ISSN: 0976-3031

Available Online at http://www.recentscientific.com

International Journal of Recent Scientific Research
Vol. 7, Issue, 9, pp. 13299-13301, September, 2016

International Journal of Recent Scientific Research

Research Article

LITERATURE REVIEW OF RECENT STABILITY INDICATING METHODS OF PHARMACEUTICAL DRUGS

Dackouo B[1]., Arama Dominique[4]., Mariko M[1]., Toure H. A[1]., Sangare M[2] and Bouklouze A[3]

[1]Laboratory of Chemistry FMOS-FAPH/University of Bamako-Mali
[2]Department of Neurology CHU-Point-G/University of Bamako-Mali
[3]Laboratory of Pharmacology and Toxicology FMPR/University of Rabat-Morocco
[4]National Directory of Pharmacy and Medicines/Ministry of Health-Republic of Mali

ARTICLE INFO

Article History:
Received 05th June, 2016
Received in revised form 21st July, 2016
Accepted 06th August, 2016
Published online 28th September, 2016

Key Words:
Stability Indicating Methods,
Pharmaceutical Drug, Review

ABSTRACT

In recent years, a certain number of stability indicating method studies of medicines has been undressed by different authors, and in many ways. We tried to discuss what has been written this last ten years, and we found that chromatographic and spectroscopic methods were more used to explore degradation products. These highly sophisticated and high-cost instrumentations used in stability indicating represent some challenges for developing country laboratories where there is sometimes a lack of qualified technicians and found to afford these equipment.

INTRODUCTION

Stability indicating methods (SIM) are required to the assessment of active ingredients and pharmaceutical drug's stability under certain conditions in order to define their expiry date. They may also be performed to identify the best storage condition [17, 20]. They are performed by submitting the analyte to stress conditions, and identifying or quantifying its active ingredient degradation products using an adequate analytical method [17, 20]. The regulatory guidelines of stability indicating are contained in the ICH Q1AR2, Q3BR2, Q6A and FDA 21 CFR [17].

Many authors tried to discuss SIM after they undertook experiments, by performing literature review or by discussing the regulatory guidelines.

The purpose of this literature review was to understand what was done this last decade about forced degradation studies to determine how the subject has been discussed and make the point of new trends in this heading.

In this study, we will also try to figure out whether there is a harmonization or not instability indicating methods.

METHOD

We collected all journal articles written that we found about stability indicating of pharmaceutical drugs from 2006 to 2016. As a result, we obtained 20 papers by using **Mendeley** ® which is internet based software for literature searching.

RESULTS AND DISCUSSION

In these last ten years, many authors focused their work on the stability indicating by investigating a literature review. It was the case of Sehrawat and all, who worked on journal articles targeting the regulatory aspects for the development of stability indicating methods to differentiate actives pharmaceutical ingredient from it potential decomposition product according to the Regulatory guidance in ICH Q1AR2, Q3BR2, Q6A and FDA 21 CFR, and made the conclusion that forced degradation study is required to demonstrate the specificity when developing such methods [17]. This was supported by Blessy and all that discussed the recent trend in forced degradation study and proposed a new strategy of conducting study on degradation mechanism and a new analytical method for stability indication development [4]. In contrast, other authors discussed their results after conducting experiments like Aubrey and all, who confirmed that the assessments of small molecule of pharmaceutical stability depend firstly on an

*Corresponding author: **Dackouo B***
Laboratory of Chemistry FMOS-FAPH/University of Bamako-Mali

