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Current Practices of Permitted Daily Exposure (PDE) Calculation and Selection

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Abstract : Cleaning validation in a pharmaceutical manufacturing facility is documented evidence that a cleaning process has effectively removed contaminants, residues from previous drug products and cleaning agents below a pre-defined threshold from the reusable tools and parts of equipment. In shared manufacturing facilities more than one drug product is prepared. After cleaning of reusable tools and parts of equipment after one drug product manufacturing, there are chances that some residues of drug substance from previously manufactured drug products may be retained on the equipment and can carried forward to the next drug product and thus cause cross-contamination. Health-based limits through the derivation of a safe threshold value called permitted daily exposure (PDE) for the residues of drug substances should be employed to identify the risks posed at these manufacturing facilities. The PDE represents a substance-specific dose that is unlikely to cause an adverse effect if an individual is exposed to or below this dose every day for a lifetime. There are different practices to calculate PDE. Data for all APIs in the public domain are considered to calculate PDE value though, company to company may vary the final PDE value based on different toxicologist's perspective or their subjective evaluation. Hence, Regulatory agencies should take responsibility for publishing PDE values for all APIs as it is done for elemental PDEs. This will harmonize the PDE values all over the world and prevent the unnecessary load on manufacturers for cleaning validation

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