e-ISSN:2320-0812
p-ISSN:2347-2340

Research and Reviews: Journal of Pharmaceutical Analysis

Method development and Validation Parameters of UV- A Commentary

Durga aruna R*

Department of Pharmacy, Vagdevi College of Pharmacy, Gurazala, AP, India

Commentary Article

Received: 04/05/2015
Revised: 27/05/2015
Accepted: 02/06/2015

***For Correspondence**

Department of Pharmacy, Vagdevi College of Pharmacy, Gurazala, AP, India

Keywords: UV spectrophotometer, Reagents, Beer's Law, Lambert's Law

ABSTRACT

Investigative routines improvement must be approved to give solid information to administrative entries. These strategies are vital for various purposes, including testing for quality control discharge, testing of steadiness tests, testing of reference materials and to give information to bolster details.

COMMENTARY

Introduction

UV-Visible spectrophotometry is one of the most frequently employed technique in pharmaceutical analysis. It involves measuring the amount of ultraviolet or visible radiation absorbed by a substance in solution. Instrument which measure the ratio, or function of ratio, of the intensity sof two beams of light in the U.V-Visible region are called Ultraviolet-Visible spectrophotometers. Validated analytical methods play a major role in achieving this goal. The results from method validation can be used to judge the quality, reliability and consistency of analytical results, which is an integral part of any good analytical practice [1].

Beer's law: It states that the intensity of a beam of parallel monochromatic radiation decreases exponentially with the number of absorbing molecules. In other words, absorbance is proportional to the concentration [2,3].

Lambert's law: It states that the intensity of a beam of parallel monochromatic radiation decreases exponentially as it passes through a medium of homogeneous thickness. A combination of these two laws yields the Beer-Lambert law [4-9].

Apparatus

A Shimadzu UV–visible spectrophotometer (UV scaled down 1700, Shimadzu Corporation, Kyoto, Japan) was utilized for all absorbance estimations with coordinated quartz cells [10-13].

Materials & Methods

All chemicals and reagents were of logical evaluation.

e-ISSN:2320-0812
p-ISSN:2347-2340

Determination of wavelength of greatest retention

Method Development

It is the procedure of demonstrating that a logical strategy is adequate for utilization to quantify the centralization of an API in a particular exacerbated measurement structure which permits disentangled strategies to be utilized to confirm that an investigation methodology, precisely and reliably will convey a dependable estimation of a dynamic fixing in an intensified arrangement [14-25].

Validation

Validation is a procedure of building up narrative proof showing that a system, procedure, or movement did underway or testing keeps up the craved level of consistence at all stages. The scientific strategy approval is vital for diagnostic technique improvement and tried widely for specificity, linearity, exactness, accuracy, range, location limit, quantization cutoff, and vigor [26-34]. In synopsis, systematic strategy advancement and acceptance permits to affirm that a precise and dependable intensity estimation of a pharmaceutical planning can be performed.

Validation parameters

The goal of the diagnostic strategy ought to be plainly comprehended since this will administer the approval attributes which need to be assessed. Average approval attributes which ought to be considered are recorded underneath [35,36]

- Linearity
- Precision
- Repeatability
- Accuracy
- Specificity
- Detection Limit
- Quantitation Limit
- Range

Linearity

Linearity of system was controlled by get ready standard arrangements at diverse focus levels. The alignment bend of medication over the focus run 15-90 µg/mL was plotted and its linearity was assessed by straight relapse investigation [37-40].

Accuracy

The exactness of an explanatory system portrays the closeness of individual measures of an analyte when the method is connected more than once to numerous aliquots of a solitary homogeneous volume of an organic lattice. Accuracy is further subdivided into inside of keep running, inside of day exactness... or repeatability, which evaluates exactness amid a solitary systematic run, and between-keep running, between day repeatability ... additionally named transitional exactness, which measures the exactness with time (regularly days) and may include diverse experts, gear, and reagents. Reproducibility is a third level of accuracy that is evaluated by method for a between lab trial (institutionalization) and is not piece of the showcasing approval dossier.

