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Original Research Article

Improving Oral Bioavailability of Meloxicam: Development and Characterization of Solid Dispersions

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Abstract:

This study investigated the development of a solid dispersion to improve the solubility and dissolution of meloxicam, a poorly water-soluble drug. Meloxicam is used to treat pain and inflammation in various conditions. The challenge was to enhance the drug's oral bioavailability by overcoming its low solubility. Two approaches were explored:

1**. Kneading method with Poloxamer 407:** This method resulted in a formulation with significantly improved solubility compared to the pure drug.

2. Solvent evaporation method with PVP K-30: While this method offered satisfactory solubility enhancement, it was not as effective as the kneading method with Poloxamer 407.Following the development of the optimized solid dispersion, a suspension formulation was prepared using various suspending agents. The optimized drug formula was then incorporated into the suspension mix. Characterization studies confirmed compatibility between the drug and excipients. FT-IR analysis showed no interaction between the drug and the carriers. Scanning electron microscopy (SEM) revealed a change in meloxicam particle morphology from crystalline to a more amorphous form, indicating a reduction in particle size and a potential explanation for the improved dissolution profile. The dissolution profile of the solid dispersion suspension prepared by the kneading method with Poloxamer 407 outperformed the one prepared with the solvent evaporation method and PVP K-30.This study demonstrates the effectiveness of the kneading method with Poloxamer 407 in developing a solid dispersion of meloxicam with enhanced solubility and dissolution. The optimized formulation exhibited good stability, acceptable drug content and release, and satisfactory rheological properties. This approach has the potential to improve the bioavailability of meloxicam and lead to a more effective oral dosage form.

Keywords: *Oral Bioavailability, Meloxicam: Solid Dispersions , FT-IR analysis, SEM*

Introduction:

Oral drug delivery remains the most preferred route of administration due to its convenience and ease of ingestion. Patients find swallowing a dosage form more comfortable and familiar compared to other routes like injections. However, for many drugs, oral delivery can be problematic and inefficient.A significant challenge in oral drug delivery is **limited drug absorption**, resulting in poor bioavailability[1,2]. Bioavailability refers to the fraction of an administered drug that reaches the systemic circulation and exerts its therapeutic effect.

Two key factors limit drug absorption from the gastrointestinal (GI) tract:

- **Poor aqueous solubility:** Many drugs are poorly soluble in water, hindering their dissolution in the GI fluids. This limits the amount of drug available for absorption through the intestinal membranes.
- **Poor membrane permeability:** Some drugs, even if soluble, may have difficulty passing through the intestinal membranes and entering the bloodstream[3,4].

Solid dispersions are a promising strategy to improve the oral bioavailability of poorly soluble drugs. These dosage forms incorporate a poorly soluble drug within a **hydrophilic carrier** in a solid state. The carrier material enhances the drug's dissolution rate and potentially its membrane permeability, leading to increased absorption and bioavailability. This study the stage for the importance of solid dispersions in overcoming challenges associated with oral drug delivery. It highlights poor solubility and permeability as key factors affecting bioavailability and introduces solid dispersions as a potential solution[2,5].

The effectiveness of a drug heavily relies on its bioavailability, which is significantly influenced by the drug's solubility. Poor solubility in water hinders a drug's absorption in the gastrointestinal tract (GI tract), ultimately impacting its therapeutic potential. This study focuses on overcoming this challenge by improving the solubility and dissolution rate of a specific poorly soluble drug.When administered orally, a drug needs to dissolve in the stomach or intestines before it can be absorbed through the GI tract and reach systemic circulation[6,7]. Drugs with poor aqueous solubility often exhibit limited absorption due to slow dissolution rates.Enhancing Solubility and Dissolution Rate: This approach targets poorly soluble drugs by increasing their solubility and dissolution rate in aqueous solutions, thereby facilitating better absorption[8].

Enhancing Permeability: This strategy focuses on drugs with low membrane permeability, aiming to improve their ability to pass through the GI membranes.This study explores solid dispersion techniques as a method to enhance the dissolution rate of a poorly soluble non-steroidal anti-inflammatory drug (NSAID), such as meloxicam, valdecoxib, or ibuprofen. NSAIDs often exhibit low bioavailability due to limited absorption.Solid dispersions incorporate a poorly soluble drug within a hydrophilic carrier in a solid state[10].

OBJECTIVES

a. To carry out the stability studies of the solid dispersion.
b. To determine that which carrier along with which method is best one to enhance the solubility and dissolution rate of Meloxicam.

