European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2008-118-Rev 00

Name of the substance:
GEMFIBROZIL

Name of holder:
ZHEJIANG EXCEL PHARMACEUTICAL CO., LTD.
No. 9 Dazha Road
Huangyan Economic Development Zone
China-318 020 Taizhou, Zhejiang Province

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2008-118-REV 00

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **GEMFIBROZIL** no. 1694 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

– Test for residual solvents by gas chromatography (Annex 2)
Ethyl formate not more than 5000 ppm

The substance is packed in a double polyethylene bag placed in a fibre drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

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Failure to comply with these provisions will render this certificate void.

This certificate is renewed from **18 February 2016** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has two annexes of 1 page each.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 22 January 2016

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

ZHEJIANG EXCEL PHARMACEUTICAL CO., LTD., as holder of the certificate of suitability

R1-CEP 2008-118-Rev 00 for Gemfibrozil

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

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