



## EFFECTIVE SEPARATION TECHNIQUES IN ISOLATION OF ANALOGOUS ISOMERS/IMPURITIES IN ACTIVE PHARMACEUTICAL INGREDIENT/ ACTIVE TECHNICALS IN AGROCHEMICALS

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### ABSTRACT

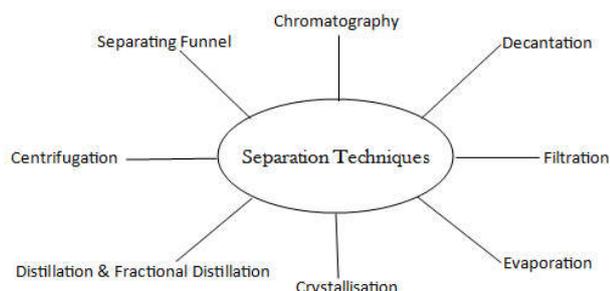
Various techniques are now a days available for isolation of impurities, analogous isomers from the active ingredient. Flash chromatography is one of the low cost technique which can be used for this work.

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### INTRODUCTION

Presence of unwanted chemicals, even in small amounts, may influence the efficacy and safety of the pharmaceutical products. Therefore impurity profiling (i.e., the identity as well as the quantity of impurity in the pharmaceuticals), is receiving critical attention from regulatory authorities. Various regulatory authorities such as the International Conference on Harmonization (ICH), the United States Food and Drug Administration (FDA), and the Canadian Drug and Health Agency (CDHA) have been legally emphasized on the purity and the identification of impurities in Active Pharmaceutical Ingredients (APIs) [1]. However, it is noted that large number of compounds under investigation in drug discovery presents a significant analytical challenge for the detection, quantitation, and characterization of the compounds alone [2].

Various techniques to purify active ingredients.



Chromatography is one of the quickest and easiest ways to separate complex mixture of compounds.

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The present work defines the application of flash / preparative chromatography instrument with auto fraction collector for separation of impurities present in active drug molecules and various isomeric agrochemicals. The isolated impurities were further quantified and qualified by sophisticated analytical instrumental techniques such as Infra-Red (IR), Nuclear magnetic resonance (<sup>1</sup>H-NMR), High performance liquid chromatography (HPLC) and Mass spectroscopy (MS). The efficiency of purification was confirmed by achieving 97-99% purity of the active molecules.

This reproducible analytical technology have been consistently represented the accurate, high throughput, robust results in impurity identification, detection, and quantification for variety of drug molecules. We envision that this impurity profiling information on biologically active molecules would help the pharma industries to speed up the developmental stage of drug candidates from IND to NDA.

Distillation, re-crystallization, and extraction are all important techniques for the purification of organic compounds. However, the technique used most commonly in modern organic research is 'flash' chromatography. In traditional column chromatography the sample to be purified is placed on top of a column containing some solid support, often silica gel. The rest of the column is then filled with a solvent (or a mixture of solvents), which then runs through the solid support under the force of gravity. The various components to be separated travel through the column at different rates and are then collected separately as they emerge from the bottom of the column. Unfortunately, the rate at which the solvent percolates through the column is slow. In flash chromatography, however, air pressure is used to speed up the flow of the solvent, dramatically decreasing the time needed to purify the sample.

Even non chromophoric compounds can be easily separated by latest models of Flash Chromatography where evaporative light-scattering *detector (ELSD)* are used

## References

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