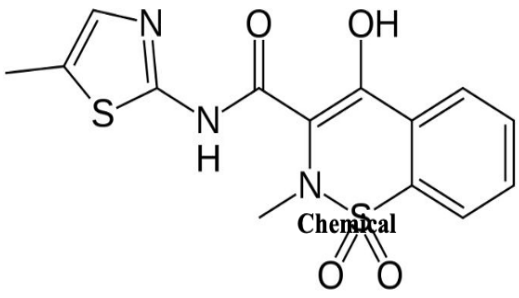

Figure 1: Chemical structure

DRUGS PROFILE
Chemical Name: 4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2benzothiazine-3-carboxamide-1,1-dioxide Preferential COX-2 inhibitor.
Molecular Formula: C14H13N3O4S2.
Molecular mass: 351.403.
Physiochemical Properties:
1. medication category: anti-inflammatory medication.
2. General appearance: Light yellow solid.
3. Odour: Odourless.
4. Melting point is 255-257°C.
5. Solubility: Water is very marginally soluble, while DMSO is very soluble.

Pharmacokinetics: ✓ Absorption: 10- 20% ✓ Protein binding: 99.4%

✓ Half-life: 15 to 20 hours.

✓ Hepatic metabolism and renal excretion[12].

Methodology

Experimental work

6.1 Physical Characterization

Organoleptic properties of Meloxicam (MLX)
Physical state – Solid crystalline powder**Colour –** Light yellow powder

Odour – Odourless

Melting point

Melting point was determined by capillary method. Using melting point apparatus it was found to be 255-257ºC, (Reported value: 255ºC).

IDENTIFICATION TEST By UV Spectrophotometer

Method: 10 mg of Meloxicam was weighed and transferred into a 100 ml of volumetric flask to dissolve in methanol and volume made up to 100 ml with methanol to make standard solution A. Then 10 ml of this solution was transferred into 100 ml of volumetric flask and the volume was made up to 100 ml with methanol to make standard stock solution B of 10µg/ml concentration. In order to determine the absorption maximum it was scanned between 200 nm to 400 nm. The solution showed maximum absorbance at □**max observed at 354 nm** which was same as reported

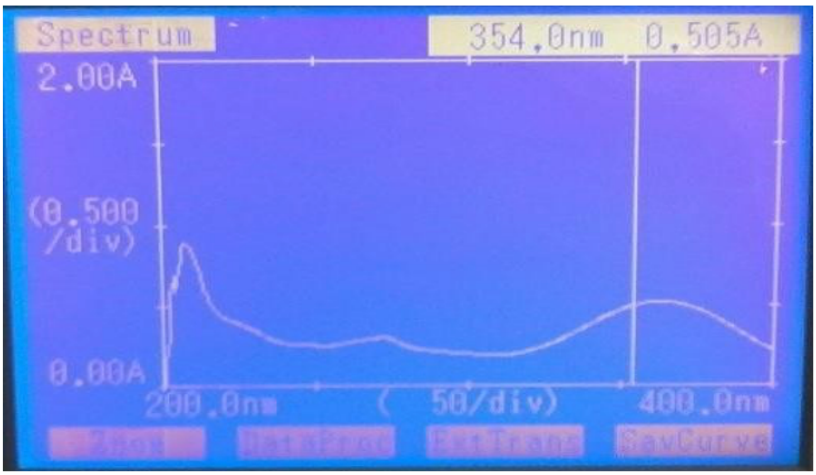

Figure 2: UV scan of Meloxicam in Phosphate buffer (pH 7.4) at □max at 354 nm

FTIR Analysis
Potassium bromide (KBr) was mixed with Meloxicam in the ratio of (100:1) and made small pellets by using high pressure hydraulic machine. FTIR of pellets was recorded using FTIR spectrophotometer at 1520 cm^{-1}.

