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R & D and Technology Development of Ultra-Gas Chromatography for Estimation of Excessive Residual Solvents

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Abstract

There are many definition of chromatography and separation of micro impurities is very personal research mind and these impurity get enter medical product. Zero residual solvent emission by the estimation of OVIs researcher never though they needed to do. Micro peaks resolution it is a sign of pooling of organic volatile impurities in formulation. This technique, depending on the nature of the compounds, gas chromatography is very efficiently found in organic volatile impurities. A pharmaceutical impurity has many routes to get merge into pharmaceutical products. It is approved by International Pharmacopoeia up to some level limit; it has recommendate to health concern for human use. They don't harm human being. A pharmaceutical impurity is unplanned synthesis of chemical entity, which has not listed chemical drug products; these are not accepted by IUPAC and other regulatory body. If it is shows in synthesis so it can be eliminated separately, identified cause by method development and solutions. So it will not get harm to anyone. There are multiple methods of segregation of impurity, organic volatile impurity can be absorb by gas chromatography method, it is under controlled to do safe and desired product as per pharmaceutical transcription. It can be leaching and forms various stages of synthesis as well as production steps. It can be eliminated before impurity proliferation goes up high in medicinal product. It has many subtitled types of impurity that can be check and eliminated through advance analytical technique. It is developed by through the understanding of environmental monitoring and defense purpose, so it is easy to remove air bubble in column and pump and get sharp linear and enough nonlinear resolution. Nonlinear peaks can extend to broad shape and it will be merging into linear peaks by the solutions selection criteria and it has a novelty of work. Also reduce the multiple using solutions and avoidance of hazardous solvent system means column don't get trouble shoot in other methods this is known other advantages of methods development for OVIs. This estimation is not unusual, when product looking around the bend educational analysis of product is important.

Keywords: GC; Pharmaceutical impurity; Active pharmaceutical ingredient; International pharmacopiea

Statement

India is the second largest country in the world of active pharmaceutical ingredient supplier. Implementation of Current good manufacturing practices intervention has chasing new heights in the field of science and technology. Acceptance of high quality product has first choice of vendors and it must be in reasonable cost, pharmaceutical impurity could not be a facility in pharmaceutical product, it has been compromising the effect of drugs. Due to ever –increasing failure rates, high cost, unsatisfactory safety profile and limited efficacy associated with production of drug key intermediate for active pharmaceutical ingredient and market cost differ by International Pharmacopeial standard. We invented economical new technology for estimation of residual solvents (so called organic volatile impurities listed in International Pharmacopoeias) by ultra-capillary GC methods.The synthesis of an active pharmaceutical ingredient (API) normally consists of several synthetic steps. Process-related impurities can be formed at any step and could ultimately appear in the final drug substance, particularly in the scale-up drug candidates. Impurities must be controlled because of their potential toxicity. Impurity control is a continuing concern of regulatory agencies and the pharmaceutical industry. The International Conference on Harmonization (ICH) was formed in the 1990s to coordinate the technical requirement for the registration of pharmaceuticals in the international union. The use of specialized injection, holding technology, time management and detection methods. Researchers have reported that OVIs with these experiences are more difficult to treat; many do not access treatment and those who do, frequently do not stay because of difficulty maintaining helping solvents coordination. The purpose of this study is to describe the experience of seeking help for residual solvents dependency by manufactures with a history of OVIs in the context in which it occurs [1-3]. Methodology & Technical Orientation: GC-2010 plus ultra-trace capillary column applications chemicals and

reagents water, methanol, ethanol, isopropyl alcohol, methylene chloride, chloroform, 1, 4-dioxane. Solvents were authorized from sigma-aldrich company (MO, USA).

Chromatographic condition following gas chromatographic specifications were selected

Column oven: inner volume: 31W × 283H × 187D mm, 17.0 liters, column pressure: 36kpa, Temp. Range: 73 ˚C (temperature dependency 50 ˚C to 73 ˚C), temp accuracy: + 1% of the temp. kelvin unit, over heat protection: up to 325ºC gradually. (b) Mobile phase: mobile phase: nitrogen (auto generator Nitrogen generator accessories and service used by almost all replication), flow rate: 10 mL/min, linear velocity: 20cm/s. (c) Injection port: temp. range: 153 ˚C, Injection port unit: Split injection unit as standard (split ratio 1:2), Auto injection unit. (d) Highest sensitivity in detectors ECD: Operational temp. Range: 153 ˚C, Type: Wide range type or linear type of amplifier. (e) Column specification: Type: Designed for residual. Composition: Cyanpropylphenyl polysoloxane (volatile), Diameter: 0.5mm I. D. x 30m lengths, Film thickness: 0.5 mm, Polarity: Polar (BP 624), Operation term: till 90 ˚C Programmed, Supplier: SGE listed manufacturer. Validation approach: Preparation of standard residual solvents. All working solutions have made with high quality grade water to get concentration of approved and banned residual solvents have prepared in combination listed in international pharmacopoeia setting). This method has established under international regulatory settings [4,5]. These experiments were conducted by means of process development, batch study, and various initial level registrations while I was at R& D Department as officer and R & D was performed in a private laboratory accredited by apex body government of India. Advances in GC through the novel techniques giving rise to new advancement. This clearly indicates that the dependency of hazards organic solvent those who banned in India is still evolving and needs close monitoring [6]. Central Drugs Standard Control Organization will see this matter over the use of residual solvents.

Significance

Pharmaceutical industry with organic solvents dependence and hazards with a history of residual solvents want help however the health and social services do not always recognize their calls for help or their symptoms of distress. Recommendations are made for treatment centers to become residual solvents trauma-informed that would help this recognition. On the basis of peak resolution identification OVIs has been easier to collect these concentrations.

Conclusion

The aacceptances limit and classification vary among the three major pharmacopoeias, usp, pheur and jp. Separation methods occupy an important place in the array of available analytical techniques, depending on the nature of the compounds, gas chromatography methods continue to be used to a large extent, especially in automated routine controls. The use of specialized injection and detection methods has reduced time of analysis. Further validation of gas chromatographic system for estimation of low level organic volatile impurities in hydro-alcoholic formulation which have been high prevalence in pharmaceutical industry. Especially hydro-alcoholic formulations there are non-existent estimation strategy for OVI activator. This method further increased its field of applications in various laboratory medicines.

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