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Solubility Determination of An Anti-Inflammatory Drug by Spectrophotometric Analysis

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ABSTRACT

The solubility of a substance becomes especially important in the pharmaceutical field because it often represents a major factor that controls the bioavailability of a drug substance. Moreover, solubility and solubility-related properties can also provide important information regarding the structure of drug substances, and in their range of possible intermolecular interactions. For these reasons, a comprehensive knowledge of solubility phenomena permits pharmaceutical scientists to develop an optimal understanding of a drug substance, to determine the ultimate form of the drug substance, and to yield information essential to the development and processing of its dosage forms.

Keywords : Development, Drug Substance, Solubility, Pharmaceutical Field.

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INTRODUCTION

Diclofenac Sodium(DS) is chemically Sodium salt of 2-[[2,6-dichlorophenyl]amino] benzene acetic acid. It is having anti-inflammatory and analgesic properties,

Solubility is defined as the maximum quantity of a substance that can be completely dissolved in a given amount of solvent, and represents a fundamental concept in fields of research such as chemistry, physics, food science, pharmaceutical, and biological sciences.¹

(1) Statement. The theory of solubility advocated by the writer in a series of papers is restated. Raoult's law will be obeyed by any liquid mixture in which the internal forces of attraction and repulsion do not change with changing composition of the mixture. When this condition holds, the solubility of a gas may be calculated approximately from its saturation pressure, and the solubility of a solid from its melting point and heat of fusion. The above condition can exist only

(a) When the components in the pure liquid state have the same internal pressures;

(b) When the different molecules are relatively symmetrical or non-polar;

(c) When the tendency to form chemical compounds is absent. Differences in either internal pressure or polarity alone produce approximately proportional positive deviations from Raoult's law and decreased solubility's. Tendencies towards chemical combination produce negative deviations and increased solubility's. Internal pressure is defined as $T (\partial P/\partial T)_{v}$; relative values can be deduced from other data, especially the solubility relations themselves. Polarity is indicated by dielectric constant, etc., and depends on the symmetry and the chemical constitution of the molecule. Chemical combinations are difficult to predict, but, in general, occur most frequently between polar molecules, especially those which can be regarded as positive and negative, or basic and acidic, respectively.

(2) Discussion of criticism by Kunerth. Kunerth has severely criticized this theory, concluding that Raoult's law and internal pressures are practically useless as a basis for predicting the solubility's of gases. This paper points out that most of the solvents Kunerth uses are highly polar. A table of gas solubility's in non-polar solvents is given. The solvents are arranged according to increasing internal pressure, and the table includes the solubility as calculated approximately by the aid of Raoult's law. Though the solubility's cover a wide range the agreement with the theory is good.²

MATERIALS AND METHODS

A double-beam Shimadzu-1800 UV- Visible spectrophotometer, with spectral bandwidth of 2 nm, wavelength accuracy ± 0.5 nm and a pair of 1-cm matched quartz cells was used to measure

absorbance of the resulting solution.

Chemicals which are used in the spectrophotometric analysis are; Solvent-Methanol, Ethanol, Glacial acetic acid, Distilled water and Diclofenac sodium in powdered form, that is the gift sample of Aldoc pharmaceutical Pvt.Ltd.Kota, Rajasthan.

Method (Shake flask method):

- 1) Clean all glass ware using detergent and dried well.
- 2) Weigh accurately about 20 mg drug sample of Diclofenac sodium powder.
- 3) Measure 20 ml of methanol solution and dissolve the drug sample in methanol.
- 4) In the same way, prepare four solvent solutions of drug sample using 20-20 ml of ethanol, acetic acid and distilled water.
- 5) Allow all the all mixture solvent solution of drug solution for shaking.
- 6) Allow all solutions for proper mixing of drug sample by using incubator shaker for 48 hours.
- 7) After 48 hours the samples are removed from shaker.
- 8) Take one by one of the solvent and λ max. Observed by using u.v. spectrophotometer.
- 9) Take the dilutions if needed of the respective sample solution in the sample cell and find the absorbance at measured wavelength.³

Determination of λ max

Firstly prepared the stock solutions of Diclofenac sodium (1 mg/ml) by using distilled water, acetic acid, methanol and ethanol. For the determination of λ max, 10ug/ml solution of diclofenac-sodium was prepared from the stock solutions. With the help of UV spectrophotometer, the maximum absorption of diclofenac-sodium in above solvent solutions was determined by wavelengths scanning at 200-400 nm. The maximum absorption a particular wavelength taken as λ max value for a given drug.⁴

Construction of standard curve of diclofenac-sodium with distilled water

Make different Concentration of Diclofenac sodium distilled water 2,4,6,8 and 10 μ g/ml and take absorbance of each sample with the help of UV spectrophotometer at 276 nm. Such drug concentration is lies that obey Beers' lamberts law. The absorbance at different wavelength are as in table-1.

