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# Formulation and Evaluation of Lornoxicam Loaded Self-Nano Emulsifying Drug Delivery System


***Prepared by*** **:**

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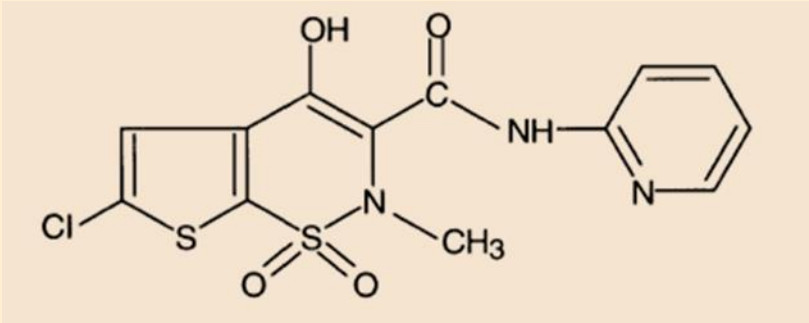

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# Introduction

- SNEDDS are isotropic mixtures of oil, surfactant, co-surfactant and drug that form fine oil-in-water Nanoemulsions when introduced into aqueous phases under gentle agitation.

- **Advantages :**
- Protection from the GI side effect
- Ease of manufacture and scale-up.
- Improvement in oral bioavailability.
- It can be easily stored since it is homogenous system and drug is not in contact with aqueous phase.

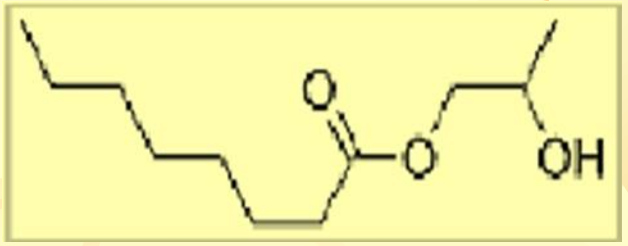
# Drug profile

| Name of drug | LORNOXICAM |
|---|---|
| Structure |  |
| Molecular weight | 371.82 gm/mol |
| BCS Classification | **Class-II (low solubility and high permeability)** |
| Water solubility | **0.0083 µg/ml** |
| Half life | **3-5 hr.** |
| Dose | 4mg (thrice daily), 8mg (twice daily) |
| Side effect | Irritation on GI tract |

# Cont…

| | |
|---|---|
| **Log P** | **2.62** |
| Protein binding | 99 % |
| **Melting Point** | **220–225 °C** |
| Category | NSAID |
| Mechanism of Action | Lornoxicam is a potent inhibitor of both COX-1 and COX-2 enzymes. which suppresses the production of prostaglandins and thromboxanes thereby reducing pain and inflammation. |
| Brand Name | Xefo tab (Nycomed), CAMRI tab (Cadila), FLEXILOR inj (Glenmark), LANAGESIC tab (Wockhardt) |

# Excipients profile

| Capryol-90 | | |
|---|---|---|
| Sr.No | Name | Indication |
| 1 | **Non-proprietary name** | **Propylene glycol monocaprylate** |
| 2 | CAS no | 31565-12-5 |
| 3 | Empirical formula | $C_{11}H_{22}O_3$ |
| 4 | **Functional Category** | **Solubilizer, Lipophilic vehicle** |
| 5 | **HLB Value** | **6** |
| 6 | Stability and storage condition | Stable under ordinary condition |
| 7 | Structure |  |

# Acrysol K-160

| Sr.No | Name | Indication |
|---|---|---|
| 1 | **Non-proprietary name** | **Polyoxyl 60 Hydrogenated Castor Oil** |
| 2 | CAS no. | 61788-85-0 |
| 3 | **Functional Category** | **Emulsifying agent; solubilizing agent; wetting agent** |
| 4 | **HLB Value** | **15-17** |
| 5 | Stability and storage condition | Stable over a broad temperature range and pH independent. |
| 6 | LD 50 (Rat, Oral) | >16.0 g/kg |
| 7 | Regulatory status | Included in the FDA Inactive Ingredients Database, Included in parenteral medicines licensed in the UK. Included in the canadian list of acceptable non-medicinal ingredients. |

# PEG-400

| Sr.No | Name | Indication |
|---|---|---|
| 1 | **Non-proprietary name** | **Macrogol 400** |
| 2 | Chemical Name | α-Hydro-o-hydroxypoly (oxy-1, 2-ethanediyl) |
| 3 | CAS no | 25322-68-3 |
| 4 | Empirical formula | $HOCH_2(CH_2OCH_2)_8*7CH_2OH$ |
| 5 | **Functional Category** | **Co-emulsifier, Ointment base, plasticizer, co-solvent** |
| 6 | **HLB Value** | **11.6** |
| 7 | Stability and storage condition | Stable in air and in solution, stored in well-closed containers in a cool, dry place. |
| 8 | Regulatory status | Included in the FDA Inactive Ingredients Database. Included In Nonparenteral Medicines Licensed In The Uk. Included in the Canadian List of Acceptable Non-medicinal Ingredients. |

# Aim

- The aim of present research work is to formulate and evaluate Lornoxicam loaded Self-Nano emulsifying drug delivery system to improve solubility, subsequently enhancement of drug dissolution.

# Rationale

- Lornoxicam is **BCS class-II** drug, having low solubility and high permeability.
- During Acute pain condition, it is required to achieve quick plasma concentration for **quick onset of action** which can be achieved by SNEDDS.
- Major side effect like **local irritation** can be prevented.

