

**Praktik Kerja di PT. Takeda Indonesia Periode 7 Maret - 29 April 2022
"Analisis Proses Pengeringan Validasi Vitacimin Lemon di PT Takeda
Indonesia Tahun 2022" = Job Training at PT. Takeda Indonesia Period
March 7th - April 29th, 2022 "Vitacimin Lemon Validation Drying
Process Analysis at PT. Takeda Indonesia In 2022"**

Adristi Arum Nabilah, author

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Abstrak

PT. Takeda Indonesia adalah salah satu perusahaan milik asing yang bergerak dalam bidang farmasi. Peraturan BPOM No. 17 Tahun 2019 tentang Persyaratan Mutu Suplemen Kesehatan membuat PT. Takeda Indonesia mengubah formulasi dari produk utamanya, yakni Vitacimin. Pada saat dilakukan validasi terhadap reformulasi tablet ditemukan adanya perubahan warna pada granul dan terjadinya melting dan mottling pada tablet. Hasil investigasi menemukan adanya kekurangan indikator proses pengeringan pada mesin fluid bed dryer sehingga ditambahkan sensor relative humidity, sensor air flow, dan sensor temperatur produk pada mesin agar granul dapat dihasilkan secara konsisten. Analisa perlu dilakukan untuk melihat pengaruh antara parameter proses pengeringan dengan granul yang telah dikeringkan oleh fluid bed dryer. Granul yang telah dikeringkan pada saat validasi proses dilakukan pengukuran LOD (Loss on Drying), PSD (Particle Size Distribution), dan Bulk & Tap Density. Ditemukan bahwa penambahan sensor pada mesin fluid bed dryer dapat memungkinkan operator untuk memantau perubahan kelembaban, laju alir udara, dan suhu pada dalam mesin fluid bed dryer. Granul yang dikeringkan selama validasi proses menunjukkan granul pada sebagian besar batch tidak kering secara merata, ukuran granul paling banyak berukuran 150 m, dan granul memiliki laju alir yang baik. Kurang meratanya pengeringan pada granul dikarenakan kelembaban udara yang masuk pada mesin dapat mencapai 81,8% sehingga perlu adanya pengaturan kelembaban udara yang masuk ke dalam mesin fluid bed dryer.

..... PT. Takeda Indonesia is a foreign-owned company engaged in the pharmaceutical sector. BPOM Regulation No. 17 of 2019 concerning Health Supplement Quality Requirements made PT. Takeda Indonesia changed the formulation of its main product, namely Vitacimin. During the validation of the tablet reformulation, it was found that there was a change in the color of the granule and there is an occurrence of melting and mottling of the tablet. The results of the investigation found a lack of drying process indicators on the fluid bed dryer machine so that relative humidity sensors, airflow sensors, and product temperature sensors were added to the machine so granules could be produced consistently. An analysis needs to be carried out to see the effect between the parameters of the drying process and the granules that have been dried by a fluid bed dryer. Granules that have been dried during the validation process are measured for LOD (Loss on Drying), PSD (Particle Size Distribution), and Bulk & Tap Density. It was found that the addition of sensors to the fluid bed dryer machine can enable the operator to monitor changes in humidity, air flow rate, and temperature in the fluid bed dryer machine. Granules that were dried during process validation showed that the granules in most of the batches were not evenly dried, the most granule sizes were 150 m, and the granules had good flow ability. The uneven drying of the granules is due to the humidity of the air entering the machine which can reach 81.8% so it is necessary to regulate the humidity of the air entering the fluid bed dryer machine.