In the writing, the accuracy of systematic strategies is frequently inadequately reported (as a result of poor estimations)

e-ISSN:2320-0812
p-ISSN:2347-2340

Precision ought to be measured utilizing at least five determinations (recreates) every focus. At least three focus levels (low, medium and high) in the scope of the normal focuses is suggested.

The accuracy of a systematic strategy is normally communicated as the difference, standard deviation or coefficient of variety of a progression of estimations.

Precisions are helpfully communicated by the relative standard deviation (RSD)

$$RSD = 100 \times \frac{SD\,assay}{X}\%$$

Inter-day precision

Repeatability is the capacity to discover a quality as close as could reasonably be expected to the same worth (10 µg/mL) with the 5 imitates over the 3 days; we have 3 appraisals of this difference (0.294, 0.866 and 0.3099) and their mean is 0.4905 i.e. the WMS [41-45].

For all intents and purposes this fluctuation is communicated as a RSD (%CV) with:

This is the most reduced conceivable variability connected with this strategy of estimation. From everyday the figured means can be marginally diverse.

Variance of repeatability (or within day variance) is composed. It is the most minimal conceivable difference for a given logical run (same day, same investigator, and so forth.). It is evaluated by the lingering of the ANOVA that is completed. It is connected with the duplicate to-reproduce variety.

Reproducibility

The variety emerging utilizing the same estimation process among diverse instruments and administrators, and over more time periods.

Accuracy

Accuracy of the system is found out by standard expansion strategy at 3 levels. The exactness of the system was controlled by computing recuperation of GFX by the technique for expansion. Known measure of GFX at 25%, 50%, 100%, and 150% was added to a prequantified specimen arrangement. The recuperation studies were completed in the tablet in triplicate each in the vicinity of placebo. The mean rate recuperation of GFX at every level was at least 99% and not more than 101 [46,47]. The recuperation studies were completed by including distinctive sums (80%,100%,120%) of the unadulterated medication to the preanalyzed plan. The arrangements were arranged in triplicates and the % recuperation was computed [49-50].

s

REFERENCES

1. Trivedi DK, Iles RK. The Application of SIMCA P+ in Shotgun Metabolomics Analysis of ZIC®HILIC-MS Spectra of Human Urine - Experience with the Shimadzu IT-T of and Profiling Solutions Data Extraction Software. J Chromat Separation Techniq. 2012; 3:145
2. AP Rani et al. Determination of Memantine Hydrochloride by Spectrophotometry using Anionic Dyes, Bromothymol Blue and Solochrome Black T, in Bulk and Tablet Dosage Forms. Chemical Sciences Journal, Vol. 2012: CSJ-60

