IOSR Journal of Applied Chemistry (IOSR-JAC)
e-ISSN: 2278-5736.Volume 8, Issue 3 Ver. I. (Mar. 2015), PP 59-62
www.iosrjournals.org

Method Development of Diphenhydramine HCl ($C_{17}H_{21}NO.HCl$) On Spectrophotometer

Syed Askary Ul Hassan
Hamdard Institute of Education and Social Sciences, Pakistan

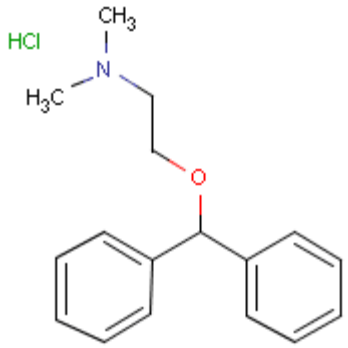
Abstract: *The purpose of method development of diphenhydramine HCl on Spectrophotometer is cost, time saving and also environment friendly method then HPLC method. When the same method perform on HPLC is highly expensive method because of the HPLC grade solvent is used for sample preparation and also long time required to run on HPLC. For the cost and time reduction method of diphenhydramine HCl transfer from HPLC to spectrophotometer. HPLC method is more accurate method as compare to spectrophotometer but highly expensive. In spectrophotometer water is use as a diluent. Water is universal solvent, easily available and less expensive as compare to HPLC grade solvent, no harmful effect on environmental then other solvent.*

Keywords:

DPH *Diphenhydramine Hydrochloride*
HPLC *High Performance Liquid Chromatography*
ICH *International Conference on Harmonisation*
USP *United States Pharmacopeia*

I. Introduction

Diphenhydramine hydrochloride (DPH-HCL) is an antihistamine medication having the compound name 2-(diphenylmethoxy)-N,N -dimethylethylamine hydrochloride and has formula $C_{17}H_{21}NO.HCl$, shows in figure 1.



Chemical Structure of Diphenhydramine hydrochloride.

Diphenhydramine is used to treat sneezing, runny nose, watery eyes, hives, skin rash, itching, and other cold or allergy symptoms. Spectrophotometer method was derived from US pharmacopoeial method which was perform in HPLC. It is comparative study on different lots & compare the result of both and the preference of Spectrophotometer method to save time, cost and analyst health. DPH is soluble in water and analyze at wavelength (λ_{max}) 254. In HPLC method of DPH is very expensive to indentify and quantify them, by pressurizing sample contained in solvent to pass through column having particular adsorbent which causes interaction responsible for separation of components of mix. Use the triethylamine and acetonitrile, triethylamine causes irritation, swelling of eyes and skin, reversible swelling of cornea, respiratory tract and acetonitrile causes fatal cyanide poisoning, due to which skin problems, musle contraction, weakness and body pain along with dizziness, headaches, cause of tremor, Inflammation of the skin, and delicate organs of human body such as lungs, liver, kidney and CNS.

In Spectrophotometers method is simple to measure electromagnetic absorption in the range of UV-region which is below then 400nm. The instrument can directly measure absorbance or indirectly measures absorbance by measuring transmittance.

Absorbance and transmittance is related with equation.

$A = -\log T$ ….(i)

Where, A is absorbance and T is transmittance

Research Instrument:

Instrument were used for analysis is LC 20AT SIL 20A HPLC & UV 1700 spectrophotometer to analysis Absorbance of the solution in ultraviolet and visible region, measure absorbance is proportion to the concentration of the solution.

II. Method:

Diphenhydramine HCl is used as an analyte. 25mg of Diphenhydramine HCl, is transfer to 50 mL volumetric flask, dissolve in and dilute with water to volume to prepare stock solution. For the analysis of accuracy and precision anlaysis was carried out by different analyst under similar conditions of temperature and pressure using spectrophotometer at λmax of 254nm. For the determination of linearity of method different dilution were prepared in range 60-140 % and absorbance is measured at 254 nm using spectrophotometer.

Solubility:

