

Common Stability Indicating Chromatographic Methods in Shelf Life Prediction of Pharmaceutical Preparations

Monajjemzadeh F*

Department of Pharmaceutical and Food Control, Tabriz University of Medical Sciences, Tabriz, Iran

Shelf life determination of different dosage forms of a drug substance should be performed prior to manufacturing as well as the final preparation to ensure the producer and also the consumer about the quality and the stability of the medicinal product before reaching the expiration date.

According to ICH guidelines (ICH Topic Q1E) the shelf life determination needs real time data and no extrapolation is permitted. For example a drug product that is labeled to be stored at room temperature should be preserved at $25 \pm 2^\circ\text{C}$ and $60 \pm 5\%$ RH (Long term studies) and the mean percentage of the remaining drug at predetermined time intervals (every 3 months for first year) should be reported in initial drug product submission and will be completed and sent over the specified expiration date to regulation authorities. The rule indicates that the time at which the line for the 95% lower one sided confidence interval of the mean intersects the lower acceptance criteria of a special drug product according to pharmacopeial monograph is to be determined as the shelf life [1]. Accordingly Arrhenius method is no longer accepted in ICH because an extrapolation to room temperature is needed to report the shelf life.

There is another ICH approach based on the quantification of the degradation product of a certain drug substance within a drug product [1]. The main prerequisite for this is the complete qualification of the degradation product and the presence or introduction of a stability indicating analytic method to distinguish between the drug compound and its degradation product [2]. In order to establish a stability indicating method, liquid and solid samples of drug substance is exposed to stress conditions such as high temperature and high humidity and or extremes of pH as well as mechanical stresses [3-6]. The proposed analytical method should be able to present the pure drug response as well as some degradation products.

Among different analytical methods special attention is given to chromatographic methods due to their ease of application and high accuracy and precision [7-18].

Different chromatographic methods can be applied in order to evaluate the stability of a drug substance within a drug product. If a drug has different dosage forms such as tablet, oral solution and or transdermal delivery systems, the stability of the drug product in each dosage form should be established individually. Usually a same analytical method linked to special extraction techniques can be applied to different drug dosage forms [19,20]. High pressure Liquid Chromatography is a beneficent analytical tool in this area.

Thin Layer Chromatography (TLC) is a simple and high output technique to follow the drug molecule and its known degradation products [21-23]. Unfortunately the only way to gain quantitative data through common TLC is to scratch the absorbent layer on the plate and subsequent analysis which is not accurate and precise and is also applied to reach preparative goals [24-27]. High pressure Thin Layer Chromatography (HPTLC) is a modern technique based on common TLC and provides reliable quantitative data [28,29]. The unique performance of HPTLC is related to its specific solvent running system as well as efficient detectors such as Photo Diode Array (PDA) and

Florescent with full scanning option [29,30]. In shelf life prediction of a new drug product, stability indicating chromatographic methods such as HPTLC and HPLC can be applied successfully.

The most time consuming step in HPLC is the method set up procedure especially in stability indicating ones. It should be noted that HPTLC is a low cost and more convenient method compared to HPLC and can be utilized in order to provide as useful data as HPLC [29,31]. The reason is based on the low solvent volume and almost cheap stationary phases compared to HPLC. Any spot in HPTLC can be detected via PDA or florescent detector qualitatively and quantitatively. If the stationary and mobile phases in HPTLC are being selected as similar as to HPLC the successful HPTLC method can be considered as a fundamental method to initialize HPLC method as well.

Acknowledgement

The author would like to thank Dr. Fatemeh Fathiazad for her practical consult in HPTLC technique.