available chromatographic or another Separative method that can quantify impurities and degradation products. In 2009 they outlined a staged approach to HPLC method development, in accordance with the regulatory guidelines of performing drugs stability indicating [1]. In 2016, Salman and all used HPLC and FT-NMR to assess the stability of Ifosfamide and its degradation products, and found that the degradation product detected by NMR was not found in HPLC-NMR [17]. Then in 2013, Bushra and all described the behavior of Ciprofloxacin Hydrochloride under acidic, basic, oxidation, UV radiation and thermal stress conditions according to ICH forced degradation study guidelines by HPLC -C18(25 cm x 4.6 mm, 5 µm, Phenomenex) and found that the oxidation condition more significant than the others [5]. Moreover, Bhutani and all used in 2007 the ICH conditions of thermal stress, hydrolysis, oxydation, and photolysis to analyse Isoniazydes by HPLC-C18 and the drug was stable at 50 and 60 ° C [2]. Then in 2008, Bianchini and all worked on Pridino mesylate by visible and long wavelength UV-light under ICH guideline under different conditions and found that acidic and photolytic conditions were more effective [3]. A forced degradation study was performed in 2014 on new drugs on conditions more severe than accelerated condition under-specificity of stability methods, in addition, they tried to figure-out how drugs are degraded, then elucidated their structure [4]. Provided the complexity instability indicating methods, Hubert and All performed in 2014 a case study using Liquid Chromatography and obtained a beneficial effect on impurity exploration instability testing [7]. Joci and all tried in 2009 to assess Eletriptan hydrobromide stability by LC and LC-MS and found that this method meets the conditions of ICH guidelines [8]. Khedr and all performed in 2008 a study of Betahistine stability indicating by HPLC and found that it was labile at light and oxygen rich media [9]. Louati and all assessed in 2011 Sulfatimethoxine by HPLC according to ICH guidelines and found that it were highly sensitive to basic hydrolysis and oxidation. They also tried to understand the mechanism of degradation of this medicine [10]. Marques and all assessed in 2011 the stability of Galantamin hydrobromid which is an anti-Alzeimer drug under stress acidic, alkaline, thermal, photolytic and oxidative conditions and found degradation under acidic, photolytic and oxidative conditions, but, in contrast the drug was stable in alkaline and elevated temperature conditions [11]. Mistiri and all investigated in 2012 Florfenicol in presence of its two identified degradation products (thiamphenicol and chloramphenicol) by LC and LC-MS and found that the drug was stable in the solid state but unstable in solution under acidic, alkaline and photolytic stress conditions [12]. Moussa and all used RP-HPLC and HPTLC to assess in 2010 the stability of Olmesartran Medoxomil in presence of its acidic and alkaline induced degradation products found a successful method as well in acidic as in alkaline stress condition [13]. Naguib and all compared in 2012 Mebeverine hydrochloride and Sulpiride in pharmaceutical preparation by multivariate regression methods of UV spectra in a stability indicating test and the proposed method was successful in pharmaceutical tablet monitoring [14]. Rajput and all monitored in 2000 Cefixim Trihydrate stability by the spectrometric method under acidic hydrolysis, alkaline hydrolysis and oxidation stress conditions and found that it degrade extremely under these conditions [15]. Vazquez and all used in 2009 HPLC-MS-MS to assess the stability of both water and fat soluble vitamins in parenteral admixture, and the method proved to be stability indicating in accordance with the ICH guidelines about the subject [19]. Not only manufactured medicines were studied but also some medicinal plants were also assessed. An assay undertaken by Syed and all in 2015 showed that the stability-indicating method could be employed to determine curcumin in bulk and emulsions [18].

Ours bibliographic study was challenged by the fact that we could not get access to the results of all these papers.

CONCLUSION

In this last decade, many authors tried to discuss stability indicating. They usually used chromatography and Infra Read /UV spectroscopy to identify or quantify forced degradation products. These methods are challenged by their high coast or their need to be performed by high skilled lab workers. These two criteria made it difficult for these analytical methods to operational in developing countries. We therefor recommend the use of capillary electrophoresis instability indicating.

