

# **Pengendalian Kualitas Obat Simarc Tablet Melalui Penerapan Metode Statistical Process Control (Kasus PT. Pratapa Nirmala Fahrenheit)**

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## **Abstrak**

Proses produksi sediaan obat tablet merupakan multi-steps process, yaitu keseragaman bobot tablet, kekerasan tablet, kerapuhan tablet, waktu hancur tablet, dissolusi, dan kadar zat aktif tablet. Setiap proses produksi dipengaruhi oleh variasi alamiah (natural variation) dan variasi buatan (assignable variation) yang menyebabkan proses produksi tidak terkendali (out-of control) serta berpengaruh terhadap konsistensi dan tercapainya spesifikasi kualitas output. Penelitian ini bertujuan untuk menganalisis tahap proses pembuatan tablet dan bagaimana penerapan metoda Statistical Process Control (SPC) dalam pengendalian kualitas obat tablet di PT. Pratapa Nirmala Fahrenheit selama periode Januari 2015 sampai Desember 2015 dilakukan untuk memperoleh data kuantitatif hasil pengukuran karakteristik kualitas tablet yaitu keseragaman bobot tablet, kekerasan tablet, kerapuhan tablet, waktu hancur tablet, dissolusi, dan kadar zat aktif tablet, untuk kemudian dianalisis menggunakan metode Statistical Process Control (SPC) dengan alat bantu kendali (control chart). Hasil penelitian menunjukkan bahwa pada tahap proses keseragaman bobot tablet, kekerasan tablet, kerapuhan tablet, waktu hancur tablet, dan kadar zat aktif tablet secara statistik termasuk in-control, sedangkan dissolusi termasuk out-of control kemudian untuk penerapan metoda Statistical Process Control (SPC) dalam pengendalian Kualitas proses pembuatan tablet pada Produk Simarc Tablet dapat mengidentifikasi apakah proses berjalan dengan baik, walaupun dalam pengolahan data hanya terdapat satu titik yang diluar kendali tapi sangat berpengaruh terhadap kualitas produk sehingga harus dilakukan perbaikan untuk meminimalisasi kesalahan kesalahan pada proses pembuatan tablet.

**Kata Kunci:** *Kualitas Obat, Statistical Process Control, Parameter uji Tablet.*

## **Abstract**

*The production process of tablet drug preparation is a multi-step process, ie tablet weight uniformity, tablet hardness, tablet fragility, tablet disintegration time, dissolution, and active tablet content. Every production process is influenced by natural variation and assignable variation which causes the production process to be out-of-control and affect the consistency and achievement of output quality specification. This study aims to analyze the stage of the process of making tablets and how the application of Statistical Process Control (SPC) method in drug quality control tablets in PT. Pratapa Nirmala Fahrenheit during the period of January 2015 until December 2015 was conducted to obtain quantitative data of measurement result of tablet quality characteristic that is uniform weight of tablet, tablet hardness, tablet fragility, tablet disintegration time, dissolution, and active substance content of tablet, then analyzed using Statistical Process Control (SPC) with the control chart tool. The results showed that in the process stage of uniformity of tablet weight, tablet hardness, tablet fragility, tablet disintegration time, and statistically active tablet content including in-control, while dissolution including out-of control then for the application of Statistical Process Control (SPC) in the Quality control of tablets production process on Simarc Tablet Product can identify whether the process is running well, although in data processing there is only one point which controlled the control but it is very influential to the quality of the product so it must be done to minimize error errors in the process of making the tablet.*

**Keywords:** *Drug Quality, Statistical Process Control, Tablet Test Parameters.*