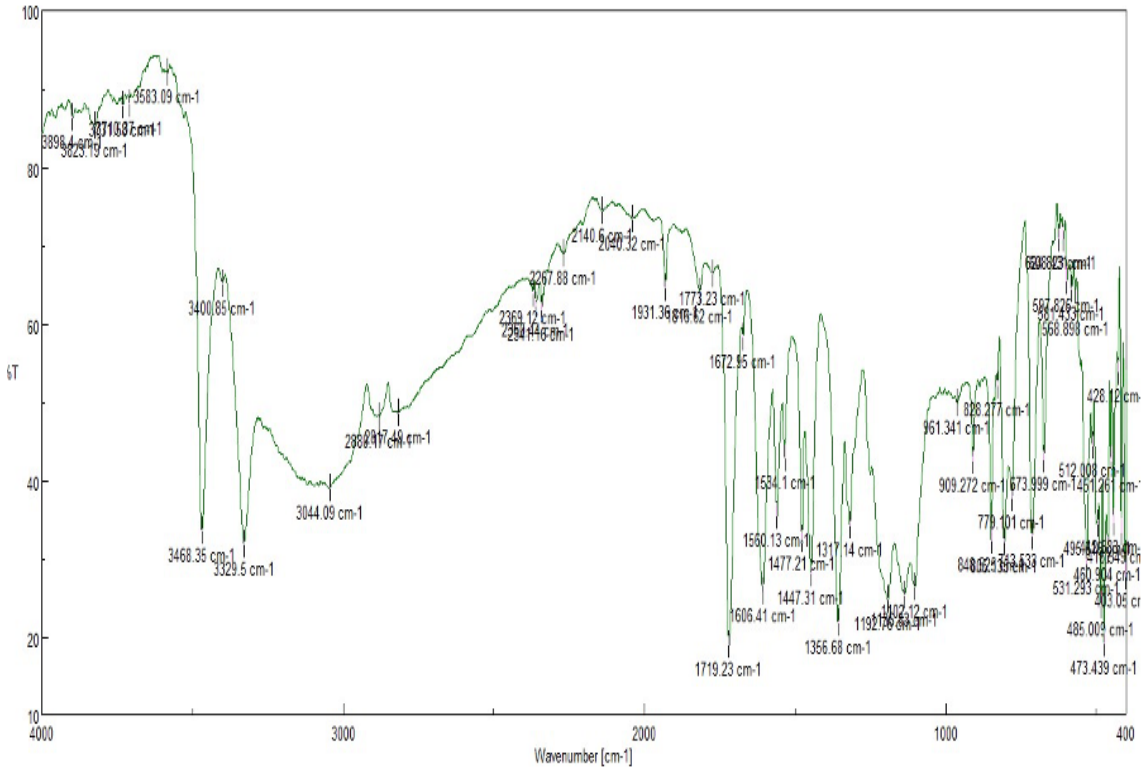

Figure 3: FTIR spectra of Meloxicam

Table 1: Interpretation of FTIR spectra of Meloxicam

S. No.	Band position (cm-1)	Assignment
1.	3468	O-H Stretching
2.	3329	N-H Stretching
3.	2140	N=C in R-N=C=S
4.	2942	C-H stretching
5.	1773	C=Ostretching

6.3. Development of analytical methodology for in vitro studies

Preparation of Calibration curve of Meloxicam in methanol at □max 354 nm

10 mg ofMeloxicam was weighed and transferred into a 100 ml of volumetric flask.The drug was dissolved in methanol by gentle shaking and volume made up to 100 ml with methanol to make standard solution A. Then 10 ml of this solution was transferred into 100 ml of volumetric flask and the volume was made upto 100 ml with methanol to make standard stock solution B of 10µg/ml concentration. Different concentrations ranging from 1□g/ml-10□g/ml were prepared by using standard stock solution B, after appropriate dilution with the methanol. Samples were analyzed using UV spectrophotometer **□max 354nm**.

Table 2: Observation table of concentration and absorbance of meloxicam in methanol

S.No.	CONCENTRATION	ABSORBANCE
1	0	0.000
2	1	0.062
3	2	0.110
4	3	0.161
5	4	0.219
6	5	0.260
7	6	0.325
8	7	0.372
9	8	0.416
10	9	0.461
11	10	0.505

Preparation of Calibration curve of meloxicam in distilled water

10 mg of Meloxicam was weighed and transferred into a 100 ml of volumetric flask. The drug was dissolved in a very little quantity of methanol by gentle shaking and volume madeup to 100 ml with distilled water to make standard solution A. Then 10 ml of this solution was transferred into 100 ml of volumetric flask and the volume was made upto 100 ml withdistilled water to make standard stock solution B of 10µg/ml concentration. Different concentrations ranging from 1□g/ml-10□g/ml were prepared by using standard stock solution B, after appropriate dilution with the distilled water. Samples were analyzed using UV spectrophotometer max 354 nm.

Table 3: Observation table of concentration and absorbance of meloxicam in distilled water

S. No.	CONCENTRATION	ABSORBANCE
1	0	0.000
2	1	0.040
3	2	0.101
4	3	0.163
5	4	0.223
6	5	0.281
7	6	0.351
8	7	0.402
9	8	0.461
10	9	0.512
11	10	0.565

Preparation of Calibration curve of Meloxicam in phosphate buffer (pH 7.4)

10 mg of meloxicam was weighed and transferred into a 100 ml of volumetric flask. The drug was dissolved in a very little quantity of methanol by gentle shaking and volume madeup to 100 ml with phosphate buffer (pH 7.4)to make standard solution A. Then 10 ml ofthis solution was transferred into 100 ml of volumetric flask and the volume was made upto 100 ml with phosphate buffer (pH 7.4)to make standard stock solution B of 10µg/ml concentration. Different concentrations ranging from 1□g/ml-10□g/ml were prepared by using standard stock solution B, after appropriate dilution with the phosphate buffer (pH 7.4). Samples were analyzed using UV spectrophotometer □**max 354 nm**.

