Analisis Klasifikasi Area Berbahaya dan Penilaian Risiko Kebakaran dan Ledakan Debu pada Proses Granulasi di PT. X = Analysis of Hazardous Area Classification and Risk Assessment of Fire and Dust Explosion in the Granulation Process at PT. X

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Abstrak

Industri farmasi merupakan industri yang memiliki risko kebakaran dan ledakan yang sangat besar karena penanganan beragam bahan kimia cair, padatan, dan gas yang mudah terbakar serta bahan kimia berbahaya lainnya. Tujuan umum dari penelitian ini adalah untuk mengklasifikasikan area berbahaya berdasarkan standar IEC 60079-10-2 serta menganalisis tingkat risiko kebakaran dan ledakan debu dalam proses granulasi pada fasilitas Non Betalactam (Multi Product Facility). Penelitian ini merupakan penelitian deskriptif semi kuantitatif yang bertujuan untuk mengklasifikasikan area berbahaya pada proses granulasi berdasarkan standar IEC 60079-10-2 dan menentukan tingkat risiko kebakaran dan ledakan debu dalam tahapan pencampuran (mixing) dengan menggunakan metode Dow's Fire Explosion Index. Populasi ini melibatkan semua bahan kimia berbahaya dan peralatan yang digunakan pada proses pembuatan obat di PT. X. Combustible dust yang digunakan dalam proses granulasi pada fasilitas Non Betalactam Facility (Multi Product Facility) berupa bahan aktif farmasi dan eksipien, seperti methyldopa hydrate, paracetamol, loperamide hydrochloride, diazepam, domperidone, prednisolone micronised, magnesium stearate. polyvidone 30, sodium starch glycolate, dan amylum maydis. Minimum Ignition Energy (MIE) yang dimiliki oleh semua bahan aktif berbeda-beda nilainya sesuai hasil uji laboratorium eksternal dengan nilai yang paling sensitif terhadap penyalaan, yaitu diazepam, methyldopa hydrate, loperamide hydrochloride, domperidone dan prednisolone micronised yang mempunyai nilai MIE 1-3 mj yang dapat menyebabkan ledakan kuat hingga sangat kuat jika memenuhi konsentrasi Minimum Explosive Concentration (MEC). Sehubungan dengan hal itu, sebelum menentukan klasifikasi area berbahaya, sangat penting untuk mengidentifikasi sumber penyalaan di area proses tersebut. Adapun sumber penyalaan tersebut bersumber dari peralatan listrik, listrik statis, dan friction/mechanical spark. Klasifikasi area berbahaya dengan kategori zona dalam proses granulasi pada fasilitas Non Betalactam (Multi Product Facility) terdiri dari zona 20 di setiap dalam chamber/container peralatan, zona 21 di setiap bukaan hopper/charging unit, tempat perilisan debu dengan radius satu meter dan zona 22 di luar zona 21 di dalam ruangan proses granulasi. Tingkat risiko kebakaran dan ledakan debu pada proses granulasi (mixing) dengan menggunakan metode granulasi basah (hybrid mixture) berdasarkan metode Dow's Fire and Explosion Index adalah risiko sedang (moderate) dengan total skor 95,1762 dengan radius paparannya sebesar 29,010 meter dan estimasi kerugiannya mencapai Rp 1.467.276.735.672. Oleh karenanya, sangat penting untuk melakukan mitigasi risiko sehingga risiko kebakaran dan ledakan debu di area proses ini berada pada risiko yang rendah.
.....The pharmaceutical industry is an industry that has a very large risk of fire and explosion due to the handling of a variety of flammable liquid, solid and gaseous chemicals as well as other hazardous chemicals. The general objective of this study is to classify hazardous areas based on IEC 60079-10-2 standards and to analyze the risk level of fire and dust explosion in the granulation process at the Non Betalactam facility (Multi Product Facility). This research is a semi-quantitative descriptive study that aims to classify

hazardous areas in the granulation process based on IEC 60079-10-2 standards and determine the risk level of fire and dust explosion in the mixing stage using the Dow's Fire Explosion Index method. This population includes all hazardous chemicals and equipment used in the drug manufacturing process at PT. X. Combustible dust used in the granulation process at the Non Betalactam Facility (Multi Product Facility) is in the form of active pharmaceutical ingredients and excipients, such as methyldopa hydrate, paracetamol, loperamide hydrochloride, diazepam, domperidone, micronised prednisolone, magnesium stearate. polyvidone 30, sodium starch glycolate, and amylum maydis. The Minimum Ignition Energy (MIE) that all active ingredients have a different value according to the results of external laboratory tests with values that are most sensitive to ignition, namely diazepam, methyldopa hydrate, loperamide hydrochloride, domperidone and micronised prednisolone which have an MIE value of 1-3 mj which can cause a strong to very strong explosion if it meets the Minimum Explosive Concentration (MEC) concentration. In this regard, before determining the classification of a hazardous area, it is very important to identify the source of ignition in the process area. The ignition sources come from electrical equipment, static electricity, and friction/mechanical spark. Classification of hazardous areas with the category of zones in the granulation process at Non Betalactam facilities (Multi Product Facility) consists of zone 20 in each equipment chamber/container, zone 21 in each opening of the hopper/charging unit, a dust release area with a radius of one meter and zone 22 outside zone 21 in the granulation process room. The risk level of fire and dust explosion in the granulation process (mixing) using the wet granulation method (hybrid mixture) based on the Dow's Fire and Explosion Index method is moderate risk with a total score of 95.1762 with an exposure radius of 29.010 meters and an estimated loss of IDR 1,467. 276,735,672. Therefore, it is very important to carry out risk mitigation so that the risk of fire and dust explosion in this process area is at a low risk.