Rule 21: ADME studies for Medical Device Classification

Classification criteria introduced by MDR 2017/745 for substance based medical devices (SBMDs) require the knowledge of substance penetration, and distribution as well as evidences of the systemic absorption of the substances or their metabolites in the application site, as an essential information (Rule 21).

EU validated replacement alternative for percutaneous penetration (OECD TG 428) principles and quality requirements is applicable as relevant EU common, harmonized and scientifically valid standard method.

VitroScreen has developed specific protocols for absorption studies on intact and injured epithelia on ex vivo skin explants and 3D human reconstructed tissues.

Our skilled team has optimized the management and successful outcome for regulatory acceptance of these complex projects: thanks to this approach, VitroScreen is a recognized leader in performing these studies.

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VitroScreen
A Visionary Future of Human Health

VitroScreen is committed to provide the Medical Devices industry with state of the art non clinical in vitro models for Medical Devices' biological evaluation: biocompatibility qualification, classification and MoA.

ISO 9001:2015 EA:34 and ISO 13485:2021, GLP certified

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Biocompatibility: The Ethical Imperative of ISO 10993-23

In the realm of medical devices development, ensuring patient's safety is paramount.
This responsibility encompasses the entire product lifecycle, including biocompatibility testing.

ISO 10993-23 emphasizes the importance of the shift towards reducing, refining and replacing animal testing, whenever possible.

Skin irritation of MD extracts has been proved to be suitable for SBDM[1] and able to justify its application to evaluate the irritation potential of medical devices, when in contact with other tissues: vaginal, bladder, colorectal, nasal and eye epithelia.

At VitroScreen since 2001 we propose Alternatives allowing our customers to adhere to the principles of reduction, refinement, and replacement, thus jointly advancing medical innovation while upholding ethical standards.

1 Pellevoisin C, Coleman KP, Hoffmann S. ISO 10993-23 In vitro irritation testing for medical devices: Substantiating applicability to mild irritants and non-extractables. Toxicol In Vitro. 2022 Aug; 82:105371. doi: 10.1016/j.tiv.2022.105371. Epub 2022 Apr 26. PMID: 35487444.

Mechanism of Action: Medical Device Qualification

According to MDR 2017/745 and MDCG 2022-5, manufacturers are required to scientifically justify the rationale for the qualification as Device and to demonstrate that the principal mode of action of such device is through physical, mechanical and chemical means.

VitroScreen has developed a science-based approach and proposes validated in vitro Models on 3D human reconstructed tissues to demonstrate substance based medical device, SBMD, mechanism of action:

- Film Forming and Persistency on Skin and Epithelia
- Protection from Pollutants, Pollen, Allergens
- pH Modification
- Protection from Acid Damage
- Osmotic Stress: Soothing and Decongestant efficacy
- Moisturizing Efficacy: Skin, Mucosae
- Re-Epithelization and Wound Healing
- Antimycotic Efficacy on Skin and Nails
- Anti-Bacterial Adhesion
- Protection Against Bacteria Induced Damages
- Customized Protocols: Ancillary Action Models to Exclude Ph.I.M. means.

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