# Literature review

## 1. Drug

| Title | Excipients | Inference | Reference |
|---|---|---|---|
| Preparation and characterisation of lornoxicam solid dispersion systems using hot melt extrusion technique | Soluplus®, PEG 400, Lutrol F127, Lutrol F68 | This Lornoxicam incorporated Solid dispersion gave higher dissolution and solubility values compared to the commercial product . | **Fule R et al.,** Journal of Pharmaceutical Investigation (2013) |
| Nano suspensions for enhancing the dissolution of lornoxicam by Antisolvent precipitation technique. | Poloxamer 407, Aerosil 200 | The amorphous LOR nanoparticles showed dramatic improvement in rate as well as extent of *in-vitro* drug dissolution. | **Shinde S et al.,** Indo American journal of pharmaceutical research(2014) |

# 2. Formulation

<table>
<tr><th>Title</th><th>Excipients</th><th>Inference</th><th>Reference</th></tr>
<tr><td>SNEDDS for enhanced dissolution of gemfibrozil</td><td><table><tr><td>lemon oil</td><td>21.62%</td></tr><tr><td>Cremophor® EL 300</td><td>32.43%</td></tr><tr><td>Capmul® MCM C8</td><td>29.73%</td></tr></table></td><td>SNEDDS of Gemfibrozil showed a significant increase in release rate compared to conventional tablets under the same conditions, 90% drug was released within 15 min in comparison to 30% from conventional tablets.</td><td>Maria A et al., International Journal of Pharmaceutics (2012)</td></tr>
<tr><td>SNEDDS for Cefpodoxime Proxetil</td><td><table><tr><td>Capryol 90</td><td>37.5%</td></tr><tr><td>Cremophor EL</td><td>50%</td></tr><tr><td>Akoline MCM</td><td>12.5%</td></tr></table></td><td>Optimized SNEDDS released CFP completely within 20 min., improve bioavailability up to 98%</td><td>Nagarsenker et al., International Journal of Pharmaceutics (2007)</td></tr>
</table>

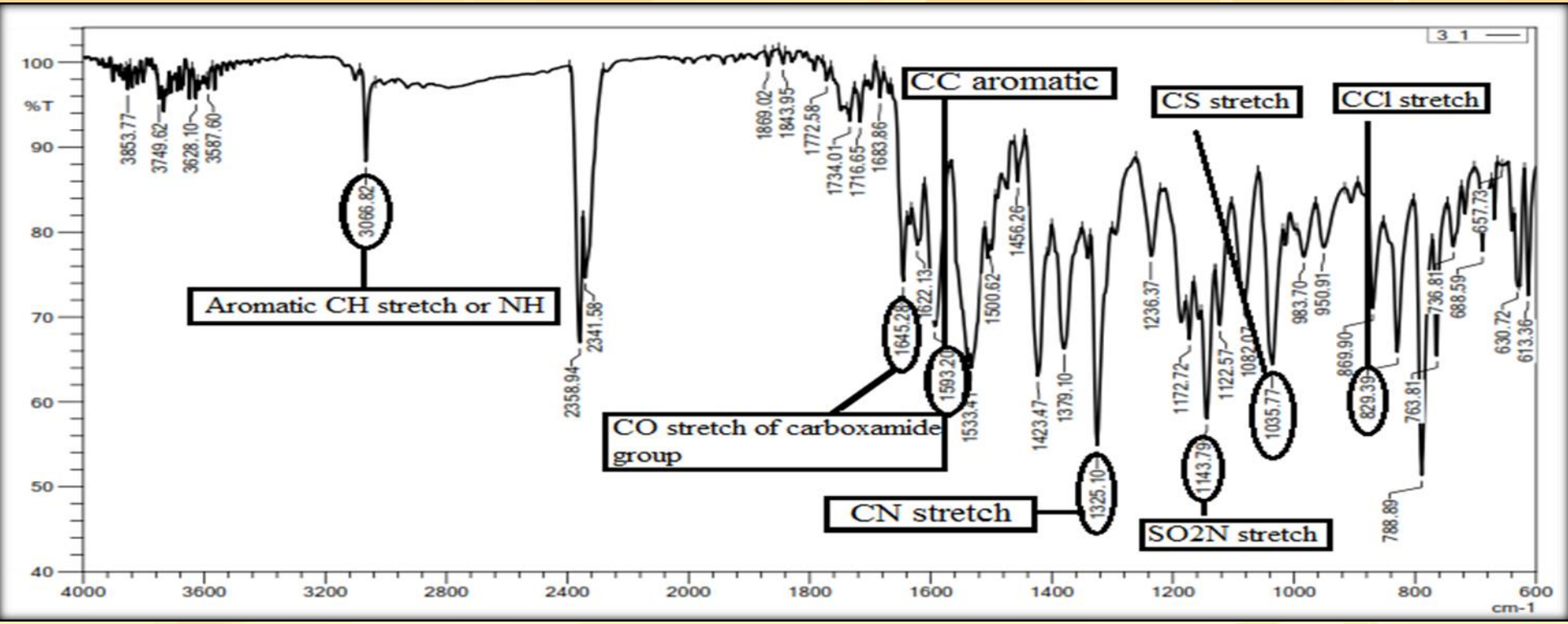
| Title | Excipients | Inference | Reference |
|---|---|---|---|
| SNEDDS of carvedilol | Capmul PG8 O<br>Cremophor EL S<br>Transcutol HP Cos | The optimized SNEDDS formulation exhibited 3–4 fold improvement in bioavailable fraction, absorption number and wall permeability of carvedilol as compared to pure drug and marketed formulation | **Singh B et al.,** Drug Delivery (2011) |
| SNEDDS of Rosuvastatin calcium | Cinnamon oil 30%<br>Labrasol 60%<br>Capmul MCM C8 10% | The relative bioavailability of self-Nano emulsified formulation showed an enhanced bioavailability of 2.45 times greater than that of drug in suspension. | **Krishnamoorthy B et al.,** Colloids and Surfaces B: Bio interfaces (2013) |

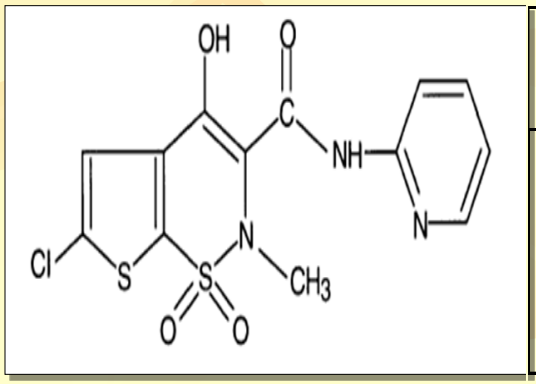
# PATENT SEARCH REPORT

- All the above patents state the formulation of Self-Nano emulsifying drug delivery system for the enhancement of solubility and dissolution of poorly water soluble components.
- In the present investigation, we are working on poorly water soluble drug Lornoxicam for the solubility and dissolution enhancement as well as for immediate release of drug.
- Lornoxicam is a Non-steroidal anti-inflammatory drug and most widely used for acute and chronic pain condition like rheumatoid and osteoarthritis. During the pain condition, it is required to reach the drug immediately to the site of action which can be possible by Self-Nano emulsifying drug delivery system.
- Lornoxicam having side effect like GI irritation which can be prevented by Self-Nano emulsification because drug will be presented in emulsifying oily globules.