Table 4: Observation table of concentration and absorbance of meloxicam in phosphate

S. No.	CONCENTRATION	ABSORBANCE
1	0	0.000
2	1	0.061
3	2	0.110
4	3	0.167
5	4	0.223
6	5	0.281
7	6	0.347
8	7	0.423
9	8	0.481
10	9	0.552
11	10	0.613

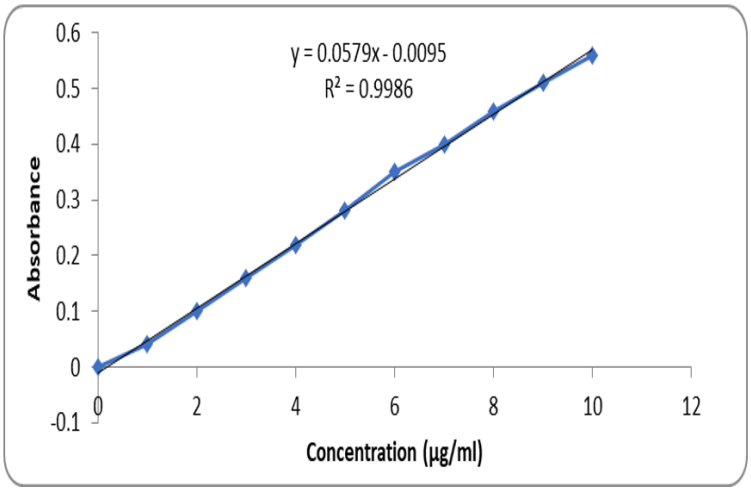

Figure 4: Calibration curve of meloxicam in phosphate buffer (pH 7.4) □max 238 nm

Solubility studies:

The solubility was determined by flask shake method. An excess amount of drug was takenin three flasks each containing water, phosphate buffer pH 7.4,methanol, and acetone. Sample were kept on a water bath maintained at 37± 0.5°C for 48 h and were thencentrifuged at 10,000 rpm for 10 min. The aliquots of suspension were filtered through a 0.45µm membrane filter. After appropiate dilution with methanol, solubility was determined using UV at 354 nm.

Table 5: Solubility of meloxicam in different solvents

Solvent	Solubility
Water	Practically Insoluble
Acetone	Slightly Soluble
Phosphate buffer pH 7.4	Soluble
Methanol	Soluble
DMF	Freely soluble

Determination of Partition Coefficient of Meloxicam

The partition coefficient of Meloxicam was determined in octanol/water system. 10 mg of drug was accurately weighed and added to a mixture containing 10 ml of each of octanol and distilled water. The flask was then shaken for 37°C for 24 h. The mixture was then transferred to a separating funnel and allowed to equilibrate for 10 h. The aqueous and octanol phase were seprated and filtered through membrane filter. After appropriate dilution concentration of drug was determined using UV spectrophotometer

Table 6: Determination of Partition Coefficient of Meloxicam

Total amount ofdrug in n- octanol/water solvent system (mg)	Amount of drug in organic phase (mg)	Total amount ofdrug in aqueousphase (mg)	Partition Coefficient
10	9.99297	0.00703	2.43

Po/w = (Coctanol / Cwater) at equilibrium

RESULT AND DISCUSSION

Pre formulation Studies

Pre formulation studies of the drug was carried out to confirm its identity and purity and also to confirm that there were no significant barriers to the development of the proposed formulation of the drug with the enlisted polymers and excipients.

Table 7: Physical property of Meloxicam

Compound name	Meloxicam
Physical appearance	Crystalline powder
Color	Yellow
Odour	Odourless
Melting point	257°C
Partition co-efficient	2.43
λ max	354 nm

Solubility Determination

Table 8: Solubility of Meloxicam in different solvents at 25°C

S. No.	Solvent	Solubility
1	Water	Practically insoluble
2	Acetone	Slightly Soluble
3	Phosphate buffer 7.4	Soluble
4	Methanol	Soluble
5	DMF	Freely soluble

Table 9: Aqueous Solubility of Meloxicamform solid dispersion prepared by Solvent Evaporation Method

