JaCVAM statement on the Vitrigel®-EIT, an alternative method for evaluating ocular irritation

At a meeting held on 10 May, 2022 at National Institute of Health Sciences (NIHS) in Tokyo, Japan, the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

Proposal: Vitrigel®-EIT (Eye Irritancy test) method can be used for eye irritation test to identify chemical substances that do not require classification and labelling under the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS) category, if negative results are obtained after understanding exemptions. Furthermore, thorough consideration must be given to the applicability domain when using this test.

This statement was released following a review prepared by the eye irritation test JaCVAM Editorial Committee to acknowledge that the results of the review and study by the JaCVAM Regulatory Acceptance Board have confirmed the usefulness of this assay.

Based on the above, we proposed the Vitrigel®-EIT method as a useful means for assessing eye irritation potential during safety assessments by regulatory agencies.

Akiyoshi Nishikawa
Chairperson,
JaCVAM Regulatory Acceptance Board

Yoko Hirabayashi
Chairperson,
JaCVAM Steering Committee

June 30, 2022

The JaCVAM Regulatory Acceptance Board was established by the JaCVAM Steering Committee, and is composed of nominees from the industry and academia.

This statement was endorsed by the following members of the JaCVAM Regulatory Acceptance Board:

Mr. Akiyoshi Nishikawa (Division of Pathology, National Institute of Health Sciences: NIHS / Saiseikai Utsunomiya Hospital) : Chairperson
Ms. Yoko Hirabayashi (Center for Biological Safety and Research: CBSR, NIHS)
Mr. Hiroshi Itagaki (ITACS Consulting)
Mr. Kazuhiko Matsumoto (Nagoya City University)
Ms. Ruriko Nakamura (National Institute of Technology and Evaluation)
Mr. Jihei Nishimura (Pharmaceuticals and Medical Devices Agency)

Term: From 1st April 2020 to 31st March 2022

Mr. Akiyoshi Nishikawa (Division of Pathology, NIHS / Nagoya Tokushukai General Hospital) : Chairperson
Ms. Yoko Hirabayashi (CBSR, NIHS)
Mr. Koichi Kojima (Food and Drug Safety Center)
Mr. Kazuhiko Matsumoto (Nagoya City University)
Ms. Ruriko Nakamura (National Institute of Technology and Evaluation)
Mr. Jihei Nishimura (Pharmaceuticals and Medical Devices Agency)

Term: From 1st April 2022 to 31st March 2024

This statement was endorsed by the following members of the JaCVAM steering Committee after receiving the report from JaCVAM Regulatory Acceptance Board:

Ms. Yoko Hirabayashi (CBSR, NIHS): Chairperson
Mr. Osamu Fueki (Pharmaceuticals and Medical Devices Agency)
Mr. Yukihiro Goda (NIHS)
Ms. Akiko Hayashi (Ministry of Health, Labour and Welfare)
Mr. Koji Ishii (National Institute of Infectious Diseases)
Mr. Yasunari Kanda (Division of Pharmacology, CBSR, NIHS)
Mr. Satoshi Kitajima (Division of Toxicology, CBSR, NIHS)
Mr. Kenichi Masumura (Division of Risk Assessment, CBSR, NIHS)
Ms. Kumiko Ogawa (Division of Pathology, CBSR, NIHS)
Mr. Takayuki Okubo (Ministry of Health, Labour and Welfare)
Mr. Keiichi Sugiyama (Division of Genetics and Mutagenesis, CBSR, NIHS)
Mr. Yuhji Taquahashi (Animal Management Section of the Division of Toxicology, CBSR, NIHS)
Mr. Masaaki Tsukano (Ministry of Health, Labour and Welfare)
Mr. Masahiko Yokota (Pharmaceuticals and Medical Devices Agency)
Mr. Takao Ashikaga (Division of Risk Assessment, CBSR, NIHS): Secretary
Mr. Hajime Kojima (Division of Risk Assessment, CBSR, NIHS): Secretary