# Identification of Drug

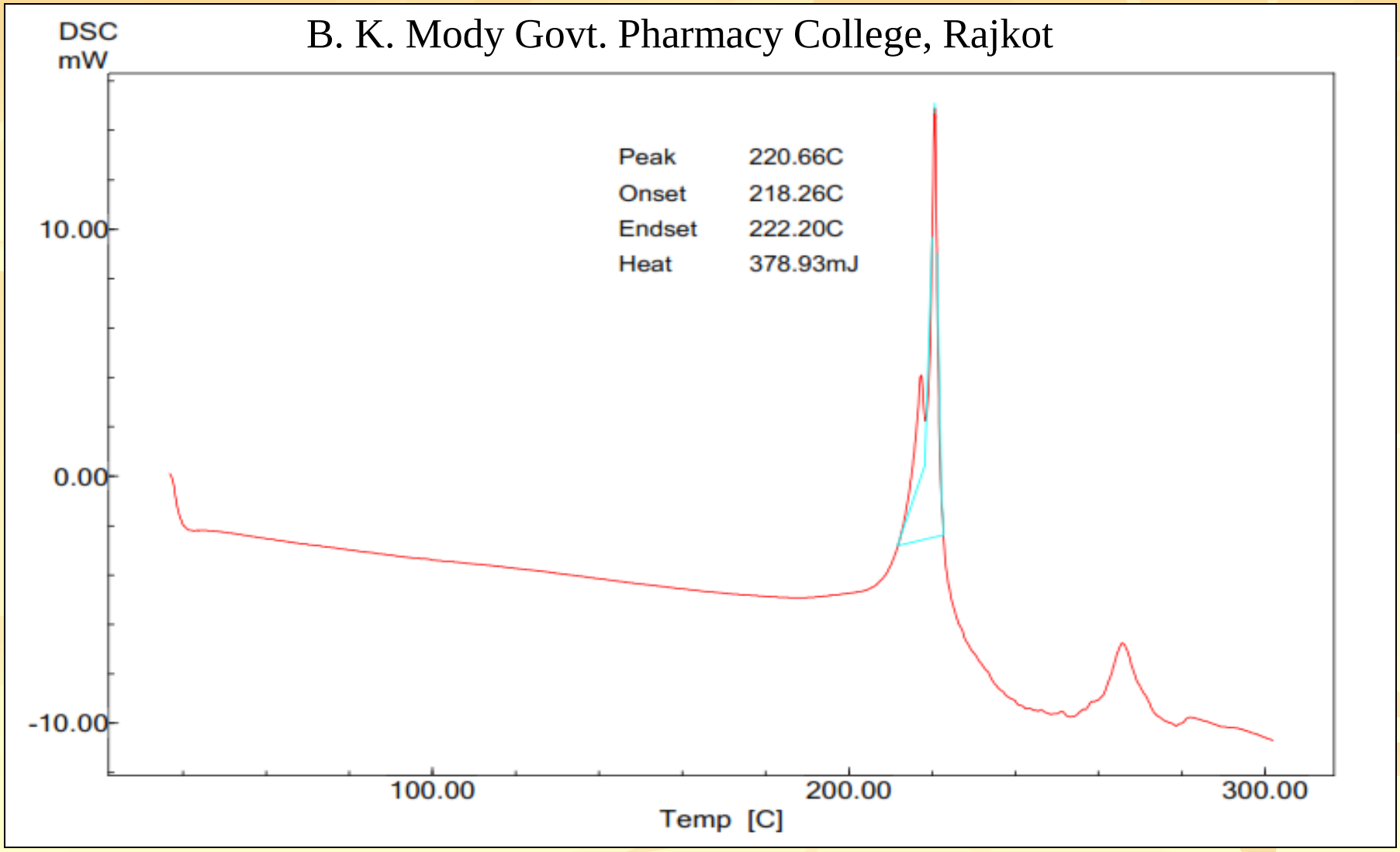
# Infrared spectroscopy



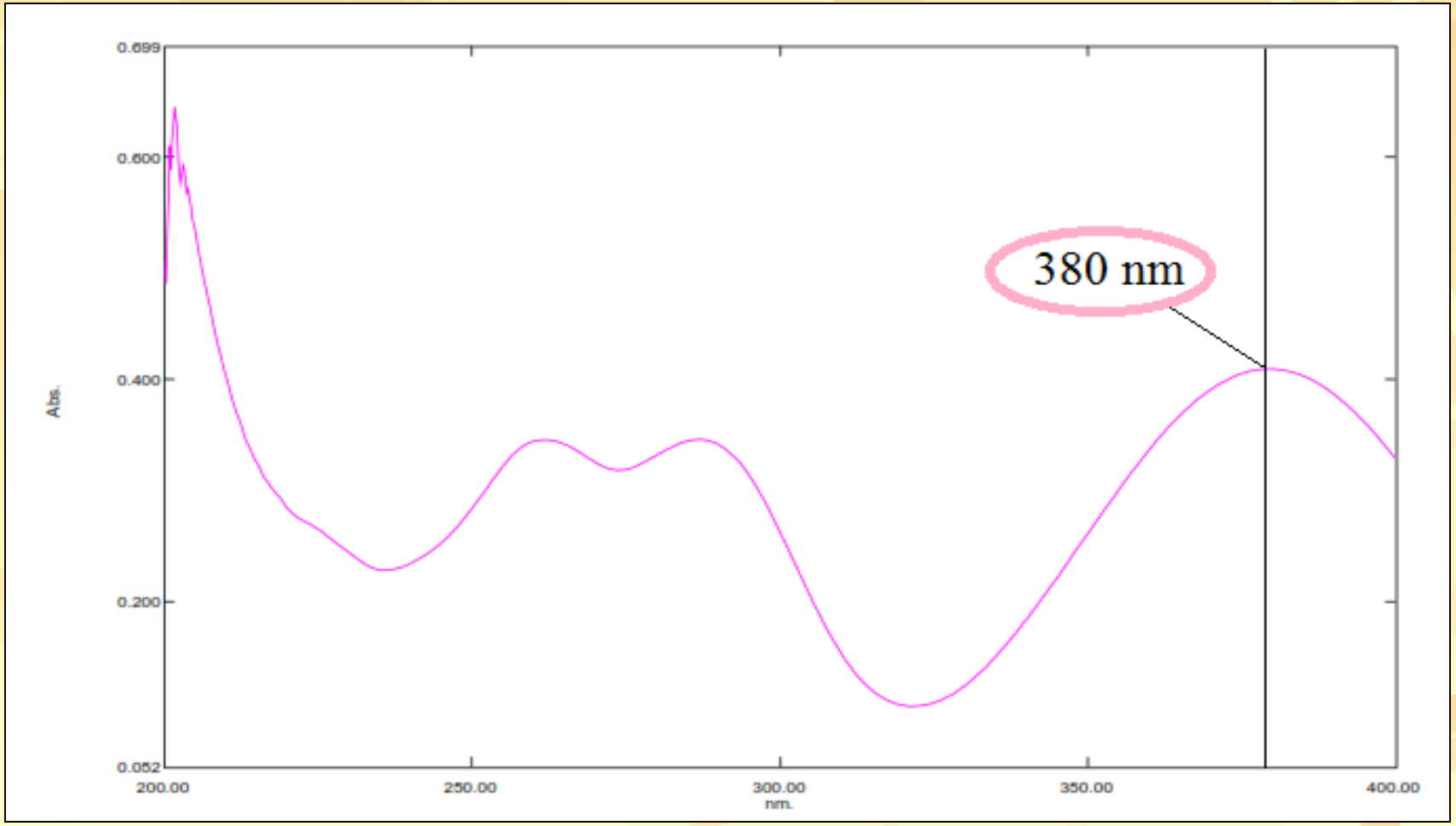

| **Wavenumber $cm^{-1}$** | 3066 | 1645 | 1593 | 1325 | 1143 | 1035 | 829 |
|---|---|---|---|---|---|---|---|
| **Functional group** | Aromatic CH stretch or NH | CO stretch of carboxamide group | CC aromatic | CN stretch | SO2N stretch | CS stretch | CCl stretch |

# DSC Thermogram of Lornoxicam



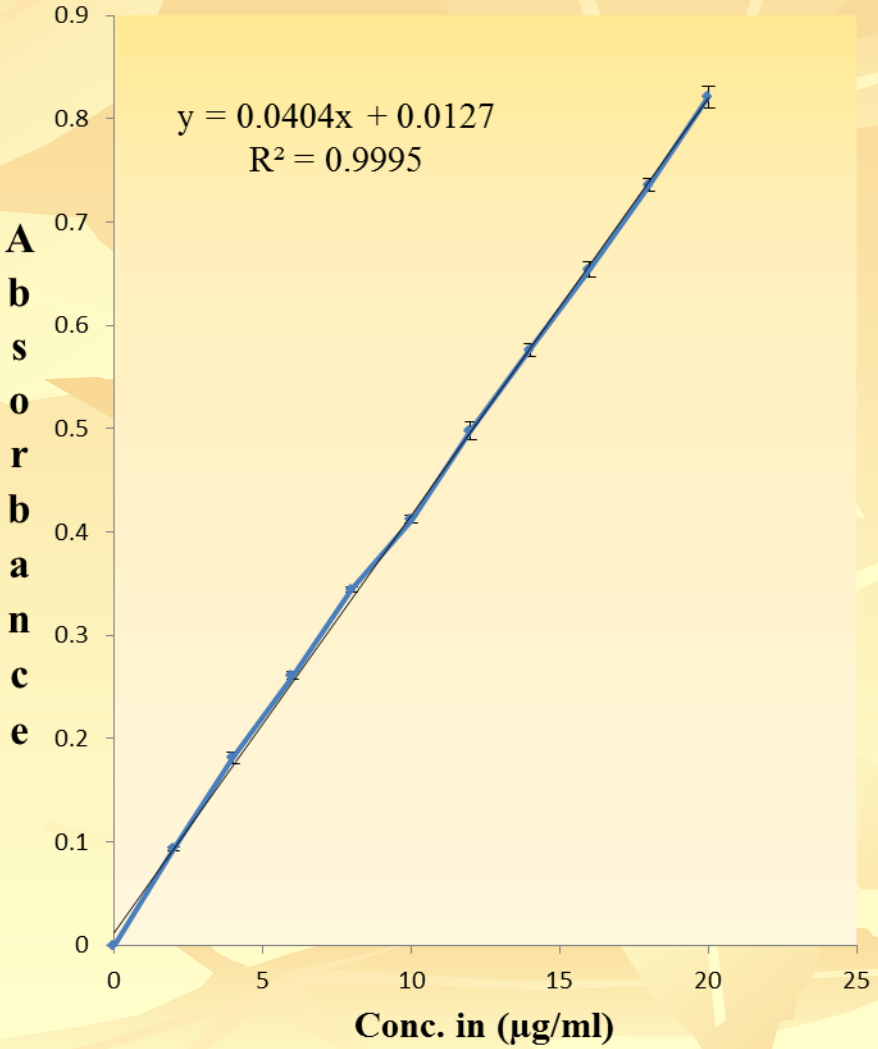
# Calibration Curve

1. Determination of $\lambda_{max}$



# 2. Calibration curve in Methanol

| Sr. No | Conc. (µg/ml) | Abs. Mean ± S.D* |
|---|---|---|
| 1 | 2 | 0.093 ± 0.002 |
| 2 | 4 | 0.181 ± 0.005 |
| 3 | 6 | 0.261 ± 0.003 |
| 4 | 8 | 0.344 ± 0.002 |
| 5 | 10 | 0.412 ± 0.003 |
| 6 | 12 | 0.498 ± 0.008 |
| 7 | 14 | 0.576 ± 0.006 |
| 8 | 16 | 0.654 ± 0.007 |
| 9 | 18 | 0.735 ± 0.006 |
| 10 | 20 | 0.821 ± 0.010 |