S. No.	Formulations	Aqueous Solubility
1	SE1	30.79 ± 0.081
2	SE2	42.61± 0.045
3	SE3	59.96 ± 0.057
4	SE4	78.02 ± 0.064
5	SE5	101.81 ± 0.053

Results have been expressed as mean ± S.D. (n = 3)

Result

At the end of 48 hrs the aqueous solubility of acyclovir was found to be 12.00 ± 0.011 µg/ml.Where as in the formulation prepared by kneading method it was 36.23 ± 0.25 to 117.17 ± 0.64µg/ml, for the formulation prepared by solvent evaporation method it was 30.79 ± 0.32 µg/ml. Data were shown in Table 11.2 to 11.3. The solubility of drug increased in linear function of carrier concentration. All the SDswere shows enhance solubility but higher in case of formulation KM5 (1:5 ratio) and SE5 (1:5). In case of Poloxamer 407 it observed higher and cooperative low in case of PVP K-30 solid dispersion. It was due to the self-emulsifying nature of Poloxamer which enhance the solubility of solid dispersion as coparision to PVP K30.The results confirmed that the extent of disruption of crystallinity of Meloxicam by Poloxamer 407 was higher than that by PVP K-30 andcrystallinity of the drug was reduced insolid dispersion formulation with polymers Poloxamer 407 and PVP K-30.

***In-vitro* Dissolution Studies**

Table 10: Dissolution study of Solid Dispersion prepared by using Poloxamerby Kneading Methodin Phosphate Buffer pH 7.4

S.No	Time (min.)	Cumulative percentage drug release					
		Pure drug	1:1	1:2	1:3	1:4	1:5
1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2	10	7.50±0.52	9.97±0.10	11.23±0.56	13.89±0.15	17.61±0.84	23.56±0.51
3	20	12.11±0.59	16.45±0.14	20.00±0.78	21.97±1.01	23.19±0.64	32.06±0.57
4	30	17.32±0.35	22.03±0.45	27.19±0.20	30.13±0.57	31.69±0.35	39.78±0.64
5	45	25.65±0.57	29.89±0.09	36.29±0.34	38.16±0.64	40.10±0.55	44.09±0.37
6	60	33.33±0.33	37.12±0.64	41.78±0.16	43.01±0.17	46.71±1.17	51.63±0.54
7	90	36.65±0.81	42.63±0.32	46.02±0.56	47.98±0.64	55.19±0.36	56.67±0.94
8	120	41.53±0.45	45.23±0.54	51.08±0.38	56.37±0.82	62.58±0.28	69.67±0.57

Results have been expressed as mean ± S.D. (n = 3)

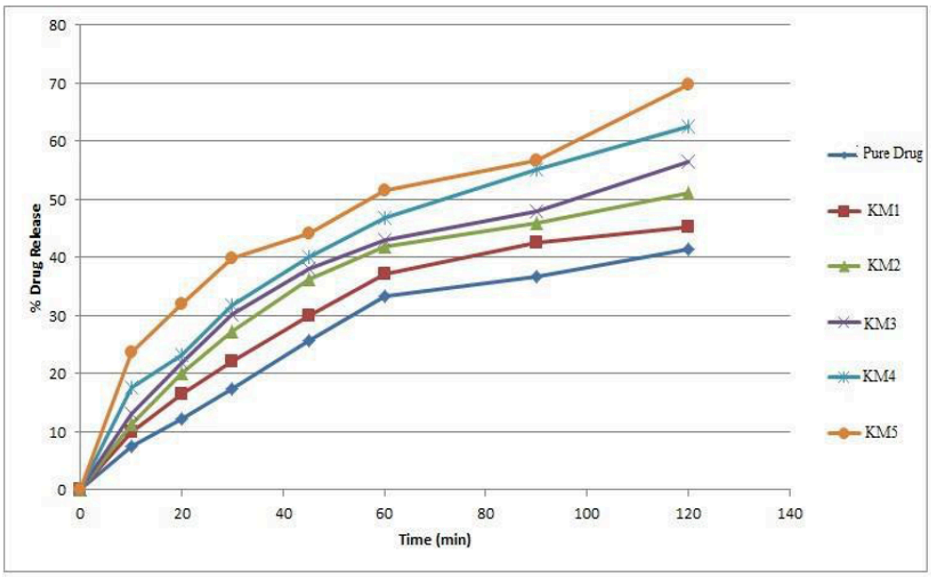

Figure 5: In vitro release profile of pure drug & formulations (KM1, KM2, KM3, KM4, KM5)

Table 11: Dissolution study of Solid Dispersion prepared by using PVP K-30 by Solvent Evaporation Method in Phosphate Buffer pH 7.4

