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CERTIFICATE OF COMPLIANCE to USP <87> and USP <88> of FLON-CHEM 1006

FLON-CHEM 1006 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 42 - NF 37) and USP chapter <87> ("Biological Reactivity Tests, *in vitro*" USP 42 - NF 37) 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: AAK58924, Eurofins Number LV20AB6238-1; Version: 1	Extract in culture medium	Not Cytotoxic
Systemic injection test	USP <88>	Analytical Report: AAL10165, Eurofins Number STULV20AA5642-1; Version: 1	4 extracts	Requirements satisfied
Intracutaneous test	USP <88>		4 extracts	Requirements satisfied
Implantation test	USP <88>		Representative samples (discs), as provided by Sponsor	Requirements satisfied

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

On the basis of the results obtained from tests, the test item FLON-CHEM 1006 **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 the extract in cottonseed oil satisfies the intracutaneous reactivity test and systemic toxicity test at 70°C.
In the cytotoxicity test the test item extract resulted **NOT CYTOTOXIC** (reactivity grade 0). The compound can be used as material for all medical devices categories described in USP <1031>.

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