In the same way, determine the of each solvent solution and prepare the standard curve of each solvent sample of diclofenac-sodium.

Construction of standard curve of diclofenac-sodium with acetic acid

Make different Concentration of diclofenac sodium using acetic acid 2,4,6,8 and 10 µg/ml and take absorbance of each sample with the help of UV spectrophotometer at 222 nm which was measured by wavelength scanning. Such drug concentration is lies that obey Beers' lamberts law. The absorbance at different wavelength are as in table-2.

Construction of standard curve of diclofenac-sodium with methanol

Make different Concentration of diclofenac sodium using methanol 2,4,6,8 and 10 µg/ml and take absorbance of each sample with the help of UV spectrophotometer at 207 nm which was measured by wavelength scanning. Such drug concentration is lies that obey Beers' lamberts law. The absorbance at different wavelength are as in table-3.

Construction of standard curve of diclofenac-sodium with ethanol

Make different Concentration of diclofenac sodium using ethanol 2,4,6,8 and 10 µg/ml and take absorbance of each sample with the help of UV spectrophotometer at 206 nm which was measured by wavelength scanning. Such drug concentration is lies that obey Beers' lamberts law. The absorbance at different wavelength are as in table-4.

RESULTS AND DISCUSSION

The sample of diclofenac sodium drug sample was freely soluble in the methanol and glacial acetic acid, soluble in ethanol, and slight soluble in distilled water shown in table-6. The following result has been found after solubility determination of an anti-Inflammatory drug by spectrophotometric analysis-

Standard Curve with water:-

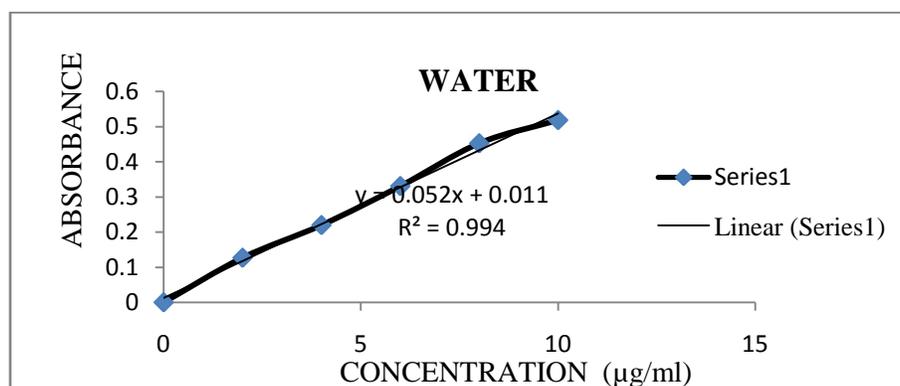
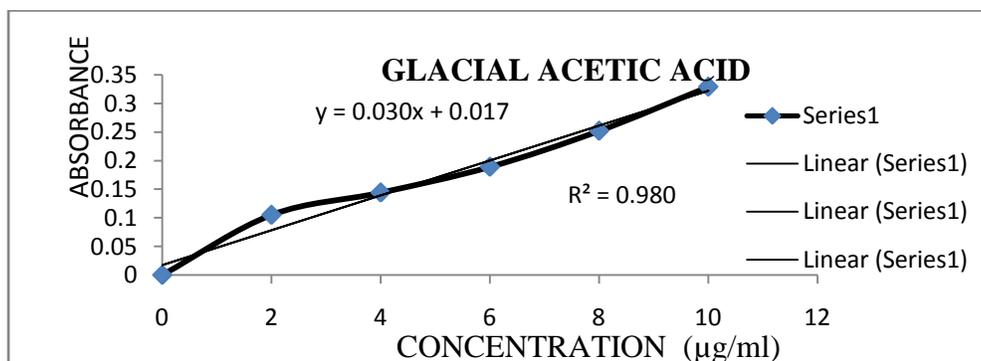
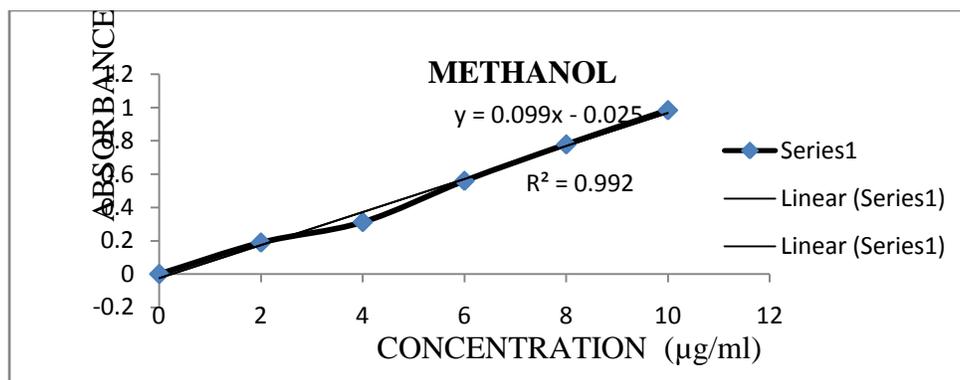
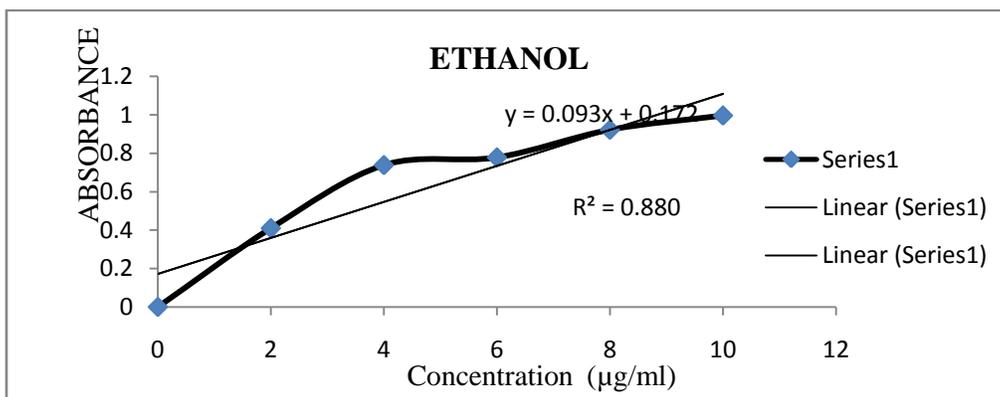