S.No	Time (min.)	Cumulative percentage drug release					
		Pure drug	1:1	1:2	1:3	1:4	1:5
1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2	10	7.50±0.52	9.19±0.34	10.72±0.28	12.01±0.64	15.69±0.16	21.61±0.21
3	20	12.11±0.59	17±0.54	19.67±0.58	20.19±0.04	21.99±0.47	30.78±0.17
4	30	17.32±0.35	21.9±0.61	25.3±0.61	27.03±0.33	29.5±0.54	34.96±0.42
5	45	25.65±0.57	27.08±0.21	31.61±0.54	33.72±0.60	34.8±0.45	41.62±0.11
6	60	33.33±0.33	32.13±0.64	38.94±0.31	40.65±0.91	39.96±0.25	49.69±0.27
7	90	36.65±0.81	38.61±0.35	43.56±0.57	47.09±0.210	46.99±0.14	55.01±0.34
8	120	41.53±0.45	42.7±0.54	48.00±0.51	51.16±0.65	57.32±0.15	65.07±0.60

Results have been expressed as mean ± S.D. (n = 3)

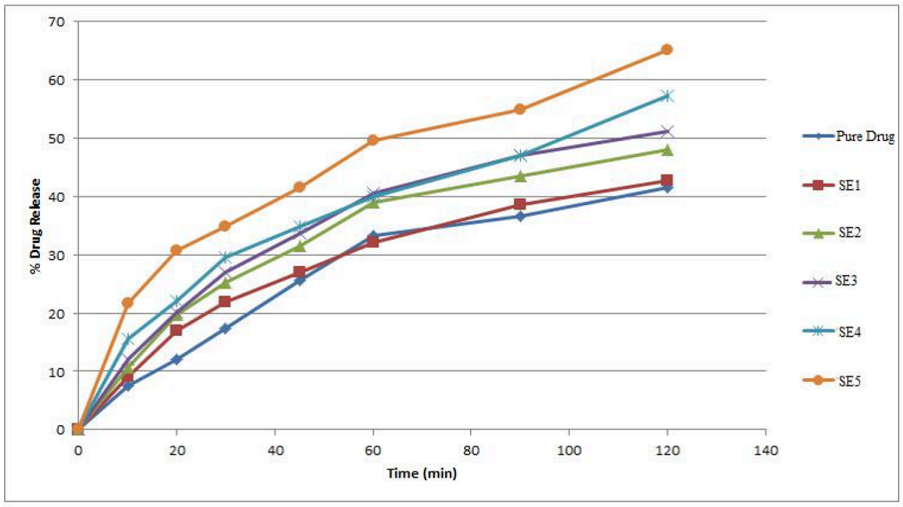

Figure 6: In vitro release profile of pure drug & formulations (SE1,SE2, SE3, SE4, SE5)