References

1. Aubry. A.F, Tattersall. P, Ruan. J. Development of stability indicating methods. *Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices 2009: 139-61*
2. Bhutani. H, Singh. S, Vir. S, Bhutani.K. K, Kumar. R, Chakraborti.A.K, Jindal. K. C. LC and LC-MS study of stress decomposition behaviour of isoniazid and establishment of validated stability-indicating assay method. *Journ.of Pharm and Biomedical Analysis 2007, 43(4) :1213-20*
3. Bianchini. R.M, Castellano. P. M, Kaufman. T. S. Validated stability-indicating HPLC method for the determination of pridinol mesylate. Kinetics study of its degradation in acid medium. *Journ of Pharm and Biomed Anal 2008, 48 (4): 1151-60*
4. Blessy.M, Patel.V, Prajapati.P.N, AgrawalY.K. Development of forced degradation and stability indicating studies of drugs-A review. *Journal of Pharmaceutical Analysis 2014, 4(3):159-65*
5. Bushra.U, Huda.N, Mostafa.M, Sultan.Z, Rahman.A. Study of forced degradation of ciprofloxacin HCl indicating stability using RP-HPLC method. *Der Pharma Chemica2013, 5 (6): 132-37*
6. European Medicines Agency. Guideline on bioanalytical method validation. *EMA Guideline 2012.July 2011;(44), 1-23*
7. Hubert.C, Lebrun.P, Houari.S, Ziemons.E, Rozet.E, Hubert.Ph. Improvement of a stability-indicating method by Quality-by-Design versus Quality-by-Testing: A case of a learning process. *Jour of Pharm and Biomed Anal 2014, (88): 401-09*
8. Joci. B, Mira. Z, Ivanovi. L, Ana. P, Jadranin. M, Vajs. V. Study of forced degradation behavior of Eletriptan hydrobromide by LC and LC-MS and development of stability-indicating method. *Journ of Pharm and Biomed Anal 2009, 50 (4): 622-29*
9. Khedr. A, Sheha. M. Stress degradation studies on betahistine and development of a validated stability-

indicating assay method. *Journal of Chromatography B 2008, 869 (1-2): 111-17*

10. Louati. K, Mistiri. F, Kallel. M, Safta. F. Stress degradation study on sulfadimethoxine and development of a validated stability-indicating HPLC assay. *Elsevier Masson SAS (Annales pharmaceutiques françaises) 2011, 69(2): 91-9*
11. Marques.L.A, Maada.I, Kanter.F.J.J, Lingeman.H, Irth.H, Wilfried.M, Niessen.A, Giera.M.Stability-indicating study of the anti-Alzheimer's drug galantamine hydrobromide. *Journ of Pharm and Biomed Analy 2011, 55(1):85 -92*
12. Mistiri.F, Louati.K, Grissa.O, Kallel.M, Safta.F. Study of forced degradation behaviour of florfenicol by LC and LC-MS and development of a validated stability-indicating assay method. *Annales Pharmaceutiques Françaises 2012, 70 (6):333-47*
13. Moussa. B,Mohamed. M, Youssef. N. Acid-alkali degradation study on olmesartan medoxomil and development of validated stability-indicating chromatographic methods. *Journal of the Chilean Chemical Society 2010, 55(2): 199-02*
14. Naguib.I.A, Darwish.H.W. Support vector regression and artificial neural network models for stability indicating analysis of mebeverine hydrochloride and sulpiride mixtures in pharmaceutical preparation: A comparative study. *Spectrochimica Acta - Part A: Molecular and Biomolecular Spectroscopy 2012, (86): 515-26*
15. Rajput.S.J, Gandhi.S.P. Study of degradation profile and development of stability indicating methods for cefixime trihydrate. *Indian Journal of Pharmaceutical Sciences 200, 71(4):438*
16. Salman.D, Peron.J.M.R, Goronga.T, Barton.S, Swinden.J, Nabhani-Gebara.S. HPLC and NMR-based forced degradation studies of ifosfamide: The potential of NMR in stability studies. *Annales Pharmaceutiques Françaises 2016, (74):119-28*
17. Sehrawat.R, Maithani.M, Singh.R. Regulatory Aspects in Development of Stability-Indicating Methods: A Review. Chromatographia 2010, 72(1):1-6
18. Syed.H.K, Liew.K.B, Loh.G.O.K, Peh.K.K. Stability indicating HPLC-UV method for detection of curcumin in Curcuma longa extract and emulsion formulation. *Elsevier Food Chemistry 2015, 170: 321-26*
19. Vazquez.R, Rotival.R, Calvez.S, Hoang.M.D, Graffard.H, Guyon.F, Do.B. Stability Indicating Assay Method on Vitamins: Application to their Stability Study in Parenteral Nutrition Admixtures. *Chromatographia 2009, 69 (7-8): 629-35*
20. Walz.R, Knauf.M. Vorgaben und Durchführung von Stabilitätsprüfungen pharmazeutischer Wirkstoffe und Arzneimittel. *Wissenschaft und Technik: Originale Pharm. Ind 200,; 70(9) :1135-39*

****

How to cite this article:

Dackouo B *et al*.2016, Literature Review of Recent Stability Indicating Methods of Pharmaceutical Drugs. *Int J Recent Sci Res.* 7(9), pp. 13299-13301.