



## SPECTROPHOTOMETRIC ANALYSIS OF TABLETS OF PIROXICAM USING MELTED NIACINAMIDE AS SOLVENT (MIXED SOLVENCY CONCEPT)

<b>R. K. Maheshwari</b>	Shri G.S. Institute Of Technology And Science, 23, Park Road, Indore - 452003 (M.P.), India
<b>Ayushi Mohadikar*</b>	Shri G.S. Institute Of Technology And Science, 23, Park Road, Indore - 452003 (M.P.), India *Corresponding Author
<b>Pawan Mulani</b>	Shri G.S. Institute Of Technology And Science, 23, Park Road, Indore - 452003 (M.P.), India
<b>Mitali Jain</b>	Shri G.S. Institute Of Technology And Science, 23, Park Road, Indore - 452003 (M.P.), India

### ABSTRACT

In the present research work, a novel method for spectrophotometric estimation of piroxicam tablets using melted niacinamide as solvent was developed. The main objective of the research is to show that solids also possess solubilizing power. The current study deals with a novel spectrophotometric analytical technique for quantitative estimation of piroxicam in tablets using melted niacinamide as solvent. According to the theory proposed by Maheshwari, each & every substance possesses solubilizing power; the substance may be a gas, solid or liquid. Niacinamide imbibes large solubilizing power to piroxicam and having approximate solubility 110 mg per gm of melted niacinamide (135°C) whereas aqueous solubility of piroxicam is 0.40 mg/ml at room temperature. Niacinamide does not interfere above 300 nm in the spectrophotometric analysis. Calibration curve of piroxicam was plotted by recording the absorbances of standard solutions of the drug (5, 10, 15, 20 and 25 microgram/ml). The absorbances were observed at 358 nm against respective reagent blanks. The percent label claims were found very close to 100.0 (99.08  $\pm$  1.764 and 100.93  $\pm$  1.303) indicating the accuracy of the proposed method. Percent recoveries estimated by the proposed method are close to 100.0 (99.92  $\pm$  1.605 to 101.74  $\pm$  1.663) with significant low values of percent coefficient of variation and standard error. Thus, it may be concluded that the proposed method is simple, safe, and precise, and excludes the use of toxic organic solvents.

**KEYWORDS :** Mixed Solvency Concept, Solubilizing Power, Spectrophotometric Analysis, Niacinamide, Piroxicam.

### INTRODUCTION

The mixed solvency concept can serve as a milestone for solubility enhancement and therefore deserves urgent attention of the scientific community to assess its efficiency and applicability. According to Maheshwari, each and every substance present on earth possesses solubilizing power, be it a solid, liquid or gas. Each substance possesses good solubilizing power for some solutes and bad solubilizing power for other solutes<sup>1-10</sup>. The main objective of the present research is to show that solids also possess solubilizing power.

Commonly used organic solvents for spectrophotometric analysis of water-insoluble drugs include methanol, ethanol, chloroform, benzene, dichloromethane, dimethylformamide, acetonitrile, ethyl acetate, toluene, carbon tetrachloride, acetone, hexane etc. The main drawbacks of organic solvents include high cost, toxicity and pollution. Organic solvents have numerous adverse effects caused by single exposure like dermatitis, headache, drowsiness, nausea, eye irritation, and long term exposure causes serious effects such as neurological disorders, chronic renal failure, liver damage, necrosis, and mutagenesis disorder. They should be replaced by other eco-friendly alternative sources. The present investigation is an attempt to show that solids can also be wisely used to act as solvent precluding the use of organic solvents. In a separate study, the author has attempted soxhlation using phenol as a solvent. The vapours of boiling phenol got condensed in the extraction chamber to effect the extraction of active constituents from a powder of crude drugs. The main objective of the present study is to demonstrate the solvent action of solids. Solid excipients can nicely be employed as solubilizers in the development of pharmaceutical dosage forms in solution form of poorly soluble drugs (mixed solvency concept)<sup>11-23</sup>.

In the present research, melted niacinamide (at 135°C) was

employed for dissolution of piroxicam tablets without using any organic solvents (therefore eco-friendly method).

### MATERIALS AND METHOD

Piroxicam API was a generous gift from M/S Alkem Laboratories Ltd., Mumbai. Piroxicam tablets were procured from the local market. All other chemicals used were of analytical grade. The instrument used was Shimadzu UV-Visible spectrophotometer (model UV-160A) with 1 cm matched silica cells.

### EXPERIMENTAL METHODS SOLUBILITY STUDIES -

The solubility of piroxicam at room temperature in water was found to be 0.40 mg/ml. Using an approximate method of solubility determination, it was found that more than 110 mg piroxicam was dissolved in one gram of melted niacinamide (at 135°C).

