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Survey of active pharmaceutical ingredients- excipient incompatibility

Nature and mechanism



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Survey Of Active Pharmaceutical Ingredients Excipient Incompatibility Nature And Mechanism

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Survey Of Active Pharmaceutical Ingredients Excipient Incompatibility Nature And Mechanism:

Survey of Active Pharmaceutical Ingredients-Excipient Incompatibility Tamilvanan Shunmugaperumal, 2010-10 To improve physico chemical properties of an active pharmaceutical ingredient API at its preformulation stage myriad of excipients having defined functional roles like solubility enhancement by co solvent micells formation and complexation intestinal permeability enhancement through the inhibition of efflux transport mechanisms stability improvement using pH adjustment cryo and lyo protectants etc are incorporated into a dosage form containing the API Although considered primarily as inactive materials the excipient s may react with the API resulting in the development of a detrimental or beneficial substance within the API loaded dosage form itself If detrimental substances are formed then the issue of API excipient incompatibility will come up and demand the reformulation of the API which is costly and time consuming This book surveys a comprehensive list of published examples of API excipient incompatibility relevant to currently or previously marketed drugs With this coverage this book also provides first hand information on the multicomponent nature and complexity of the excipients to the formulation scientist Herb-Drug Combinations Shanmugam Hemaiswarya, Pranav Kumar Prabhakar, Mukesh Doble, 2022-10-05 Plant extracts or their pure natural constituents have been used traditionally for thousands of years for treating diseases with considerable success in India and other Asian countries In addition they have also been used as complements or supplements with conventional medicine This book discusses the latest research in the application of combination therapy namely herbs and drugs in the treatment of a range of communicable and non communicable diseases to achieve a synergistic effect This synergy may help in reducing the amount of drug its toxicity side effects and development of resistance as well as improve its efficacy The book also discusses the pharmacodynamic and pharmacokinetic parameters experimental tools to determine the impact of combination computational approaches to identify synergy statistical analysis of data and clinical and regulatory issues The book is useful for researchers in the fields of pharmacology pharmacy and medicinal chemistry and those working in pharmaceutical and nutraceutical industries This book could open up new strategies to focus on multiple targets to combat complex diseases unlike the single targeted drugs that are being currently marketed by the pharmaceuticals industries *Dissertation Abstracts International* ,1987

Journal of Applied Chemistry ,1964 **Index to Theses with Abstracts Accepted for Higher Degrees by the Universities of Great Britain and Ireland and the Council for National Academic Awards** ,2004 **The Effect of a Source Change for an Active Pharmaceutical Ingredient (API) Or Excipient on the Finished Drug Product** Mohamed Chan, 2016 The global cost of health care is increasing year after year and one of the ways governments and health care providers are looking to reduce cost is by reducing the cost of drug products The generic industry is under tremendous pressure to remain competitive in the market place by reducing the cost of their product with the main cost factor being the active pharmaceutical ingredient and some of the excipients used in the manufacture of the drug product These companies

are expected to follow the required guidelines set out by the international regulatory authorities and more specifically of the countries they intent to market their product in if they are planning to change the source of the material These regulatory guidelines are general in nature with a focus on safety and efficacy and the evaluation of an alternate source of material by pharmaceutical companies varies greatly from company to company The evaluation is conducted mainly on the basis of chemical and physical data from the Certificate of Analysis comparing the current and alternate source to determine equivalency Differences in process and critical processing parameters of the material can have significant impact on the behavior of the chemical which may not be detectable through evaluation of the Certificates of Analysis It is therefore critical to study properties that are not captured on the Certificate of Analysis such as polymorphism melting point solubility particle shape packing tendencies among other aspects of the material that are important for the performance of the material in the drug product formulation and manufacturing process The differences in these properties can have significant impact on the unit operations during the manufacturing process as well as the critical quality attributes and the stability of the drug product The evaluation is conducted by utilizing various tools of analytical and process testing to determine the physical performance physicochemical evaluation chemical evaluation and functional performance evaluation for the active pharmaceutical ingredient and excipient The evaluation of the Certificate of Analysis will also need to be more in depth and go beyond the alternate source meeting the specifications as there can be significant differences with the results obtained even though they meet specification It is important to identify these differences earlier in the evaluation stage and to assess the impact if any on the manufacturing process and the drug product prior to introducing the change This study was conducted with active pharmaceutical ingredients selected based on the processing unit operations such as direct compression process metformin HCl dry compaction gabapentin and hot melt process fenofibrate The selection of the excipients was based on their functional properties such as binders copovidone NF EP and super disintegrant croscarmellose Sodium NF EP allowing for evaluation with respect to differences in functionality if any from the different sources Additionally the copovidone NF EP is the binder in the gabapentin USP tablet formulation while the croscarmellose Sodium NF EP is the super disintegrant in the fenofibrate EP BP tablet formulation An example of this challenge is that the evaluation of Certificate of Analysis for the materials supplied from two companies and two sources revealed differences in tests required for the two materials and a significant difference in some of the results obtained however both materials met their respective Certificate of Analysis specifications Several tests beyond the Certificate of Analysis were performed and significant differences were also observed in many of these as well The two sources were evaluated with respect to the compression process and the alternate source of material did show significant challenges during the tablet compression process and did not meet some of the in process critical quality attributes test The in vitro performance for both sources were comparable however the recommendation will be not to proceed with the alternate source There were many differences

between the sources of all the materials evaluated including differences in particle size morphology moisture manufacturing process and residual solvents among others The impact on the manufacturing unit operation varies from no impact for the fenofibrate EP BP materials to not meeting the critical quality attributes for metformin HCl tablets with the new source of the active pharmaceutical ingredients This study indicates the importance of a systematic evaluation of a material from an alternate source with respect to the performance of the manufacturing process drug product and their critical quality attributes understanding the impact of these changes to the material and having the ability to correlate these to potential issues with the manufacturing process and drug product critical quality attributes prior to introducing an alternate source of material is critical

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