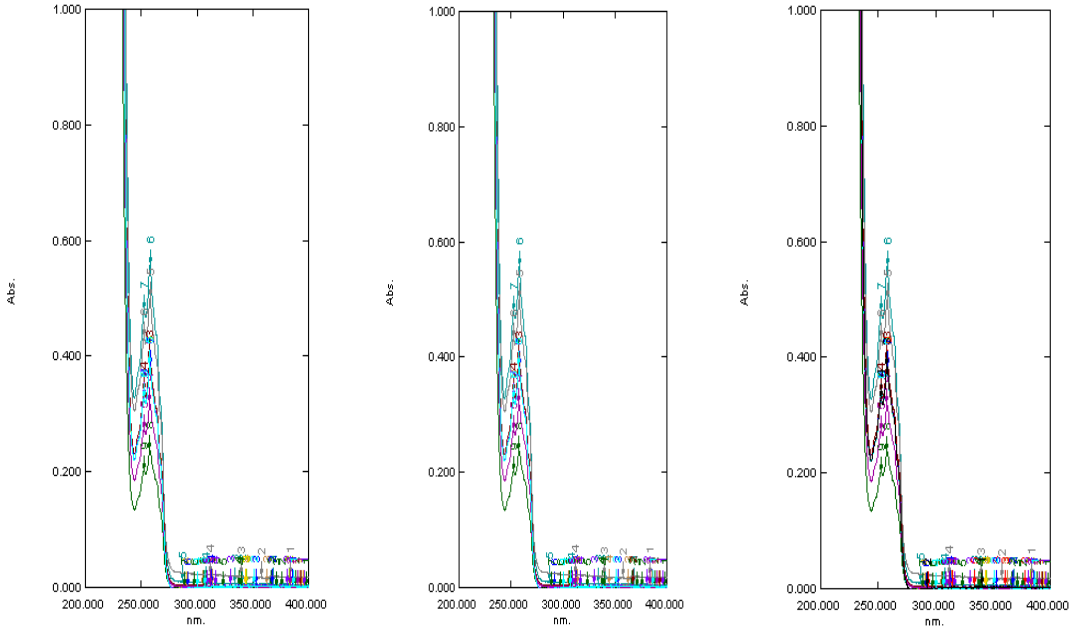
Dissolvable material is mostly focused around the physical and concoction properties of the solute and dissolvable and temperature, weight, and pH of the arrangement. Also measured the degree of the dissolving of a substance in a given dissolvable fixation and immersion, where including more solute does not expand the amassing of the arrangement and start to encourage unreasonable measures of disintegrated. Solubility of compound Diphenhydramine HCl in different solvents as water, alcohol and chloroform

Accuracy:

Accuracy is the closeness of determined value as compared with the actual value or standard value. Accuracy Based on observations it can be concluded that HPLC and Spectrometric method both are accurate as experimental values **w**ere approaching the standard value that is fluctuation of experimental value in comparison with actual values was quite low. Thus both methods are supposed to be equally reliable for the measurement of Diphenhydramine HCl.

Precision:

Precision is the measure of closeness of experimental data point obtained by same or different analyst on several time replication of experiment. The precision of measurement of Diphenhydramine HCl using spectrum for study spectrometric method

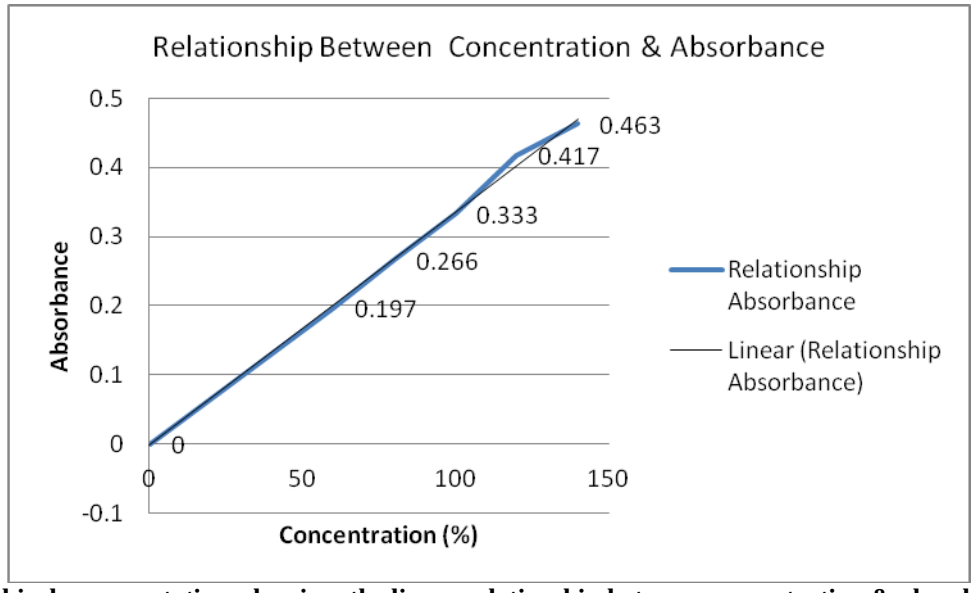


Precision in Spectrum of Diphenhydramine HCl by Spectrophotometer.

Linearity:

Linearity is the direct dependency of one factor on other. There was concentration study of diphenhydramine HCL, 5 samples of diphenhydramine HCL is 60%, 80%, 100%, 120%, 140% w/v were determined spectrometrically by observing the absorbance. It has been evaluated that the sample obeys Beer's lambert law. In this work absorbance and concentration has linear relation which can be evaluated based on linear regression R^2 values which is approaching unity. The values were presented as

Concentration (%)	Absorbance
60	0.197
80	0.266
100	0.333
120	0.417
140	0.463



Graphical representation showing the linear relationship between concentration & absorbance.

