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MEETING ABSTRACTS

IN VITRO BIOCOMPATIBILITY TESTING OF MEDICAL DEVICES *IN VITRO*: CHALLENGES OF SAMPLE PREPARATION ACCORDING TO THE ISO 10993-12

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The ISO standard 10993 for medical device testing was accepted over three decades ago. During that period, ISO standard was changing and adapted based on the growing knowledge on adverse effects and regulatory needs. The term, medical devices, includes various products that are used in medicine, but their terapeutic effect is not acchieved by pharmacological, immunological or metabolic means. These products have different mechanical, physical and chemical properties. The procedures described in the ISO 10993 cover testing of raw materials as well as final products. However, composition of medical devices can be quite complex, and it may sometimes be challenging to follow procedures laid down by the ISO 10993. The ISO 10993-12, reviewed in 2021, describes in detail the essentials of the sample preparation undergoing the *in vivo* or in vitro testing (i.e. extraction into polar and non-polar solvents). Unfortunately, there is only a little guidance for materials absorbing the extraction solvents (ISO, 2018; ISO, 2021a; ISO, 2021b).

In our study, we tested medical devices used in dental/oral care. Among these products are adhesive pasted for dentures and cream for ulcer treatment. These formulations have shown to be highly solvent absorbing. We have performed several procedures for extracting such materials, using different ratios of the material/extractant and including/excluding the orbital shaking of the sample. The achieved extracts were subsequently tested in line with the ISO 10993-5 using 3T3 NRU assay and ISO 10993-23 using 3D reconstructed human tissue model of epidermis and another, non-keratinised epithelia, used to mimic the soft tissues in the oral cavity.

The results show that the exctract preparation procedure considerably influenced the results of the experiments. In the static conditions, the preparations showed significantly lower cytotoxic proppetries compared to the mixed extracts. Non-keratinised 3D epithelial tissue model was more sensitive to the preparations than 3D skin tissue, as expected. The testing battery helped us to predict possible side effects of the selected MD materials used in the oral cavity.

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Keywords: Medical devices; Biocompatibility; Sample preparation; ISO 10993-12; ISO 10993-5

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