Council of Europe
EUROPEAN DIRECTORATE FOR
THE QUALITY OF MEDICINES

CERTIFICATION OF SUITABILITY OF MONOGRAPHS OF THE EUROPEAN PHARMACOPOEIA

Certificate No. R0-CEP 1999-088-Rev 02

Name of the substance:
GUAIFENESIN

Name of holder:
SYNTHOKEM LABS PRIVATE LIMITED
B-5 Industrial Estate
Sanathnagar
IND - 500 018 Hyderabad, Andhra Pradesh

Site of production:
SYNTHOKEM LABS PRIVATE LIMITED
B-5 Industrial Estate
Sanathnagar
IND - 500 018 Hyderabad, Andhra Pradesh

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 1999-088-REV 01

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site of production mentioned above, IND - 500 018 Hyderabad, Andhra Pradesh, we certify that the quality of the substance is suitably controlled by the monograph **GUAIFENESIN** (no. 0615, Ph. Eur. 4th Ed. and any subsequently revised version) only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

— Test for residual solvent by gas chromatography (Annex 1)
Toluene not more than 250 ppm

The submitted dossier must be updated every five years or after any significant modification of the manufacturing method that may alter the quality, safety or efficacy of the product or require changing the specifications of the monograph.

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

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

Postal Address: 226 Avenue de Colmar (entrance rue Schertz) B.P. 907 — F 67029 Strasbourg Cedex 1
Telephone: 03.88.41.29 47 - Fax 03.88.41.27.71 - E-mail: certification@pheur.org

29 This certificate is granted within the framework of the procedure established by the European
30 Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a period of five years
31 starting from **27 June 2001**. Moreover, it is granted according to the provisions of Directive
32 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related
33 guidelines.

34 This certificate has 34 lines and one annex of 2 pages.

Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 29 July 2003

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

SYNTHOKEM LABS PRIVATE LIMITED, as holder of the certificate of suitability

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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)*

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

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