3. Androniki Tosca. Evaluation of pigmented skin lesions with optical computed tomography. J Clin Exp Dermatol Res. 2014; 5: 2
4. Anju A et al. Novel mass spectrometry method for the quantification of immuno-suppressant drug in human whole blood. J Anal Bioanal Techniques 2012; 3:7
5. U. Sravani et al. Derivative spectrophotometric methods for the determination of Zolpidem Tartrate. J Bioequiv Availab. 2012; 4: 3
6. C. N. Saketha et al. Spectrophotometric methods for the determination of Zolpidem Tartrate in acetate buffer. Bioequiv Availab. 2012; 4: 3
7. G. Hima Bindu et al. Analytical method development for the determination of Olopatadine. J Bioequiv Availab.2012; 4.3
8. Divya et al. Derivative spectrophotometric method for the determination of Olopatadine. J Bioequiv Availab. 2012; 4.3
9. V. Amrutha Sindhuja and M. Mathrusri Annapurna. Derivative spectrophotometric method for the determination of Moxifloxacin in pharmaceutical formulations. J Bioequiv Availab. 2012; 4.3
10. Igarashi H et al. Characteristic Features of an Analytical Column with a Pentafluorophenylpropyl Stationary Phase Applied To a Determination of a Fluorinated Phenyl Alanyl Derivative Compound, Gw823093, In Human Urine Using an Lc-Esi-Ms/Ms Method. J Anal Bioanal Techniques. 2011; S5:001.
11. An LTT et al. Statistical Analysis of Protein Microarray Data: A Case Study in Type 1 Diabetes Research. J Proteomics. Bioinform. 2014; S12:003.
12. Kalyon DM et al. Twin Screw Extrusion Based Technologies Offer Novelty, Versatility, Reproducibility and Industrial Scalability for Fabrication of Tissue Engineering Scaffolds. J Tissue Sci Eng. 2013; 4: e126.
13. Zhang Y. Ideal Open Access (OA2) and the Lineage of Reproducibility. Adv Genet Eng. 2013; 2:e102.
14. Zhang Y. Open Access (OA) and the Heritage of Research Reproducibility. Aging Sci. 2013; 1:e104.
15. Dare M et al. Method Validation for Stability Indicating Method of Related Substance in Active Pharmaceutical Ingredients Dabigatran Etexilate Mesylate by Reverse Phase Chromatography. J Chromatogr Sep Tech. 2015; 6:263.
16. Lu Y et al. Development and Optimization of a RP-HPLC Method to Quantify Midazolam in Rat Plasma after Transdermal Administration: Validation and Application in Pharmacokinetic Study. Pharm Anal Acta. 2015; 6:329.
17. Kumari KP et al. Stability Indicating RP-HPLC method Development and Validation of Salicylic Acid in Choline Magnesium Trisalicilate (Trilisate) Tablets. J Pharma Care Health Sys. 2014; 1:120.
18. Gupta V et al. HPLC Method Development for Naringenin and its Glucoside in Rat Serum and their Bioavailibilty Studies. J Bioequiv Availab; 2012; S14:010.
19. Omer HA et al. Histopathological Changes in Placenta of Rat Induced by Levtricetam. Int J Neurorehabilitation. 2014; 1:134.
20. Zankhana Pramodchandra Sheth. Formulation and characterization of osmotic delivery of Levetiracetam. Pharmaceut Anal Acta. 2013; 4:2
21. Shweta T et al. A case study of phenytoin-induced Stevens-Johnson syndrome in seizure disorder patient with type 2 Diabetes mellitus. J Pharmacovigilance. 2014; 2:5
22. Sengottuvel Viswanathan. Drug utilization study of anti-epileptic drugs in pediatric population. J Neurol Neurophysiol. 2014; 5:5
23. Rajesh Kumar Guru et al. A comparative 2D QSAR analysis of levetiracetam & its analogs: The inhibitor of glioblastoma, by different statistical techniques: MLR, PLS, SVM, ANN. Med chem; 2013 3:4
24. Biro S et al. A Comparative Study of Olmesartan and Valsartan on Insulin Sensitivity in Hypertensive Patients with Diabetes Mellitus or Impaired Glucose Tolerance (OVIS Study). Clin Pharmacol Biopharm. 2014; 3:118.
25. Sanad MH and Borai EH Chromatographic Separation and Utilization of Labeled 99mTc-Valsartan for Cardiac Imaging. J Mol Imag Dynamic. 2014; 4:114.
26. Hafez HM et al. Quantitative Determination of Amlodipine Besylate, Losartan Potassium, Valsartan and Atorvastatin Calcium by HPLC in their Pharmaceutical Formulations. J Chromatograph Separat Techniq. 2014; 5:226.