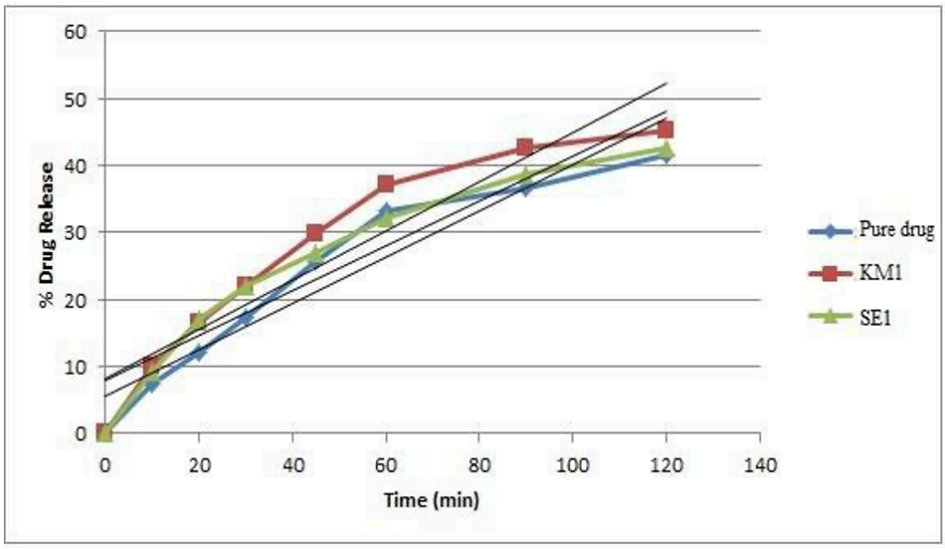

Figure 3: Dissolution profile of Solid Dispersion (1:1)w/w ratio

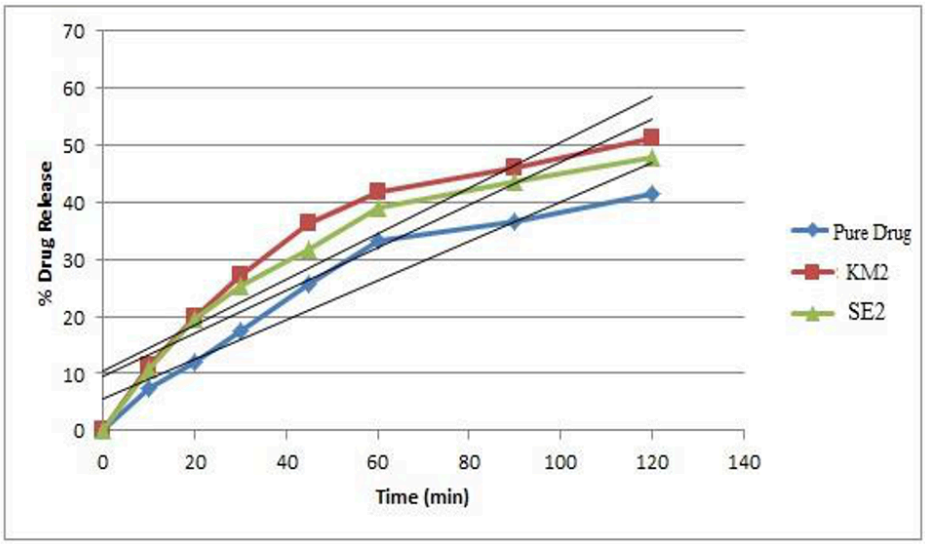

Figure 4: Dissolution profile of Solid Dispersion (1:2)w/w ratio

Result

Percentage drug dissolved within 120 min. in phosphate buffer pH 7.4 were reported in table 9.9 and 9.10, the graphical representation of the dissolution profile of pure drug and formulations were shown in Figure 9.16 to 9.22. The percentage drug released data from various formulations was found in the range of 42.70±0.54% to 69.67±0.57% within 120 minutes. The pure drug exhibited only 41.53±0.45 % of release. *In vitro* release studies reveal that there is marked increase in the dissolution rate of meloxicam from all SDs as compare to pure drug.The dissolution of drug increase with increase in the carrier ratio in the formulations. The maximum drug release was found in the formulation KM5 (1:5 ratio of drug: Poloxamer 407) is 69.67± 0.57%. The order of drug dissolution from different carriers is Poloxamer 407 > PVP K-30. The solubility of drug increase due to increase wettability of drug in presence of hydrophilic polymers. Studies on dissolution enhancement and mathematical modeling of drug release of a poorly water-

soluble drug using water soluble carriers. The solid dispersion prepared by Kneading and solvent evaporation methods showed a significant increase in dissolution rate with increase in the amount of Poloxamer and PVP K-30. Formulation KM5 shows maximum release 69.67± 0.57% in 120 min. (Figure 9.22) and also formulations SE5, showed maximum release in 120 min, among the other preparation of SDs prepared by Kneading method and solvent evaporation method respectively. In general the dispersion prepared by kneading method showed faster release of meloxicam fallowed by solvent evaporation method. The enhanced dissolution rates of SDs may be due to many factors such as decreased particle size of drug, specific form of drug in these SDs, in addition to the increase in drug wettability and preventing of drug aggregation by each polymer. Furthermore, all polymers affected the crystallinity of the drug could be considered as an important factor in enhancement the dissolution rate. It is known that amorphous drug represents the most ideal case for fast dissolution. Thus *in-vitro* drug release was best for solid dispersion KM5.On the basis of aqueous solubility and further *in-vitro*drug release studies, the formulation KM5 selected as the best formulation for further studies. The results are shown in Table 9.9, 9.10 and Figure 9.16 -9.22

Evaluation of Blank Suspension

Table No. 12: Powder Characterization of Blank Suspension

Formulation Code	Angle of Repose	Carr's Index	Hausner's Ratio
A1	26.45^0±0.68	21.89	1.232
A2	28.27^0 ±0.72	22.06	1.224
A3	24.54^0±0.81	21.99	1.234
A4	25.73^0±0.14	22.12	1.226
A5	23.44^0±0.44	21.56	1.239
A6	22.64^0±0.86	21.93	1.237

*S.D.(n=3)

