Certification of Substances Division

Certificate of suitability
No. R1-CEP 1999-168-Rev 03

Name of the substance:
LACTULOSE, LIQUID
660 g/l, 700 g/l

Name of holder:
RELAX LIMITED
Level 3, Skyparks Business Centre
Malta International Airport
Malta-LQA 4000 Luqa

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 1999-168-REV 02

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 **LACTULOSE, LIQUID** no. 924 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis water is used as solvent.

The test for methanol described in the monograph is not necessary since this solvent is not used in the synthesis.

The holder of the certificate has declared the 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.

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

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

This certificate is renewed from **14 May 2009** 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 one annex of 1 page.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 1 August 2014

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

RELAX LIMITED, as holder of the certificate of suitability

R1-CEP 1999-168-Rev 03 for Lactulose, liquid

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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F-67081 Strasbourg (France)
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European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
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Annex 1: Sites of manufacture for R1-CEP 1999-168-Rev 03

Manufacture of Lactulose, liquid:
LACSA (PTY) LIMITED
72 Ballantrae Road
Merebank
South Africa-4052 Durban, KwaZulu Natal