Residual exposure from contaminated overalls in pharmaceutical industry

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ABSTRACT

The present study aims to assess the secondary exposure of workers and their co-workers from used overall contaminated with active pharmaceutical ingredient (API) at secondary pharmaceutical manufacturing plant. Patients are cured of certain illnesses if the active-containing drug is prescribed and taken at the right dose. However, workers involved in the manufacturing processes are exposed to higher doses of the actives due to the nature of their work and are at risk of its pharmacological effects. It is also thought that significant amount of actives can be deposited in the workers’ overall and re-suspended as the overall is taken off in the changing room. Others that are present in the same room can be indirectly exposed via inhalation to high concentration of actives that are re-suspended. The author has decided to pursue this study on the basis of personal experience of some workers who have seen dust liberated upon removal of their overall which may potentially be detrimental to health.

The results of the study showed direct exposure of workers exceeded the occupational exposure limit or OEL (40 mcg/m³) of Chlorpromazine HCI in all tasks performed across the different unit operations. The statistical analysis (t-test) of secondary exposures of workers and co-workers showed that 99% of the time they will be exposed above the OEL. Furthermore, the weight of the API explains about 57.8% of the variability in workers’ secondary exposure. This means that for every 5kg of API introduced into the unit operation, the workers’ secondary exposure increases by 1.286 mcg/m³. Similarly, the workers’ secondary exposure explains about 65.1% of the variability in co-workers’ secondary exposure which means that for every 1 mcg/m³ increase in workers’ secondary exposure, co-workers’ secondary exposure increases by power of 0.820. Further study is required to identify other factors which may affect workers and co-workers’ secondary exposure.

The findings suggest that interventions should be introduced at the source of exposure. The manufacturing batch record should be reviewed to include instruction to process active into smaller portions less than 90kg to reduce secondary exposures below the OEL. It is highly recommended to put in place containment measures to control excessive dust generated across the different unit operations. Moreover, it is important to educate
workers about the risks associated with handling of API and reinforce good work behaviours to lessen exposure. It is worth considering the need to isolate the workers and ensure that respiratory protective equipment (RPE) is being worn while removing their overall. The risk of secondary exposure can be effectively managed if the aforementioned control measures are in place and in use.

The results of this study could be beneficial to future undertakings, i.e. development of drug formulation. Quantity of active to be used and design processes which involves human intervention are some of the factors which should be taken into account and evaluated during the initial stages of product and process validation to mitigate the risks of high exposure.