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E-IPA-Encyclopedia of Impurity Profile (IP) for API

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Abstract
A number of factors associated with lower to high susceptibility to impurity and better control on impurity multiplication has been reported. Specified impurity ABCDE and other detectable impurity F, those substances would, if present at a sufficient level detected by one or other of the test. They are limited by the general acceptance criteria for other/unspecified impurities and /or by the general monograph substance for pharmaceutical use. It has therefore not necessary to identify those impurities for demonstration of compliance. Whether, certain chemical reaction can take place, to what extent chemical conversions can occur, the effect of temperature and pressure on the behaviour of a chemical reaction, the driving force of each of several competing reactions taking place, and the amount of heat released are some of the aspects of chemical process impurities emission. Energy of a system entering a process plus any addition during the process, the conversion into reaction mass , those time for exposures to the impurity entrapment, that impurity has known slash impurity and it has not been unusual work, it has unknown impurity. Slash impurity in the staring materials could follow the same reaction pathways and carry forward to the final drug. Identification of impurity in pharmaceuticals has a crucial task and one of the most important tools that can be used to predict the factor of those impurities in reactions has chemistry thermodynamics.In this study slash impurity has irrelevant trace element accepted as unaccepted chemical entity it has relatively inconsistent solubility and show only weak adsorption at the surfaces of compound.However, a possible sorption mechanism for such trace impurity has the structural incorporation in product. We investigated interactions occur between slash impurity and compound at standard condition.This encyclopedia involving bioanalytical methods for slash impurity studies of pharmaceuticals for suitable method selection with thousands of combinations and searches against those methods (1). Most scrutinized literature was collected from different sources including PubMed (2). This database has been curetted using published methods for all most all pharmaceuticals. Required information for regular method development/validation such as IUPAC name, structure, solubility, chromatographic conditions, instrumentation information like UPLC detection parameters, sample preparations, recovery trials, limit of detection and limit of quantification, Tmax, Cmax etc., for routine application in SI studies of pharmaceuticals was incorporated including official pharmacopeias information such as European Pharmacopeia, Japan Pharmacopeia and Canadian Pharmacopeia. Database includes drug based bioanalytical methods covering most required fields and external database links of important drug portals such as drug bank, Rxlist, MEDLINE plus, KEGG Drug ID, KEGG Compound ID, Merck manual, PubChem compound ID, PubChem substance ID and USFDA (3). Searching/querying the database is through drug name, chemical formula or structural search by smiles format. Keen selections of bioanalytical methods for pharmaceutical analysis or regular quality control are also possible with E-IPA (4). E-IPA was built understanding the needs of pharmaceutical industry and pharmacies including R&D, CROs, process developemt laboratory and laboratotyworking on SI studies. Presently it has nearly of 1 method and it will be updated regularly.

Keywords: API, UPLC, Milli-Q water

1. Introduction

1.1 Chromatographic conditions

The method was developed using an Acquity UPLC™ 1.8 µm column with quaternary pump and gradient mobile phase containing a mixture of 0.01 M potassium dihydrogen ortho-phosphate, pH adjusted to 3.0 with ortho-phosphoric acid and acetonitrile (40:60 v/v). The

mobile phase was filtered through nylon 0.22 µm membrane filters and degassed. The flow rate of the mobile phase was 0.2 mL/min. The column temperature was maintained at 35 °C and the eluted compounds were monitored at the wavelength of 230 nm. The sample injection volume was 5 µl.

1.2 Standard solution preparation

Milli-Q water and methanol in the ratio of 20:80 v/v was used as diluent. A stock solution containing 0.56 mg/mL was prepared by a dissolving appropriate amount of drug in diluent. The final concentration of solution was 0.1 µg/mL. Appropriate dilutions were made with diluent to obtain solution containing 0.5, 1.0, 5.0, and 50 µg/mL.

2. Conclusion

Large research studies in recent years have shown that the risk of impurity transmission into drug is greatly reduced and some methods work better than others. A new sensitive UPLC method has been developed for the simultaneous determination of IP on the pharmaceutical manufacturing surface and also to control the efficiency of the equipment cleaning. The method was validated in accordance with ICH guidelines and found to be specific, precise, accurate, linear, robust and rugged. Hence, the method can be used as part of a technology for impurity trends and its isolation in process chemistry of pharmaceutical product.

3. Acknowledgement

This method has established under international regulatory requirements. This reserach were done while I was a R & D Dept. as officer at Aarti Drugs Ltd.Trapur MIDC Mumbai.

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