Evaluasi Efektivitas Pengendalian Pajanan Active Pharmaceutical Ingredient (API) Pada Pekerja di PT. XY - Studi Kasus Pembuatan Tablet Obat Dhasolone 5 mg = Control Effectiveness Evaluation of Exposure of Active Pharmaceutical Ingredient (API) to Workers in PT. XY - Case Study on Manufacture of Dhasolone 5 mg Tablet

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Abstrak

Industri farmasi tidak lepas dari pemakaian API (Active Pharmaceutical Ingredient) sebagai bahan aktif dalam produksi obat-obatan yang dapat berdampak pada gangguan kesehatan pekerjanya. Tujuan dari penelitian ini untuk melakukan evaluasi efektivitas pengendalian pajanan API pada proses pembuatan tablet obat Dhasolone 5 mg menggunakan Prednisolone sebagai bahan aktifnya yang termasuk OHC (Occupational Hazard Category) 4 dan dapat menyebabkan gangguan hormonal dengan adanya penurunan kortikotropin. Penelitian ini merupakan survei analitik kuantitatif dengan mengambil sampel pajanan debu API Prednisolone dan dilakukan analisis laboratorium menggunakan HPLC-UV (High Performance Liquid Chromatography-Ultra-Violet) sesuai metode BV-2012-25247. Metode lainnya yang digunakan dalam penelitian ini juga mengacu pada SNI 7325:2009 untuk pengambilan sampel pajanan debu respirabel yang dilakukan analisisinya secara gravimetri. Populasi dalam penelitian ini adalah pekerja pada proses pembuatan tablet obat Dhasolone 5 mg, yang meliputi tahapan penimbangan, pengayakan, granulasi, pencetakan tablet dan pengemasan primer dengan mengambil sampel pajanan personal awal sebanyak 15 orang. Hasil pengukuran awal menunjukkan pajanan Prednisolone di bagian penimbangan, pengayakan, dan granulasi memiliki hasil peringkat pajanan pada kategori 4 (pajanan tidak terkendali dengan baik). Kemudian dilakukan perbaikan proses kerja melalui pemasangan enclosure system (dispensing booth) pada proses penimbangan sehingga dilakukan pengukuran pajanan personal kembali dengan hasil pengendalian tersebut efektif mengendalikan risiko pajanan pada pekerja dari rata-rata geometrik (GM) 100±1,68 µg/m³ menjadi 0,44±6,72 µg/m³. Pada proses lainnya, pengendalian pajanan dilakukan melalui administrasi dan Alat Pelindung Diri (APD). Pengendalian melalui APD juga dikatakan efektif mengendalikan pajanan API tersebut dengan penggunaan unit PAPR (Powered Air Purifying Respirator) yang memiliki nilai APF (Assigned Protection Factor) 1.000 di atas minumum APF yang dipersyaratkan, yaitu 250. Penilaian terhadap kefektifan penggunaan PAPR ini juga dilakukan menggunakan data surrogate, yaitu data hasil pengukuran pajanan personal terhadap debu respirabel yang dilakukan pada pekerja di bagian pengayakan, granulasi, dan cetak tablet. Secara umum dari hasil pengukuran, pengendalian melalui penggunaan PAPR ini efektif mengendalikan pajanan debu respirabel (karakteristiknya sama dengan API) dengan hasil pajanan berada pada kategori 2 yang menandakan pajanan terkendali dengan baik dan memiliki probabilitas sebesar 97,8%. Sementara pengendalian secara administrasi, terdapat kesenjangan yang perlu dilakukan perbaikan melalui implementasi komunikasi bahaya API serta sosialisasi terkait prosedurnya.

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The pharmaceutical industry cannot be separated from the use of API (Active Pharmaceutical Ingredient) as

an active ingredient in the production of medicines that can have an impact on the health of its workers. The purpose of this study was to evaluate the effectiveness of API exposure control in the process of making Dhasolone 5 mg drug tablets using Prednisolone as the active ingredient which belongs to OHC (Occupational Hazard Category) 4 and can cause hormonal disturbances with a decrease in corticotropin. This research is a quantitative analytical survey by taking dust exposure samples from API Prednisolone and laboratory analysis using HPLC-UV (High Performance Liquid Chromatography-Ultra-Violet) according to the BV-2012-25247 method. Another method used in this study also refers to SNI 7325:2009 for sampling of respiratory dust exposure which is analyzed gravimetrically. The population in this study were workers in the process of making Dhasolone 5 mg drug tablets, which included the stages of weighing, sifting, granulating, tablet compression and primary packaging by taking samples of initial personal exposure as many as 15 people. The results of the initial measurement showed that the exposure to Prednisolone in the weighing, sieving, and granulation section had an exposure rating of category 4 (exposure was not well controlled). Then the work process was improved through the installation of an enclosure system (dispensing booth) in the weighing process so that personal exposure measurements were carried out again with the results of this control effectively controlling the risk of exposure to workers from the geometric average (GM) of 100±1.68 g/m3 to 0 ,44±6.72 g/m³. In other processes, exposure control is carried out through administration and Personal Protective Equipment (PPE). Control through PPE is also said to be effective in controlling API exposure by using a PAPR (Powered Air Purifying Respirator) unit which has an APF (Assigned Protection Factor) value of 1,000 above the minimum required APF, which is 250. An assessment of the effectiveness of using PAPR was also carried out using data surrogate, which the measurement data of personal exposure to respirable dust carried out on workers in the sieving, granulation, and tablet compression sections. In general, from the measurement results, control through the use of PAPR is effective in controlling respiratory dust exposure (characteristics are the same as API) with the exposure result being in category 2 which indicates the exposure is well controlled and has a probability of 97.8%. While controlling administratively, there are gaps that need to be improved through the implementation of API hazard communication and socialization related to the procedure.