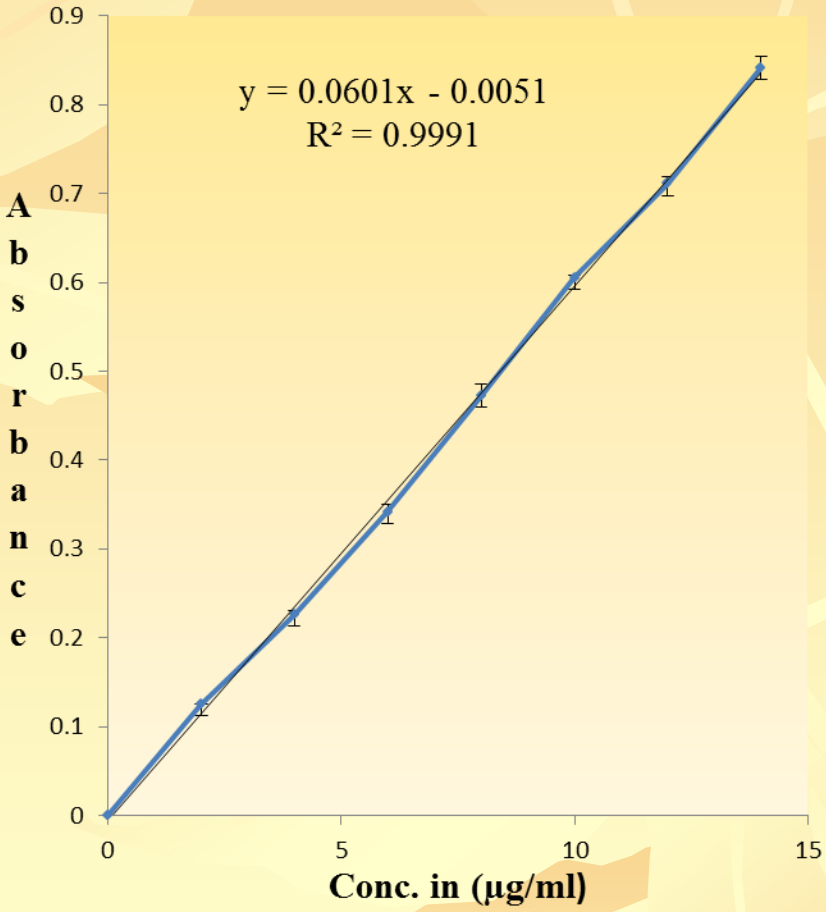



*Data expressed as mean ± SD (n = 3).

# 3. Calibration curve in 0.1 N HCl

| Sr. No | Conc. (µg/ml) | Abs. Mean ± S.D* |
|---|---|---|
| 1 | 2 | 0.125 ± 0.001 |
| 2 | 4 | 0.225 ± 0.004 |
| 3 | 6 | 0.341 ± 0.008 |
| 4 | 8 | 0.472 ± 0.013 |
| 5 | 10 | 0.605 ± 0.002 |
| 6 | 12 | 0.711 ± 0.007 |
| 7 | 14 | 0.841 ± 0.013 |

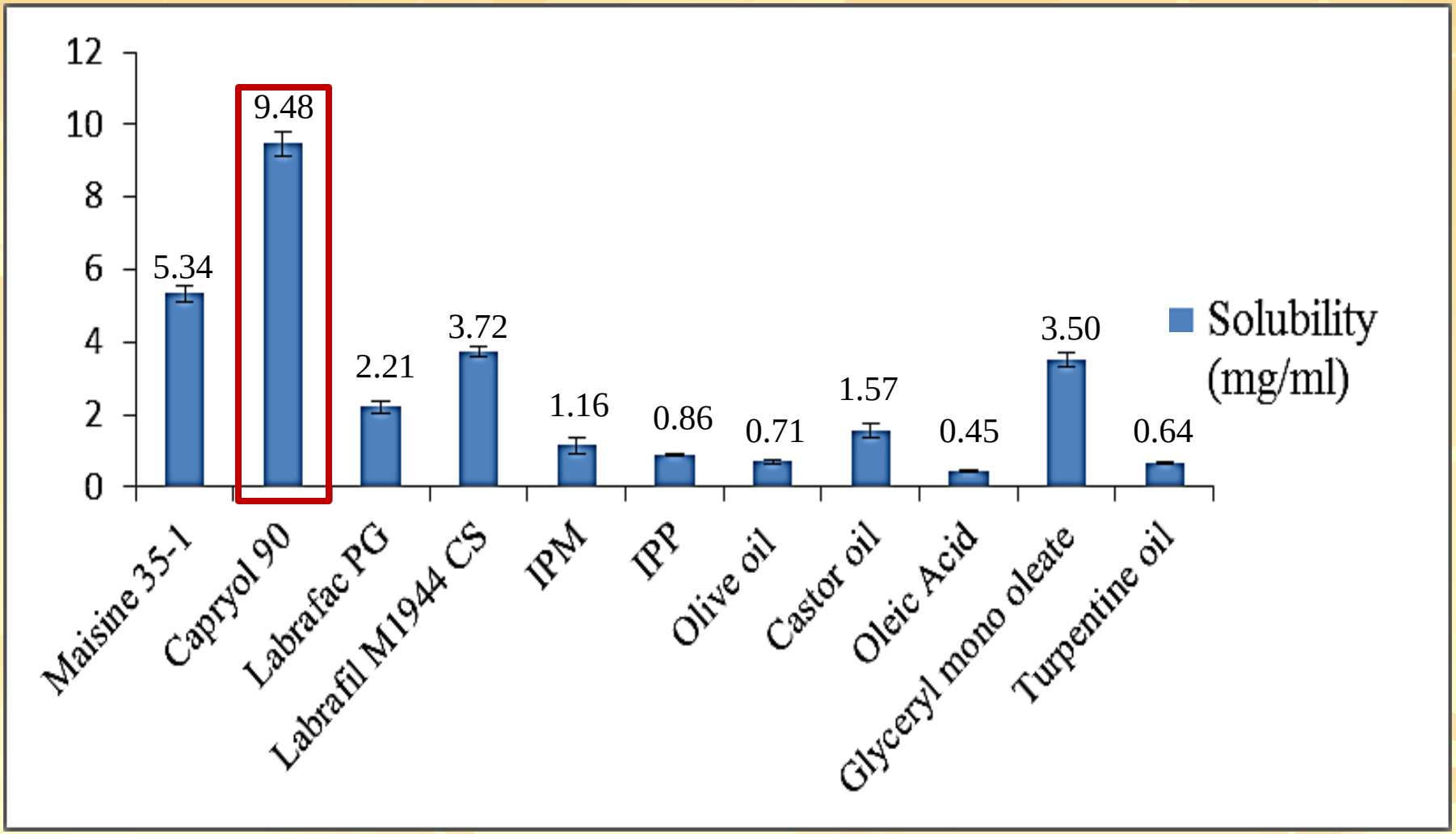
*Data expressed as mean ± SD (n = 3).



