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BPOM Regulation No. 6/2025 (Supplements Stability Test)[P1]

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I. Introduction

Over the years, the consumption of supplements in Indonesia has notably increased, particularly following the COVID-19 pandemic. This surge can be attributed to heightened awareness among individuals of the importance of safeguarding their health against illnesses.

As a result of the increased demand, there has also been a rise in the number of suppliers and the variety of supplements available. In this context, it is crucial to ensure the quality of these supplements in the market to achieve the original goal of maintaining and enhancing health effectively.

In connection with this, the Indonesian National Agency of Drug and Food Control, known as *Badan Pengawas Obat dan Makanan* ("**BPOM**"), recently issued Regulation Number 6 of 2025 on Guidelines for Stability Testing of Health Supplements enacted on 21 February 2025 ("**BPOM Regulation 6 of 2025**"). These guidelines typically outline the procedures and standards for testing the stability of health supplements to ensure their safety, efficacy and shelf life. Stability testing is crucial for determining how a product maintains its quality over time under various environmental conditions.

BPOM is responsible for regulating and supervising the safety, efficacy and quality of drugs and food products, including supplements, in Indonesia. BPOM plays a crucial role in ensuring that the supplements available in the market meet established health standards and are safe for consumption.

II. Parties to follow the guidelines

Health supplements are substances or preparations intended to complement nutritional needs, maintain, enhance and/or improve health functions, possessing nutritional value and/or physiological effects, containing one or more ingredients such as vitamins, minerals, amino acids and/or other non-plant materials that can be combined with plant materials. In light of this, business actors need to ensure whether their products fall under this definition and therefore must follow the guidelines.

Stability testing is the testing of finished health supplement products according to the stability testing protocol to establish or confirm the shelf life of the finished health supplement products. This stability testing guidelines must be followed by:

(a) business actors, in ensuring the quality of finished health supplement products before they are distributed in the Indonesian territory; and
(b) BPOM, in evaluating the implementation of health supplement stability testing conducted by business actors as part of the registration of health supplements.

Health supplement products, as mentioned in point (a) above, are those that have completed all stages of the health supplement manufacturing process.

III. Testing aspects

The primary areas covered by the health supplement stability testing guidelines include:
(a) stability test design;
(b) evaluation; and
(c) labelling statements.

The health supplement stability testing must be conducted at a testing facility, which can either be an accredited laboratory or an internal industry laboratory that holds a good manufacturing practice certificate.

In designing a stability test, several aspects must be considered based on the nature and characteristics of the test product. These aspects include batch selection, specifications, testing frequency, reduction design (such as matrixing or bracketing), storage conditions and the packaging system (container and closure).

Storage conditions encompass temperature, light and humidity, and should be clearly specified on the labelling, reflecting the product's stability evaluation. Special handling instructions regarding storage must be communicated effectively. It is important to avoid vague terms like "room temperature" and instead specify the exact preferred temperature.

IV. Conclusion

Stability is a critical factor in ensuring the quality of health supplements. It is determined through a series of tests designed to confirm that the finished product, within its packaging system, is stored under conditions that meet specified requirements up to the designated shelf life. Health supplement stability testing is conducted to ascertain the shelf life of the finished product, along with its packaging system, under the established storage conditions.

Business actors must assess whether their products are classified as health supplements according to BPOM Regulation 6 of 2025 and, consequently, adhere to the guidelines. Furthermore, those who have performed health supplement stability testing prior to the enactment of BPOM Regulation 6 of 2025 must ensure compliance with the provisions of this regulation within one year of its enactment.

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