

C E R T I F I C A T E

Cytotoxicity of the Test Material:
"Electrolyte solution Friscolyt C"

Manufacturer/Distributor:
Mettler Toledo GmbH

Scientific Background and Normative Requirements

"Electrolyte solution Friscolyt C" is a liquid component used in electrodes for pH measurement for example in bioreactors in the pharmaceutical industry.
Based upon this intended use, and in accordance with DIN EN ISO 10993-1: 1998 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing - the biological risk of cytotoxicity was evaluated under conditions of industrial use.

The following results were obtained:

Assessment

Cytotoxicity

The potential of cytotoxicity of the aforementioned test material was investigated by using the elution test method in accordance with DIN EN ISO 10993-5 and USP 26, 2003, Chapter 87 (mdt report 04z043).
The test material caused a growth inhibition of 88% in the 60% diluted extract (represent 1:833 v/v) which decreased with lower extract concentrations. At the concentration of 30% (represent 1:667 v/v) and less no growth inhibition was detected.

Conclusion

According to the provision of the manufacturer the 30% extract concentration is identified to be the worst case situation in the industrial use of the tested chemical "Electrolyte solution Friscolyt C". The worst case is defined as a complete depletion of "Electrolyte solution Friscolyt C" contained in a pH electrode into the content of a bioreactor of minimum size utilized in the pharmaceutical industry.

Based upon the study results obtained, and considering the provisions of the harmonised standard DIN EN ISO 10993-1 it is concluded that the intended use of the "Electrolyte solution Friscolyt C" causes no relevant cytotoxic effects in its industrial application environment.



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