# Preliminary study

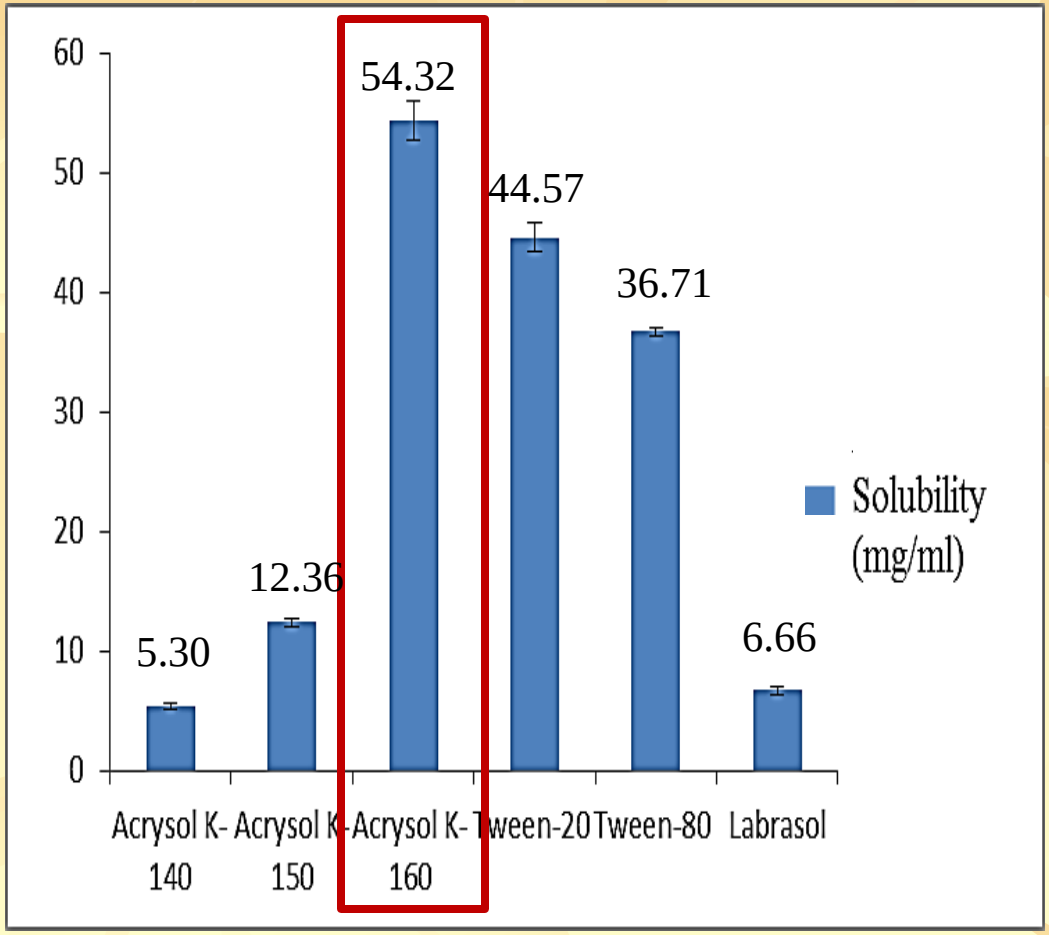
1. Solubility study in various Oils, Surfactants, Co-Surfactants
2. Surfactant screening
3. Co-surfactant screening
4. Ternary phase diagram

# Solubility study in various oils




Data expressed as mean ± SD (n = 3).

