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European Directorate for the
Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability

Name of the substance:
TIMOLOL MALEATE

Name of holder:

Site(s) of production:

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production mentioned above, we certify that the quality of the substance is suitably controlled by the current version of the monograph **TIMOLOL MALEATE** no. 572 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis acetone is used as solvent. Its residual content is limited by the test for loss on drying described in the monograph with a limit of not more than 0.5%.

The re-test period of the substance is 5 years if stored in an inner semi-transparent polyethylene bag and an outer black polyethylene bag and placed in an HDPE 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.

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 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

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.

This certificate is renewed from **27 July 2009** according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has :
lines.

On behalf of the
Director of EDQM

Strasbourg, 15 June 2011

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

, as holder of the certificate of suitability

for TIMOLOL MALEATE

Laboratoire CHAUVIN

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

J416 rue Samuel Morse,CS 99535, 34961 Montpellier Cedex 2, France

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)*

Product: VIZITRAV DUO 40 microgrammes/mL + 5 mg/mL, collyre en solution

Procedure no. DK/H/2713/001/DC - France

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)*:

October 06, 2016 **(Managing Director)**

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