

CERTIFICATE OF COMPLIANCE to USP <87> and USP <88> of FLON-CHEM 1075

FLON-CHEM 1075 is meant to be used as a mechanical seal in devices and in industrial plants of the pharmaceutical sector where active pharmaceutical ingredients (API), API intermediates and drugs are produced.

It has been tested following United States Pharmacopoeia USP chapter <88> ("Biological reactivity tests, *in vivo*" USP 41 - NF 34) and USP chapter <87> ("Biological Reactivity Tests, *in vitro*" USP 41 - NF 34) at Test Facility Eurofins Biolab S.r.l. and the tests performed were Cytotoxicity, Systemic injection, Intracutaneous reactivity and Implantation.

The extractions were carried out at 50°C according to USP <88> and 37°C for 24 hours in dynamic conditions according to USP <87>.

Test results are summarized below in Table 1.

Test performed	Standard method	Test report number	Tested Sample	Conclusion
Cytotoxicity	USP <87>	Analytical Report: AAB41903, Eurofins Number LV18AB6316-1; Version: 1.000	Extract in culture medium	Not Cytotoxic
Systemic injection test	USP <88>	Analytical Report: AAB70770, Eurofins Number: STULV18AA2368- 1, Version: 1.000	4 extracts	Requirements satisfied
Intracutaneous test	USP <88>		4 extracts	Requirements satisfied
Implantation test	USP <88>		Disc of test sample, with Ø=10mm and thickness 1 mm	Requirements satisfied

Table 1: Summary of *in vivo* and *in vitro* biological reactivity tests

Based on results obtained from tests, the test item FLON-CHEM 1075 **satisfies USP class VI** - 50°C requirements. In addition the extracts in sodium chloride injection and PEG 400 satisfy the intracutaneous reactivity test and systemic toxicity test **at 121°C** and extract in cottonseed oil satisfies the intracutaneous reactivity test and systemic toxicity test at 70°C.

In the cytotoxicity test the cells treated with the test item extract resulted **NOT CYTOTOXIC** (reactivity grade 2). The compound can be used as material for all medical devices categories described in USP <1031>.

This test report may not be reproduced in part unless expressly approved in writing by Eurofins Biolab S.r.l.
The test results relate only to the tested items. Sampling, except specific indication on test report, is always intended to be made by the Sponsor.
Characterization of the test sample is under Sponsor responsibility.

Eurofins Biolab Srl – via B.Buozzi 2, Vimodrone (Milano), Italy - P.IVA / VAT Number: 007620140960
Tel: +39-022507151 – Fax: +39-0225071599 – E-mail: InfoFarma@eurofins.com

Reviewed and electronically signed for Study Analyst Approval by
Maddalena Lazzarin, Employee
for Eurofins Biolab Srl, on 16-Jan-2019 16:09:13 UTC+01:00
Reviewed and electronically signed for Study Analyst Approval by
Paolo Pescio, employee
for Eurofins Biolab Srl, on 16-Jan-2019 16:09:32 UTC+01:00