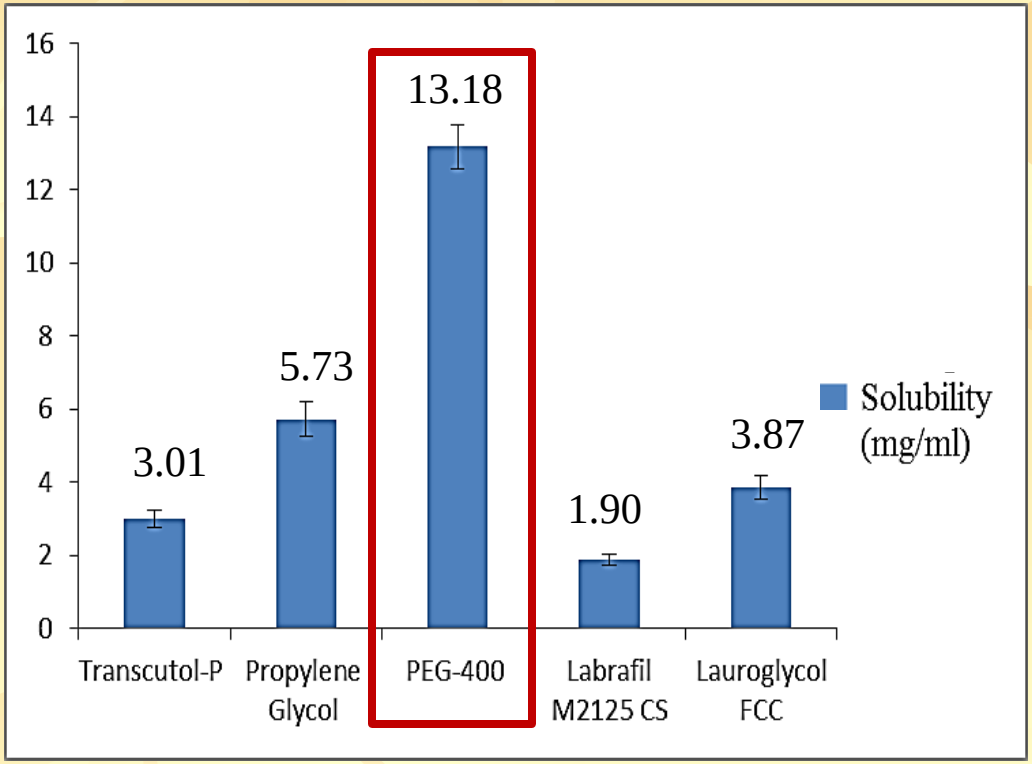
# Solubility study and screening of Surfactants




| Surfactant | % Transmittance |
|---|---|
| Tween-20 | 96.09 |
| Tween-80 | 89.4 |
| Acrysol K-150 | 94.7 |
| Acrysol K-160 | 99.4 |
| Labrasol | 39.2 |

Data expressed as mean ± SD (n = 3).

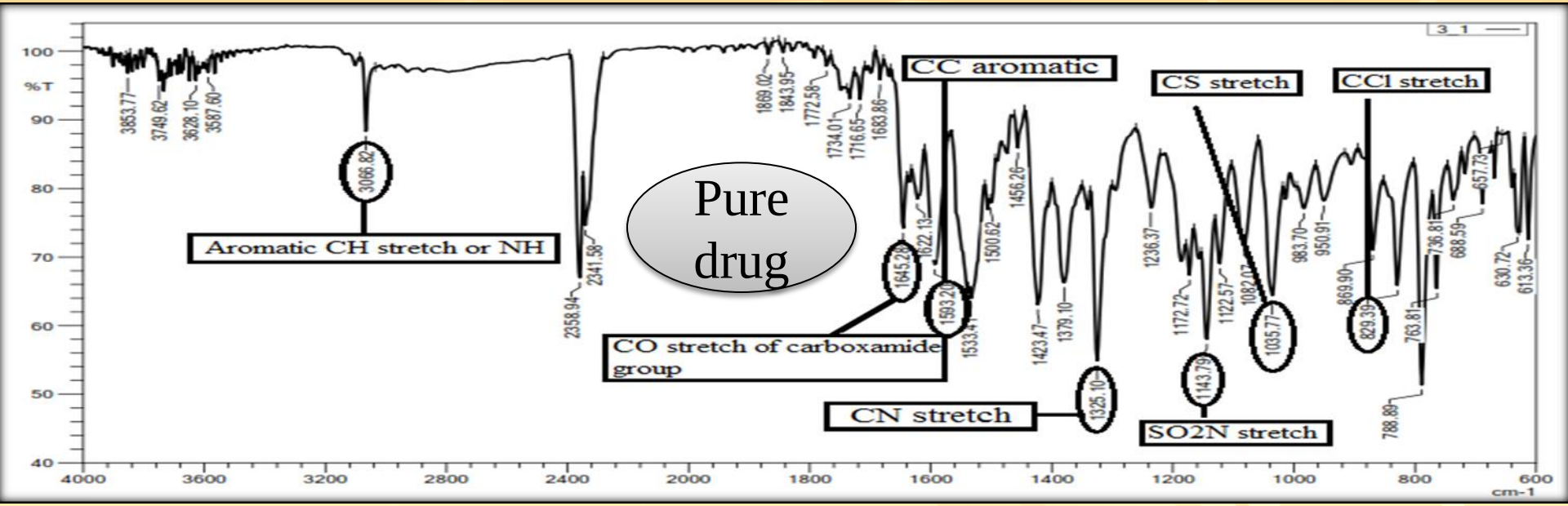
# Solubility study and screening Co-Surfactants

