gnosis China
Room 1001, Hong Kong Plaza
(South Tower), 283 Huaihai Middle Rd., LuWan District,
200021 - Shanghai, China