Figure-1 Standard curve of diclofenac sodium with water

Standard Curve with acetic acid:-**Figure-2 Standard curve of diclofenac sodium with glacial acetic acid****Standard Curve with methanol:-****Figure-3 Standard curve of diclofenac sodium with Methanol****Standard Curve with ethanol:-****Figure-4 Standard curve of diclofenac sodium with Ethanol****Table-1 Absorbance of drug with distilled water :-**

Sr No.	Concentration (µg/ml)	Absorbance
1	2	0.127
2	4	0.220
3	6	0.331
4	8	0.453
5	10	0.519

Table-2 Absorbance of drug with acetic acid :-

Sr No.	Concentration ($\mu\text{g/ml}$)	Absorbance
1	2	0.105
2	4	0.144
3	6	0.189
4	8	0.252
5	10	0.329

Table-3 Absorbance of drug with methanol :-

Sr No.	Concentration ($\mu\text{g/ml}$)	Absorbance
1	2	0.189
2	4	0.312
3	6	0.560
4	8	0.779
5	10	0.985

Table-4 Absorbance of drug with ethanol :-

Sr No.	Concentration ($\mu\text{g/ml}$)	Absorbance
1	2	0.410
2	4	0.738
3	6	0.778
4	8	0.922
5	10	0.996

Note: - All above tables for the preparation of standard curve graph.

Table-5 Absorbance of drug (10 $\mu\text{g/ml}$) in different solvents from shake flask method

S.No.	Solvent	Absorbance
1	Distilled Water	0.453
2	Glacial acetic acid	0.294
3	Methanol	0.889
4	Ethanol	0.978

Table-6 Resulting solubility of diclofenac-sodium in different solvents

S.No.	Solvent	Solubility
1	Ethanol	Freely Soluble
2	Glacial acetic acid	Freely Soluble
3	Methanol	Soluble
4	Distilled Water	Slight Soluble

CONCLUSION

The solubility of given sample of an anti-inflammatory drug which is diclofenac sodium by using different solvents was found to be maximum for methanol solvent. Thus, it may be concluded that the proposed method as well as methanol is improved, simple, eco-friendly and may prove to be of great importance in pharmaceutical analysis.

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