Relative Standard Deviation:

Calculate RSD with the help of result comes from the precision of a sample analyze is 0.17%. USP standard describe that development method relative standard deviation not more than 2%. Our develop method qualify USP standard and successfully applicable in practically in quality assurance lab. By this method reduces the analysis cost, reduce the analysis time and as well as eliminate the hazard solvent that influence the human life and environment.

Acknowledgements

Authors are thankful to friend Zain ul Abedeen, Omair Adil, Umar Wahab and Syed Ebad Ali for providing all Support to complete this work successfully.

III. Conclusion

A simple accurate, precise, reproducible and cost effect method of Diphenhydramine hydrochloride on spectrophotometer. The linearity of absorbance / concentration was determined at different concentration which show the linear relationship between concentration and absorbance to obey the lambert beer law. RSD found 0.17%. no use of organic solvent, eliminate the harmful effect on environment. Method successfully apply on initial material anf finish good method.

References

[1]. Arun Arun Kumar Mishra, Arvind Kumar , Amrita Mishra, IJPSR (2010).
[2]. Development and validation of uv spectrophotometric method for estimation of diphenhydramine hydrochloride in soft gelatin capsule ijpsr (2010), Vol. 1, Issue 8 (Suppl.)
[3]. Basavaiah K., & Charan V. S. (2003). Precipitation and complex formation reactions based titrimetric and spectrophotometric methods for the determination of diphenhydramine hydrochloride. Indian Journal of chemical technology. 10, 382-385.

[4]. Burcu devrim, erdal dinc and asuman bozkir (2014). fast determination of diphenhydramine hydrochloridein reconstitutable syrups by cwt, pls and pcr methods, acta poloniae pharmaceutica and drug research, vol. 71 no. 5 pp. 721 to729
[5]. Caddy B., Fish F., & Tranter J. (1975). A rapid and sensitive spectrophotometric procedure for the determination of diphenhydramine and related ethers. Analyst.100, 563-566.
[6]. El-Didamonya A. M., &Moustafab M. A. (2010). Spectrophotometric determination of diphenhydramine hydrochloride in pharmaceutical preparations and biological fluids via ion-pair formation. Arabian Journal of Chemistry. 3(4), 265–270.
[7]. El-Shahat M. F., Abdel Badei M. M., &Daifullah A. A.(1992).Spectrophotometric determination of ephedrine HCl, cinchonine HCl, chlorpheniramine maleate, atropine sulphate and diphenhydramine HCl by solvent extraction of reineckate complexes. J Chem Technol Biotechnol. 54(2),75-81.
[8]. Fakhry K. R., &Mohammed Hassan K. A. (2013). Formulation and evaluation of diphenhydramine HCl release from different semi-solid bases. World Journal of Pharmaceutical research. 2(5), 1-15.
[9]. K. Basavaiah., V.S. Charan. (2002). Titrimetric and spectrophotometric assay of some antihistamines through the determination of the chloride of their hydrochlorides. Il Farmaco. 57, 9–17.
[10]. M. A. Korany, Mona Bedair and F. A. El-Yazbi. (1986). Use of orthogonal polynomials for unequal intervals to eliminate interference in spectrophotometric analysis. Simultaneous determination of ephedrine hydrochloride and diphenhydramine hydrochloride in two-component mixtures. Analyst. 111, 41-44.
[11]. Maren Haag, Michael Brüning, Karl Molt. (2009). Quantitative analysis of diphenhydramine hydrochloride in pharmaceutical wafers using near infrared and Raman spectroscopy. Analytical and Bioanalytical Chemistry. Springer Link. 395(6), 1777-1785.
[12]. Matsui F., &French W. N. (1971). Analysis of binary mixtures of pharmaceutical amines by the acid dye technique. 60(2), 287-291.
[13]. Stephen R. Byrn , Constance W. Graber , Sharon L. Midland. (1976). Comparison of the solid and solution conformations of methapyriline, tripelennamine, diphenhydramine, histamine, and choline. The infrared-x-ray method for determination of solution conformations. The journal of Organic Chemistry. ACS Publication. 41(13), 2283–2288.
[14]. Tipparat P., Lapanantnoppakhun S., Jakmunee J., &Grudpan K. (2002). Determination of diphenhydramine hydrochloride in some single tertiary alkylamine pharmaceutical preparations by flow injection spectrophotometry. Journal of Pharmaceutical and Biomedical Analysis. 30, 105–112.
[15]. Wafaa S. Hassan., Magda M. El-Henaweea., &Ayman A., Goudab. (2008). Spectrophotometric determination of some histamine H1-antagonists drugs in their pharmaceutical preparations. Spectrochimica Acta Part A. 69, 245–255.
[16]. Wiktor Kemula, Adam Hulanicki, Andrzej Janowski. (1960). Microdetermination of chloride in water. Talanta. 7(1–2),65–69.
[17]. United State Pharmacopoeia 30 NF 25
[18]. Validation of analytical method by Agilent Technologies.