

VALIDASI METODE ANALISA RESIDU MOMETASONE FUROATE DAN CIP100 SETELAH PROSES PEMBERSIHAN PERALATAN PRODUKSI DI INDUSTRI FARMASI “XYZ”

Amaandika Galih Arintowibowo

Magister Farmasi Fakultas Farmasi Universitas Surabaya

Ririn Sumiyani

Kusuma Hendrajaya

ABSTRAK

Pada penelitian ini, metode Analisa HPLC dan *Total Organic Carbon (TOC)* telah dikembangkan dan divalidasi untuk penentuan jumlah residu Mometasone furoate dan CIP100 pada permukaan peralatan produksi krim Mometasone furoate 0,1% dan untuk mengkonfirmasi efisiensi prosedur pembersihan. Mometasone furoate dan CIP100 telah dipilih berdasarkan pendekatan penilaian kasus terburuk. Batas nilai kontaminasi mometasone furoate yang ditetapkan adalah 0,846 mg /cm² dan batas nilai kontaminasi CIP100 yang ditetapkan adalah 0,014 mg /cm² yang tidak boleh dilampaui selama uji pembersihan peralatan secara berurutan. Mometasone furoate menunjukkan linearitas yang baik dalam kisaran 0,1 – 1,0 ppm untuk metode HPLC dan CIP100 menunjukkan linearitas yang baik dalam kisaran 2,0 – 10,0 ppm untuk Analisa TOC. Persentase pemulihan Mometasone furoate dan CIP100 ditemukan dalam batas 95,12 % dan 99,93% masing-masing dalam metode HPLC dan TOC. Kedua metode ini akurat, efisien, efektif dan sensitif untuk penentuan kuantitatif Mometasone furoate dan CIP100 pada permukaan peralatan produksi jauh di bawah batas kontaminasi. Metode yang divalidasi terbukti memuaskan untuk demonstrasi validasi pembersihan residu Mometasone furoate dan CIP100 pada permukaan peralatan produksi krim Mometasone furoate 0,1%.

Kata kunci : Mometasone Furoate; Validasi Pembersihan; Permukaan Peralatan Produksi; analisa *Total Organic Carbon (TOC)*; HPLC

VALIDATION METHOD OF RESIDU MOMETASONE FUROATE AND
CIP100 RESIDU ANALYSIS AFTER THE CLEANING PROCESS OF THE
PRODUCTION EQUIPMENT IN THE “XYZ” PHARMACEUTICAL
INDUSTRY

Amaandika Galih Arintowibowo

Master of Pharmacy at the Faculty of Pharmacy, University of Surabaya

Ririn Sumiyani

Kusuma Hendrajaya

ABSTRACT

In this study, the HPLC and Total Organic Carbon (TOC) Analysis methods have been developed and validated for the determination of the residual amounts of Mometasone furoate and CIP100 on the surface of 0.1% Mometasone furoate cream production equipment and to confirm the efficiency of the cleaning procedure. Mometasone furoate and CIP100 have been chosen based on the worst case assessment approach. The limit of the value of established mometasone furoate contamination is 0.846 mg / cm² and the specified limit of contamination value of CIP100 is 0.014 mg / cm² which should not be exceeded during the cleaning test of the equipment in sequence. Mometasone furoate shows good linearity in the range 0.1 - 1.0 ppm for the HPLC and CIP100 methods showing good linearity in the range 2.0 - 10.0 ppm for TOC Analysis. The percentage of recovery of Mometasone furoate and CIP100 was found in the limits of 95.12% and 99.93% respectively in the HPLC and TOC methods. Both of these methods are accurate, efficient, effective and sensitive for quantitative determination of Mometasone furoate and CIP100 on the surface of production equipment well below the contamination limit. The validated method proved satisfactory for demonstration of the validation of residual cleansing of Mometasone furoate and CIP100 on the surface of the 0.1% Mometasone furoate cream production equipment

Keywords : Mometasone Furoate; Cleaning Validation; Surface of Production Equipment; Analysis of *Total Organic Carbon (TOC)*; HPLC