DECLARATION OF CONFORMITY

Cytotoxicity of the Test Material: "Electrolyte gel Rheolid"

Distributor: Knick Elektronische Messgeräte GmbH & Co. KG

Scientific Background and Normative Requirements

"Electrolyte gel Rheolid" is a viscous Polymer used in electrodes of type SE 555 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: 2010 "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management system" - 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 31, 2008, Chapter 87 (mdt report 10z055).
Following dilutions of the viscous Polymer were examined: 1:36, 1:72, 1:144, 1:288 which exhibited growth inhibitions between 100 % and 15 %.
However, the applied extract concentrations of 0.69 % (dilution of 1:144) and 0.35 % (dilution of 1:288) of the electrolyte gel "Rheolid" showed no cytotoxic reaction.

Conclusion

According to the provision of the manufacturer the extract concentration of 0.69 % (dilution of 1:144) is identified to be the worst case situation in the industrial use of the tested chemical "Electrolyte gel Rheolid". The worst case is defined as a complete depletion of the "Electrolyte gel Rheolid" contained in a pH electrode into the content of a bioreactor of respective 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 gel Rheolid" causes no cytotoxic effects in its industrial application environment.

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-P-974.98.05

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02.08.2010

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02 Aug 2010

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