# Press Release

## IVIVC Enhancer, a novel accessory for dissolution test to be launched

**OSAKA and Saitama, Japan, 30, 10, 2020 -** Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President & CEO: Isao Teshirogi, Ph.D.; hereinafter "Shionogi") and Nihon Validation Technologies Corp. (Head Office: Saitama, Japan; President & CEO: Atsushi Tanabe; hereinafter "Nihon Validation Technologies") announce that IVIVC Enhancer ("the Product"), a novel accessory for elution tests, will be launched on November 2, 2020. The Product was devised, applied for patent and put into practical use by Shionogi. It is manufactured and marketed in and outside Japan by Nihon Validation Technologies.

Dissolution tests are stipulated in the Japanese Pharmacopoeia and used worldwide for quality inspection of pharmaceutical products during development and after marketing as well as for bioequivalence evaluation required for regulatory application of generic drugs. In recent years, IVIVC [1] research has been actively conducted to predict the absorption of oral preparations from the gastrointestinal tract based on the results of dissolution tests. The conventional dissolution test for prediction of absorbability of oral preparations has posed issues in the process of mechanical stirring tests of solutions: When stirring at a low speed to reproduce the actual stirring potential in the gastrointestinal tract, "mounts" (conical deposits of disintegrated substances) are formed by precipitation of insoluble substances, which causes variations in elution of drug substances and makes it difficult to obtain accurate data.

The Product was devised by Shionogi's CMC [2] Division as an accessory to solve the issue of mount formation from the actual viewpoint of test researchers, and it can be easily attached to existing general-purpose dissolution test equipment. Because of such advantages, it can be used by many research institutes. IVIVC Enhancer will enable the user to obtain more accurate drug elution data under test conditions close to the environments in the gastrointestinal tract. The Product is expected to improve accuracy of drug absorption prediction and to reduce time and costs for research and development of oral preparations.

Nihon Validation Technologies started operations in 2002 as a validation and technical service provider for dissolution testers and related equipment. Now, the company supports its clients' departments engaged in special fields, including drug discovery, formulation development, and quality testing based on technical services on validation and calibration, in addition to being an authorized distributor of standard equipment for analysis described in the USP (US Pharmacopeia) and EP (European Pharmacopeia).

Many pharmaceutical companies have highly evaluated Nihon Validation Technologies, in particular, for sales of and support to the world's most advanced equipment which accelerates IVIVC research, such as instruments for absorption prediction of drug substances and

subcutaneous absorption of injectable drugs.

Shionogi hopes to solve problems faced by patients and society in a more comprehensive manner through our self-transformation from a conventional drug discovery company focusing on offering medications to a healthcare provider that continuously renders new value to society based on our determination to achieve the 2030 Vision "Building Innovation Platforms to Shape the Future of Healthcare."

With Nihon Validation Technologies' high technical capabilities for IVIVC and Shionogi's R & D strength, including CMC, the two companies will support development of oral formulations, aiming to maximize value by making the best use of drug efficacy and reducing adverse reactions, and will be closer to patients for better therapy and improved quality of life.

Note 1) IVIVC (In-vitro in-vivo correlation): Correlation between in-vitro and in-vivo profiles

Note 2) CMC (Chemistry, Manufacturing and Control): Research related to a wide range of fields, from non-clinical/clinical trials to approval acquisition and commercial production, such as formulation development, manufacturing method research, quality standard setting and study development.

[Product overview]

Brand name: IVIVC Enhancer

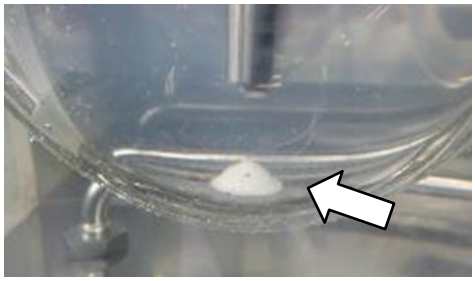
Materials: Stainless steel (SUS304) and PTFE

Date of Launch: November 2, 2020

Product photo:

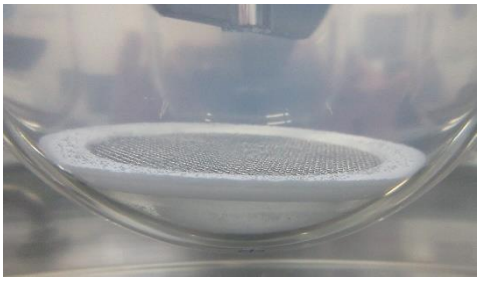
Image of use:

【When it is unused】



Mounts are formed under low stirring conditions.

【When it is used】



By using the Product, formulation of mounts is unlikely to occur under low stirring conditions.

**Forward Looking Statement**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also, for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

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