27. Seetharaman R, Lakshmi KS. Development and Validation of a Reverse Phase Ultra Performance Liquid Chromatographic Method for Simultaneous Estimation of Nebivolol and Valsartan in Pharmaceutical Capsule Formulation. J Chromatograph Separat Techniq. 2014; 5:229.
28. D. SANTHI. REMOVAL OF FLUORIDE BY USING DRUMSTICK BARK AND ITS LEAVES. Jr. of Industrial Pollution Control. 2007; 23: 357-359
29. Tyagi A et al. HPTLC-Densitometric and RP-HPLC Method Development and Validation for Determination of Salbutamol Sulphate, Bromhexine Hydrochloride and Etofylline in Tablet Dosage Forms. Pharm Anal Acta. 2015; 6:350.
30. Patelia EM et al. Bio-Analytical Method Development and Validation for Estimation of Lume fantrine in Human Plasma by Using Lc-Ms/Ms. Biomedical Data Mining. 2015; 3:111.
31. Chauhan A et al. Analytical Method Development and Validation: A Concise Review. J Anal Bioanal Tech. 2015; 6: 233.
32. Sujana K et al. A Novel Validated Analytical Method Development for the Binary Mixture of Mebeverine and Chlordiazepoxide in Pharmaceutical Formulation and its Application to Stress Studies. Pharm Anal Acta. 2015; 6:324.
33. Behera S et al. UV-Visible Spectrophotometric Method Development and Validation of Assay of Paracetamol Tablet Formulation. J Anal Bioanal Techniques. 2012; 3:151.
34. Naser L. Rezk Innovation in method development; Drugs solubility and stability during bioanalysis process. J Bioequiv Availab. 2012; 4.3
35. Shalini Gupta and Saurabh Srivastava. Development and validation of HPLC method for the determination of 5-fluorouracil as intra oral nanogel for oral cancer treatment. J Cell Sci Ther. 2015; 6:2
36. Sonawane LV et al. Bioanalytical Method Validation and Its Pharmaceutical Application- A Review. Pharm Anal Acta. 2014; 5:288.
37. Asha latha. Identification, estimation & determination of residual solvents of Olanzapine in bulk & formulation by HPLC, GC & IR. Pharmaceut Anal Acta. 2013; 4:2
38. Nikunj Patela et al. Stability indicating RP-HPLC method for simultaneous estimation of Diclofenac potassium, Paracetamol and Methocarbamol. Pharmaceut Anal Acta. 2013, 4:2
39. Magda Ali Akl. Development and validation of a liquid chromatographic method for the determination of cefdinir residues on manufacturing equipment surfaces. J Anal Bioanal Tech. 2013; 4:5
40. Hafez HM. Quantitative Determination of Amlodipine Besylate, Losartan Potassium, Valsartan and Atorvastatin Calcium by HPLC in their Pharmaceutical Formulations. Pharm Anal Acta. 2014; 5:300.
41. Antil P. UPLC Method for Simultaneous Determination of Valsartan & Hydrochlorothiazide in Drug Products. J Chromat Separation Techniq. 2013, 4:182.
42. Schindera C et al. Early Development of Arterial Hypertension in an Infant with Valsartan Fetopathy. J Neonatal Bio. 2012; 1:103.
43. Sunkara G et al. Assessment of Ethnic Differences in the Pharmacokinetics and Pharmacodynamics of Valsartan. J Bioequiv Availab. 2010; 2: 120-124.
44. Nevado JJB et al. Reliable and Sensitive SPE-HPLC-DAD Screening of Endocrine Disruptors Atrazine, Simazine and their Major Multiresidues in Natural Surface Waters: Analytical Validation and Robustness Study Perfomance. J Chromatograph Separat Techniq. 2014; 5:215.
45. Anbumathi P et al. Quantitative Analysis of a Dynamic Cell Cycle Regulatory Model ofSchizosaccharomyces pombe. Curr Synthetic Sys Biol. 2013; 1:105.
46. Schrum AG and Gil D. Robustness and Specificity in Signal Transduction via Physiologic Protein Interaction Networks. Clin Exp Pharmacol. 2013; S3:001.
47. Passe U. The Next Challenges Ahead: Design Integration and Robustness. J Archit Eng Tech. 2012; 1:e105.
48. Li H and Wang L. Consistent Estimation in Generalized Linear Mixed Models with Measurement Error. J Biomet Biostat. 2012; S7:007.
49. Fayyad MK et al. Effect of Temperature, Wavelength, pH, Ion Pair Reagents and Organic Modifiers' Concentration on the Elution of Cystatin C. Stability of Mobile Phase. J Anal Bioanal Tech. 2010; 1:103.

50. Asha latha. Identification, estimation & determination of residual solvents of Olanzapine in bulk & formulation by HPLC, GC & IR. Pharmaceut Anal Acta. 2013; 4:2