### CALIBRATION CURVE -

10 gm niacinamide was taken in a 500ml volumetric flask and it was heated carefully on the heating mantle. As soon as niacinamide was melted, 50 mg of standard sample of piroxicam was added and the flask was shaken to dissolve the drug. Intermittent heating and shaking were done for the complete dissolution of the drug. Then, 400 ml of hot distilled water (90°C) was transferred carefully (little at a time) to the volumetric flask and the contents are shaken for about 5 minutes. The flask was allowed to cool to attain the room temperature. Then, the volume was made up 500ml with distilled water. This was the stock solution of the drug (100  $\mu$ g/ml). By appropriate dilution of this stock solution with distilled water, standard solutions of the drug (10, 20, 30, 40, 50  $\mu$ g/ml) were prepared and their absorbances were noted at 358 nm against the respective reagent blanks and using these values, the calibration curve was obtained.

Then, 400 ml of hot (90°C) distilled water was carefully (little at a time) added to the flask and the flask was shaken for about 5 minutes. Then, the flask was allowed to cool to attain room temperature and the volume was made up to the mark with distilled water. After filtration through Whatman filter paper no.41, 5 ml filtrate was diluted to 50 ml with distilled water and the absorbance was noted at 358 nm against reagent blank. Using the calibration curve the drug, content was computed. Similar treatment was done for formulation II. All analysis were performed thrice.

#### PROPOSED METHOD -

20 tablets of piroxicam, formulation I were weighed and

**Table 1: Analysis of Commercial Tablets of Piroxicam with Statistical Evaluation (n=3)**

Tablet Formulation	Label Claim Per Tablet (mg)	% Label Claim Estimated (Mean $\pm$ SD)	% Coefficient of Variation	Standard Error
I	20	100.93 $\pm$ 1.303	1.291	0.752
II	20	99.08 $\pm$ 1.764	1.780	1.018

**Table 2: Results of Recovery Studies with Statistical Evaluation (n=3)**

Tablet Formulation	Drug Present in Pre-Analysed Tablet Powder Taken (mg)	Pure Drug Added (Spiked) (mg)	% Recovery Estimated (Mean $\pm$ SD)	% Coefficient of Variation	Standard Error
I	50	15	100.48 $\pm$ 1.466	1.459	0.846
II	50	30	100.67 $\pm$ 1.064	1.057	0.532
III	50	15	101.74 $\pm$ 1.663	1.635	0.510
IV	50	30	99.92 $\pm$ 1.605	1.606	0.581

#### RESULTS AND DISCUSSION

The aqueous solubility of piroxicam at room temperature was 0.40 mg/ml whereas the solubility of piroxicam in melted niacinamide was found to be 110 mg per gram of melted niacinamide at 135°C. It is evident from Table I that the percent drug estimated in the formulation I and II were 100.93  $\pm$  1.303 and 99.08  $\pm$  1.764, respectively. The values are very close to 100.0, indicating the accuracy and precision of the proposed method. Further, Table II shows that the range of percent recoveries varied from 99.92  $\pm$  1.605 to 101.74  $\pm$  1.663 which are again very close to 100.0, indicating the accuracy of the proposed method. Proposed analytical technique is supported significantly by small values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error (Table I & II).

#### CONCLUSION

The mixed solvency concept can be successfully employed in increasing solubility and analytical estimation of various drugs. A large number of poorly water-soluble drugs having absorption maxima above 300 nm can be tried for estimation by this method. Such solid as solvent (niacinamide) can be used in place of costly and toxic organic solvents.

#### REFERENCES

1. Maheshwari RK. "Mixed-solvency approach"- Boon for solubilization of poorly soluble drugs. *Asian Journal of Pharmaceutics* 2010; Jan-March: 60-63.
2. Maheshwari RK. Solubilization of ibuprofen by mixed solvency approach. *The Indian Pharmacist* 2009; 8(87):81-84.
3. Maheshwari RK. "Mixed-solvency" -A novel concept for solubilization of poorly water-soluble drugs. *Delving J. Tech. Eng. Sci.* 2009; 1(1):39-43.
4. Maheshwari RK, Upadhyay N, Jain J, Patani M, Mathuria KC. New spectrophotometric estimation of naproxen tablet formulation employing mixed solvency concept (at 331 nm). *International Journal of Pharmacy and Technology* 2011; 3(4):3618-3623.
5. Maheshwari Y, Mishra DK, Mahajan SC, Maheshwari P, Maheshwari RK, Jain J. Novel pharmaceutical application of mixed solvency in the formulation development of syrups (liquid oral solutions) of poorly water-soluble drugs. *International Journal of Pharmacy* 2013; 3(4):753-758.
6. Soni LK, Solanki SS, Maheshwari RK. Solubilization of poorly water-soluble drug using mixed solvency approach for aqueous injection. *British Journal of Pharmaceutical Research* 2014; 4(5):549-568.
7. Rajesh Kumar Maheshwari, "Solid as solvent", Novel spectrophotometric analysis of satranidazole tablets using phenol as solvent. *The Indian Pharmacist* 2014; XII:37-40.
8. Maheshwari RK. Potentiation of solvent character by mixed solvency concept: A novel concept of solubilization. *Journal of Pharmacy Research* 2010; 3(2):411-413.

crushed to get a fine powder. Ten grams of niacinamide was kept in a 500 ml volumetric flask and the flask was carefully heated on the heating mantle to melt the niacinamide. After complete melting of niacinamide, tablet powder equivalent to 50mg of the drug was transferred to the flask and the flask was shaken for 10 minutes with intermittent heating and shaking.

