

Assessment of Potential Chemical Exposure to Betamethasone Valerate and Clobetasol Propionate in Pharmaceutical Manufacturing Laboratories

Authors : Nadeen Felemban, Hamsa Banjar, Rabaah Jaafari

Abstract : One of the most common hazards in the pharmaceutical industry is the chemical hazard, which can cause harm or develop occupational health diseases/illnesses due to chronic exposures to hazardous substances. Therefore, a chemical agent management system is required, including hazard identification, risk assessment, controls for specific hazards and inspections, to keep your workplace healthy and safe. However, routine management monitoring is also required to verify the effectiveness of the control measures. Moreover, Betamethasone Valerate and Clobetasol Propionate are some of the APIs (Active Pharmaceutical Ingredients) with highly hazardous classification-Occupational Hazard Category (OHC 4), which requires a full containment (ECA-D) during handling to avoid chemical exposure. According to Safety Data Sheet, those chemicals are reproductive toxicants (reprotoxicant H360D), which may affect female workers' health and cause fatal damage to an unborn child, or impair fertility. In this study, qualitative (chemical Risk assessment-qCRA) was conducted to assess the chemical exposure during handling of Betamethasone Valerate and Clobetasol Propionate in pharmaceutical laboratories. The outcomes of qCRA identified that there is a risk of potential chemical exposure (risk rating 8 Amber risk). Therefore, immediate actions were taken to ensure interim controls (according to the Hierarchy of controls) are in place and in use to minimize the risk of chemical exposure. No open handlings should be done out of the Steroid Glove Box Isolator (SGB) with the required Personal Protective Equipment (PPEs). The PPEs include coverall, nitrile hand gloves, safety shoes and powered air-purifying respirators (PAPR). Furthermore, a quantitative assessment (personal air sampling) was conducted to verify the effectiveness of the engineering controls (SGB Isolator) and to confirm if there is chemical exposure, as indicated earlier by qCRA. Three personal air samples were collected using an air sampling pump and filter (IOM2 filters, 25mm glass fiber media). The collected samples were analyzed by HPLC in the BV lab, and the measured concentrations were reported in (ug/m³) with reference to Occupation Exposure Limits, 8hr OELs (8hr TWA) for each analytic. The analytical results are needed in 8hr TWA (8hr Time-weighted Average) to be analyzed using Bayesian statistics (IHDataAnalyst). The results of the Bayesian Likelihood Graph indicate (category 0), which means Exposures are de "minusus," trivial, or non-existent Employees have little to no exposure. Also, these results indicate that the 3 samplings are representative samplings with very low variations (SD=0.0014). In conclusion, the engineering controls were effective in protecting the operators from such exposure. However, routine chemical monitoring is required every 3 years unless there is a change in the processor type of chemicals. Also, frequent management monitoring (daily, weekly, and monthly) is required to ensure the control measures are in place and in use. Furthermore, a Similar Exposure Group (SEG) was identified in this activity and included in the annual health surveillance for health monitoring.

Keywords : occupational health and safety, risk assessment, chemical exposure, hierarchy of control, reproductive

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