References

1. ICH Harmonised Tripartite Guideline Evaluation for Stability Data Q1E.
2. Carstensen JT, Rhodes CT (2000) Drug Stability: Principles and Practices. Informa Healthcare.
3. Aulton ME, Taylor K (2013) Aulton's pharmaceuticals: The design and manufacture of medicines. Elsevier Health Sciences.
4. Bakshi M, Singh B, Singh A, Singh S(2001) International Conference on Harmonization : The ICH guidance in practice: stress degradation studies on ornidazole and development of a validated stability-indicating assay. J Pharm Biomed Anal 26: 891-897.
5. Singh S, Junwal M, Modhe G, Tiwari H, Kurmi M, et al. (2013) Forced degradation studies to assess the stability of drugs and products. Trends Analyt Chem 49: 71-88.
6. Jain D, Basniwal PK (2013) Forced degradation and impurity profiling: recent trends in analytical perspectives. J Pharm Biomed Anal 86: 11-35.
7. Singh S, Singh B, Bahuguna R, Wadhwa L, Saxena R (2006) Stress degradation studies on ezetimibe and development of a validated stability-indicating HPLC assay. J Pharm Biomed Anal 41: 1037-1040.
8. Singh S, Bakshi M (2000) Guidance on Conduct of Stress Tests to Determine Inherent Stability of Drugs. Pharm Technol 4: 1-14.

*Corresponding author: Farnaz Monajjemzadeh, Department of Pharmaceutical and Food Control, Tabriz University of Medical Sciences, Tabriz - 5166414766, Iran, Tel: +984113392606; E-mail: Monajjemzadeh@tbzmed.ac.ir

Received July 22, 2014; Accepted July 24, 2014; Published July 28, 2014

Citation: Monajjemzadeh F (2014) Common Stability Indicating Chromatographic Methods in Shelf Life Prediction of Pharmaceutical Preparations. J Mol Pharm Org Process Res 2: e116. doi: [10.4172/2329-9053.1000e116](http://dx.doi.org/10.4172/2329-9053.1000e116)

Copyright: © 2014 Monajjemzadeh F. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited

9. Chaudhari BG, Patel NM, Shah PB (2007) Stability indicating RP-HPLC method for simultaneous determination of atorvastatin and amlodipine from their combination drug products. *Chem Pharm Bull (Tokyo)* 55: 241-246.
10. Chaudhari BG, Patel NM, Shah PB, Patel LJ, Patel VP (2007) Stability-indicating reversed-phase liquid chromatographic method for simultaneous determination of atorvastatin and ezetimibe from their combination drug products. *J AOAC Int* 90: 1539-1546.
11. Patil KR, Rane VP, Sangshetti JN, Shinde DB (2009) Stability-indicating LC method for analysis of lornoxicam in the dosage form. *Chromatographia* 69: 1001-1005.
12. Ramesh T, Rao PN (2013) Development and validation of a stability-indicating RP-HPLC assay method and stress degradation studies on dapiprazole. *J Chromatogr Sci* 51: 856-860.
13. Prashanth KN, Basavaiah K, Raghu MS, Xavier CM, Vinay KB (2013) Determination of Flunarazine Dihydrochloride in Bulk Drug and Tablets by RP-UPLC: A Stability-Indicating Assay. *Proceedings of the National Academy of Sciences, India Section A: Physical Sciences* 83: 79-88.
14. Hammouda ME, Abu El-Enin MA, El-Sherbiny DT, El-Wasseef DR, El-Ashry SM (2013) Microemulsion Liquid Chromatographic Method for Simultaneous Determination of Simvastatin and Ezetimibe in Their Combined Dosage Forms. *Journal of analytical methods in chemistry* 2013: 1-9
15. Zaazaa HE, Mohamed AO, Abdelkawy M, Hawwam MA (2013) Stability indicating chromatographic techniques for the determination of pipoxolan HCl. *Journal of Applied Pharmaceutical Science* 3: 66-73.
16. Mohamed NA, Ahmed S, El Zohny SA (2014) A specific high-performance thin-layer chromatography with fluorescence detection for the determination of some a; 1-Blockers. *J Liq Chromatogr Relat Technol*
17. Monajjemzadeh F, Hassanzadeh D, Valizadeh H, Siahi MR, Shahbazi Mojarrad J, et al. (2009) Assessment of feasibility of Maillard reaction between baclofen and lactose by liquid chromatography and Tandem mass spectrometry, Application to Pre formulation studies. *AASP Pharm Sci Tech* 10: 649-659.
18. Monajjemzadeh F, Ebrahimi F, Zakeri-Milani P, Valizadeh H (2014) Effects of Formulation Variables and Storage Conditions on Light Protected Vitamin B12 Mixed Parenteral Formulations. *Adv Pharm Bull*.
19. AlAani H, Alashkar I, Karabet F (2013) Development and validation of stability-indicating RP-HPLC method for the determination of Levocabastine HCl in bulk drug and in ophthalmic suspensions. *Arabian Journal of Chemistry*.
20. Varghese SJ, Ravi TK (2013) quantitative simultaneous determination of fenofibrate, atorvastatin, and ezetimibe in tablets using gradient high-performance column liquid chromatography and high-performance thin-layer chromatography. *J Liq Chromatogr Relat Technol* 37: 2784-2799
21. Belal F, Ibrahim F, Khedr A, Elawady T (2014) Stability Indicating TLC Method for the Determination of Rosuvastatin and Identification of Some Degradation Products Using Electrospray Ionization Mass Spectrometry. *J Liq Chromatogr Relat Technol* 37: 1114-1132.
22. Ahmad S, Rizwan M, Parveen R, Mujeeb M, Aquil M (2008) A validated stability-indicating TLC method for determination of forskolin in crude drug and pharmaceutical dosage form. *Chromatographia* 67: 441-447.
23. Sanyal S, Datta A, Chakrabarti A (1992) Stability indicating TLC method for the quantification of tinidazole in pharmaceutical dosage form-iv fluid. *Drug Dev Ind Pharm* 18: 2095-2100.
24. Monajjemzadeh F, Hassanzadeh D, Valizadeh H, Siahi-Shadbad M R, Mojarrad J S, Robertson T A, et al. (2011) Detection of gabapentin-lactose Maillard reaction product (Schiff's Base): Application to solid dosage form preformulation. Part 1. *pharmind: The Pharmaceutical Industry* 73: 174-177.
25. Bebawy LI (1998) Stability-indicating method for the determination of meloxicam and tetracaine hydrochloride in the presence of their degradation products. *Spectrosc Lett* 31: 797-820.
26. Lotfy HM, Abd El-Moneim Abosen MM, El-Bardicy MG (2010) Stability-indicating methods for the determination of famciclovir in the presence of its alkaline-induced degradation product. *Drug Test Anal* 2: 188-199.
27. Abdel-Fattah LS, El-Sherif ZA, Kilani KM, El-Haddad DA (2010) HPLC, TLC, and first-derivative spectrophotometry stability-indicating methods for the determination of tropisetron in the presence of its acid degradates. *J AOAC Int* 93: 1180-1191.
28. Spangenberg B, Poole CF, Weins C (2011) Quantitative thin-layer chromatography: a practical survey. Springer.
29. Loescher CM, Morton DW, Razic S, Agatonovic-Kustrin S (2014) High performance thin layer chromatography (HPTLC) and high performance liquid chromatography (HPLC) for the qualitative and quantitative analysis of *Calendula officinalis*—Advantages and limitations. *J Pharm Biomed Anal* 98: 52-59.
30. Zlatkis A, Kaiser RE (2011) HPTLC-high performance thin-layer chromatography. Elsevier.
31. Ansari MJ, Ahmad S, Kohli K, Ali J, Khar RK (2005) Stability-indicating HPTLC determination of curcumin in bulk drug and pharmaceutical formulations. *J Pharm Biomed Anal* 39: 132-138.

Citation: Monajjemzadeh F (2014) Common Stability Indicating Chromatographic Methods in Shelf Life Prediction of Pharmaceutical Preparations. *J Mol Pharm Org Process Res* 2: e116. doi: [10.4172/2329-9053.1000e116](https://doi.org/10.4172/2329-9053.1000e116)

Submit your next manuscript and get advantages of OMICS Group submissions

Unique features:

- User friendly/feasible website-translation of your paper to 50 world's leading languages
- Audio Version of published paper
- Digital articles to share and explore

Special features:

- 350 Open Access Journals
- 30,000 editorial team
- 21 days rapid review process
- Quality and quick editorial, review and publication processing
- Indexing at PubMed (partial), Scopus, EBSCO, Index Copernicus and Google Scholar etc
- Sharing Option: Social Networking Enabled
- Authors, Reviewers and Editors rewarded with online Scientific Credits
- Better discount for your subsequent articles

Submit your manuscript at: <http://www.omicsonline.org/submission/>