#### RECOVERY STUDIES -

Recovery studies taking 15 mg and 30 mg of pure drug as spiked drug together with pre-analysed tablet powder equivalent to 50 mg drug) were performed using the same proposed method.

9. Jain S, Maheshwari RK, Nema RK, Singhvi I. Development and validation of simple UV-spectrophotometric method of quantitation of domperidone in solid dosage formulations using mixed solvency concept. *Research and Reviews: A Journal of Drug Design and Discovery* 2017; 4(2):19-23.
10. Maheshwari RK, Shilpkar R. Formulation development and evaluation of injection of poorly soluble drug using mixed solvency concept. *International Journal of Pharma and Biosciences* 2012; 3(1):179-189.
11. R.K. Maheshwari, Shruti Jain, Anjali Padria, Pawan Mulani, Jaydeep Singh Baghel, Neelesh Maheshwari, "Eco-friendly extraction using solids"-A novel application of mixed solvency concept. *Journal of Drug Delivery & Therapeutics* 2019; 9(2):244-249.
12. Bhawsar N, Maheshwari RK, Ansari A, Saktawat Y. New spectrophotometric estimation of gatifloxacin in the tablets using mixed solvency approach. *International Journal of Pharmaceutical Science* 2011; 2(2):270-274.
13. Vijayranga G, Deveswaran R, Bharath S, Basavaraj BV, Madhavan V. Development of an analytical method for spectrophotometric estimation of ketoprofen using mixed solvency approach. *International Journal of Pharmaceutical Sciences and Research* 2012; 4:1053-1056.
14. Maheshwari RK, Upadhyay N, Jain J, Patani M, Pandey R. New spectrophotometric analysis of gatifloxacin tablets utilizing mixed solvency concept (at 288 nm). *Der Pharmacia Lettre* 2012; 4(1):1-4.
15. Maheshwari RK, Rajagopalan R. Formulation and evaluation of paracetamol syrup made by mixed-solvency concept. *Der Pharmacia Lettre* 2012; 4(1):170-174.
16. Prashant B, Rawat S, Mahajan YY, Galgatte UC, Maheshwari RK. Formulation development and evaluation of aqueous injection of poorly soluble drug made by novel application of mixed solvency concept. *International Journal of Drug Delivery* 2013; 2:152-166.
17. Maheshwari RK, Karawande VU. Application of novel concept of mixed solvency in the design and development of floating microspheres of furosemide. *International Journal of Pharmacy and Pharmaceutical Sciences* 2013; 15:167-195.
18. Sreegirisprasad B, Gupta VRM, Devanna N, Ramadevi M, Vishnuvarethan Rao G. Mixed Solvency Concept: A promising tool to enhance solubility of poorly soluble drug aceclofenac. *International Journal of Pharmaceutical Chemical and Biological Sciences* 2012; 3:338-342.
19. Agrawal A, Maheshwari RK. Formulation development and evaluation of in situ nasal gel of poorly water-soluble drug using mixed solvency concept. *Asian Journal of Pharmaceutics* 2011; 5(3):131-140.
20. Maheshwari RK, Gupta S, Gharia A, Garg SK, Shilpkar R. Simple eco-friendly spectrophotometric estimation of tinidazole tablets by application of mixed-solvency technique. *Bulletin of Pharmaceutical Research* 2011; 1(1):22-25.
21. Jain S, Maheshwari RK, Nema RK, Singhvi I. New spectrophotometric estimation frusemide in the tablets using mixed solvency concept. *International Journal of Current Advanced Research* 2017; 6(12):8510-8513.
22. Maheshwari RK, Putliwala M, Padiyar A. Novel approach for spectrophotometric estimation of naproxen in tablet dosage form using solids (eutectic liquid of phenol and niacinamide) as solubilizing agent (mixed solvency concept). *Asian Journal of Pharmaceutical Research* 2015; 5(1):25-28.
23. Maheshwari RK, Dahima R. "Solid as solvent"-Novel spectrophotometric analytical technique for quantitative estimation of tinidazole in tablets using solids (eutectic liquid of phenol and lignocaine hydrochloride) as solubilizing agents (mixed solvency concept). *Journal of Drug Delivery and Therapeutics* 2017; 7(3):127-130.