Table 13: Evaluation of Blank Suspension

Blank Suspension Code	Viscosity 100 RPM	Sedimentation Rate (1 Hour)	Ease of Redispersibility %	pH
A1	842.4±2.11	0.39±0.03	90±0.04	4.5±0.03
A2	615.1±0.56	0.32±0.07	95±0.04	4.5±0.04
A3	747.4±1.45	0.36±0.03	100±0.02	4.5±0.04
A4	574.9±2.38	0.31±0.08	100±0.06	4.5±0.03
A5	583.5±0.45	0.30±0.10	100±0.02	4.5±0.08
A6	356.9±2.01	0.18±0.02	100±0.02	4.5±0.02

*S.D. (n=3)

Result

In the initial stage of the formulation development, the preparation of a blank suspension was carried out by varying the ingredients especially the suspending agent used in the formulation. The optimized composition was selected from the different ingredient compositions. From the results of viscosity formulation A6 was selected, for further incorporation of SDs drug, as shown in the Table No 9.12. The selection was based on the parameters like ease of redispersibility, sedimentation rate and pH. The blank dry suspension was evaluated for the flow properties including the angle of repose, bulk density, tapped density, Hausner's ratio, Carr's Compressibility index and particle size analysis. It was observed that dry suspension powder possessed good flow properties (Table No. 6,7)

Table 14: Evaluation parameters of dry suspension of Meloxicam

Formulation Code	Bulk Density	Tapped Density	Hausner's Ratio	Carr's Index	Angle of Repose
A6KM5	1.3157±0.006	1.7857±0.002	1.3572	26.31%	23.08^0±0.62
A6SE5	1.0204±0.001	1.3888±0.007	1.3610	26.53%	27.83^0±0.81

*Formulation Code A6 was selected for the final formulation of suspension containing the taste masked drug
*S.D. (n=3)
A6KM5-Optimized Dry suspension of Poloxamer 407 and Meloxicam
A6SE5- Optimized Dry suspension of PVP K-30 and Meloxicam

Accelerated Stability Studies

Table 15: Stability Study Data at 40^0 C/75% RH

	40^0 C/60% RH			
Formulation Code	**1st week**	**2nd week**	**3rd week**	**4th week**
A6KM5	92.73%	89.16%	84.71%	78.35%
A6SE5	93.25%	88.07%	82.41%	76.45%

Table 16: Stability Study Data at 30^0 C/60% RH

	30^0 C/60% RH			
Formulation Code	**1st week**	**2nd week**	**3rd week**	**4th week**
A6KM5	95%	89.41%	84.44%	76%
A6SE5	96.66%	92.8%	89.23%	80%

Table 71: Stability Study Data at 30^0 C/60% RH

25^0 C/60% RH				
Formulation Code	**1st week**	**2nd week**	**3rd week**	**4th week**
A6KM5	94.73%	90%	85.71%	81.81%
A6SE5	99.25%	95.71%	92.41%	86.45%

*Standard Deviation (n=3)

The chemical stability of meloxicam is of prime importance of suspension. Hence, the preparation was subjected for stability studies.The developed Formulation A6KM5 and A6SE5 were found to be stable after analysing various concentrations of excipients and combinations of drug with taste masking agents. The satisfactory improvement of the taste was the soul of the entire project and finally it was achieved in the optimized formulation at 30^0 C/60% RH[12,13]. The optimized formulation remained stable for the period of one month. The sedimentation rate was found to be 1. But ease of re dispensability was decreased by 10 %. There was no variation in the organoleptic characters like colour and odour. Results of dissolution studies indicate that optimized suspension formulation has better dissolution[12-15]..

Conclusion

The dissolution studies were well exhibited, the rheological studies revealed were satisfactory, the percentage of drug content and the percentage of drug release were obtained within the acceptable limits, and the suspension remained stable for one month thanks to the kneading method. It is possible to draw the conclusion that the solid dispersion of Meloxicam by Kneading method was superior in every aspect related to the formulation. Based on the results of characterization investigations, it has been determined that the solid dispersion of Meloxicam- Poloxamer 407 exhibits an increase in Meloxicam dissolution. This transformation of Meloxicam into a less crystalline or amorphous state is responsible for this enhancement. With polymer Poloxamer 407, the kneading method of making SD was found to be satisfactory since it demonstrates an excellent result with a high drug content. Formulation KM5 demonstrated enhanced solubility as well as dissolution when compared to pure medication, out of the ten formulations that were prepared initially. According to the results of the IR investigation, there is no evidence of medication interactions with the carrier. Even though the pure medication was crystalline in nature, the SEM research reveals that the surface shape changed to become amorphous. By utilizing the solid dispersion approach, it is possible to draw the conclusion that the solubility of the medicine Meloxicam, which is not very soluble, may be significantly improved. Furthermore, the carrier Poloxamer 407 has been shown to boost the drug's dissolution without triggering any interaction.

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