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European Directorate for the
Quality of Medicines & HealthCare



Certification of Substances Division

Certificate of suitability

No.

1 *Name of the substance:*
2 **TIMOLOL MALEATE**

3 *Name of holder:*
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8 *Site(s) of production:*
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THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE

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

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

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

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

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

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
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29 Manufacture of the substance shall take place in accordance with the Good
30 Manufacturing Practice and in accordance with the dossier submitted.

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

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

35 This certificate has :
36 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**

**HORUS PHARMA, 148 Avenue Georges Guynemer
Cap Var D2 06700 Saint Laurent du Var France**

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)*

Product: Travoprost-Timolol Horus Pharma

Procedure no. DK/H/2708/001/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):

September 22, 2016

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