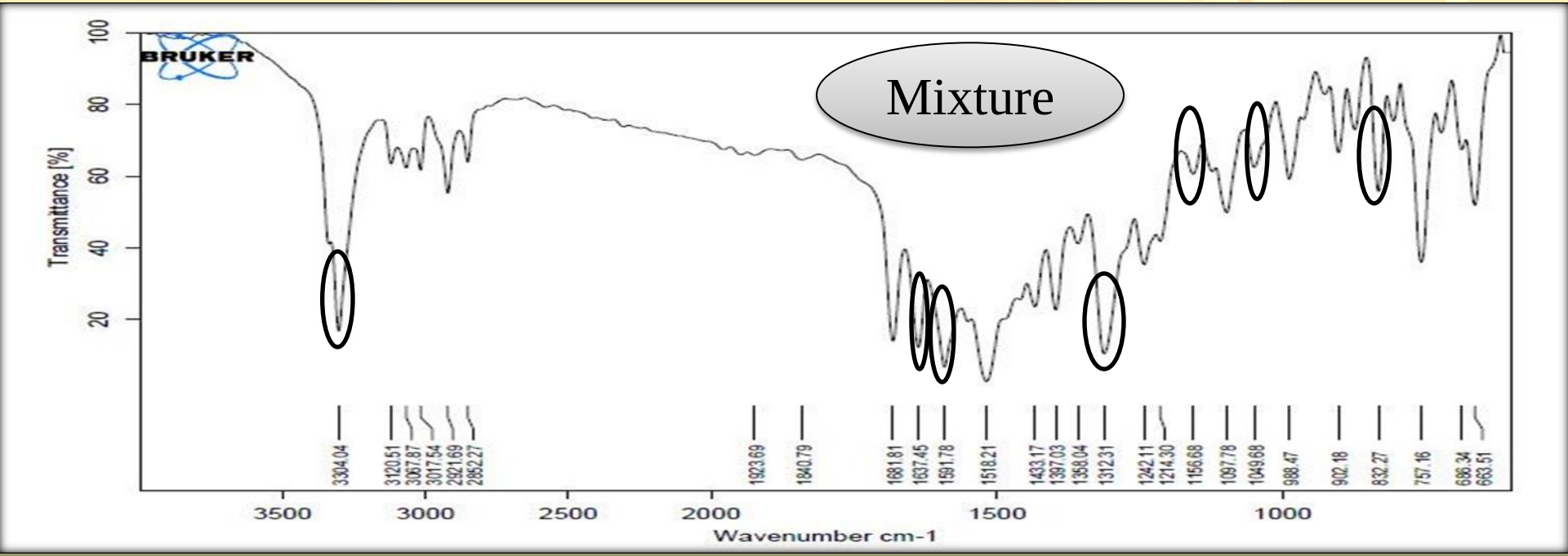



| Name of surfactant | % Transmittance |
|---|---|
| PEG-400 | 98.9 |
| Propylene Glycol | 97.3 |
| Transcutol P | 98.2 |
| Lauroglycol FCC | 88.3 |
| Labrafil M 2125CS | 81.5 |

Data expressed as mean ± SD (n = 3).

# Drug excipient compatibility study



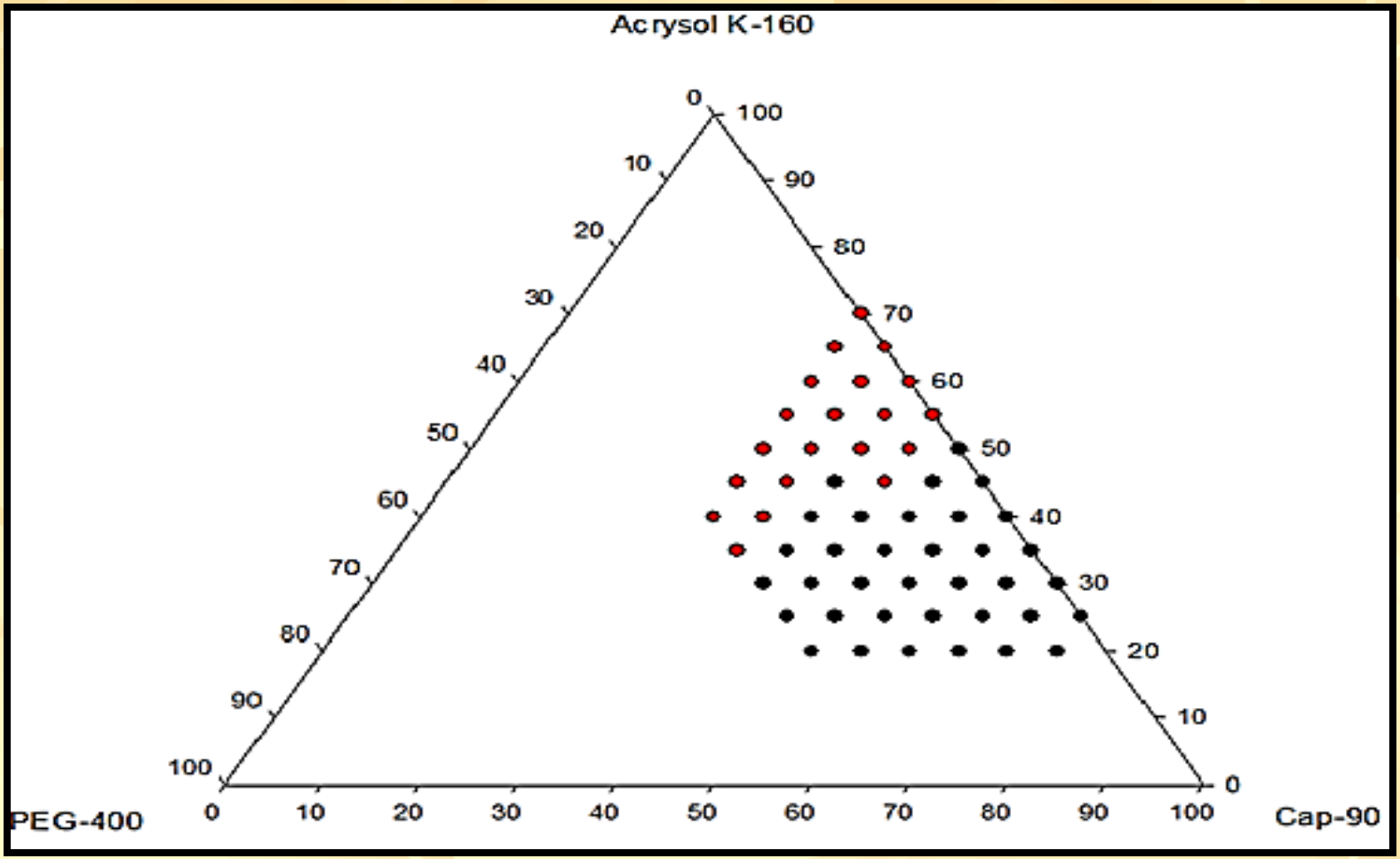
# Ternary phase diagram

| Components | Range |
|---|---|
| Capryol-90 | 30-75 % |
| Acrysol-K 160 | 20-70 % |
| PEG 400 | 0-30 % |

For example…..

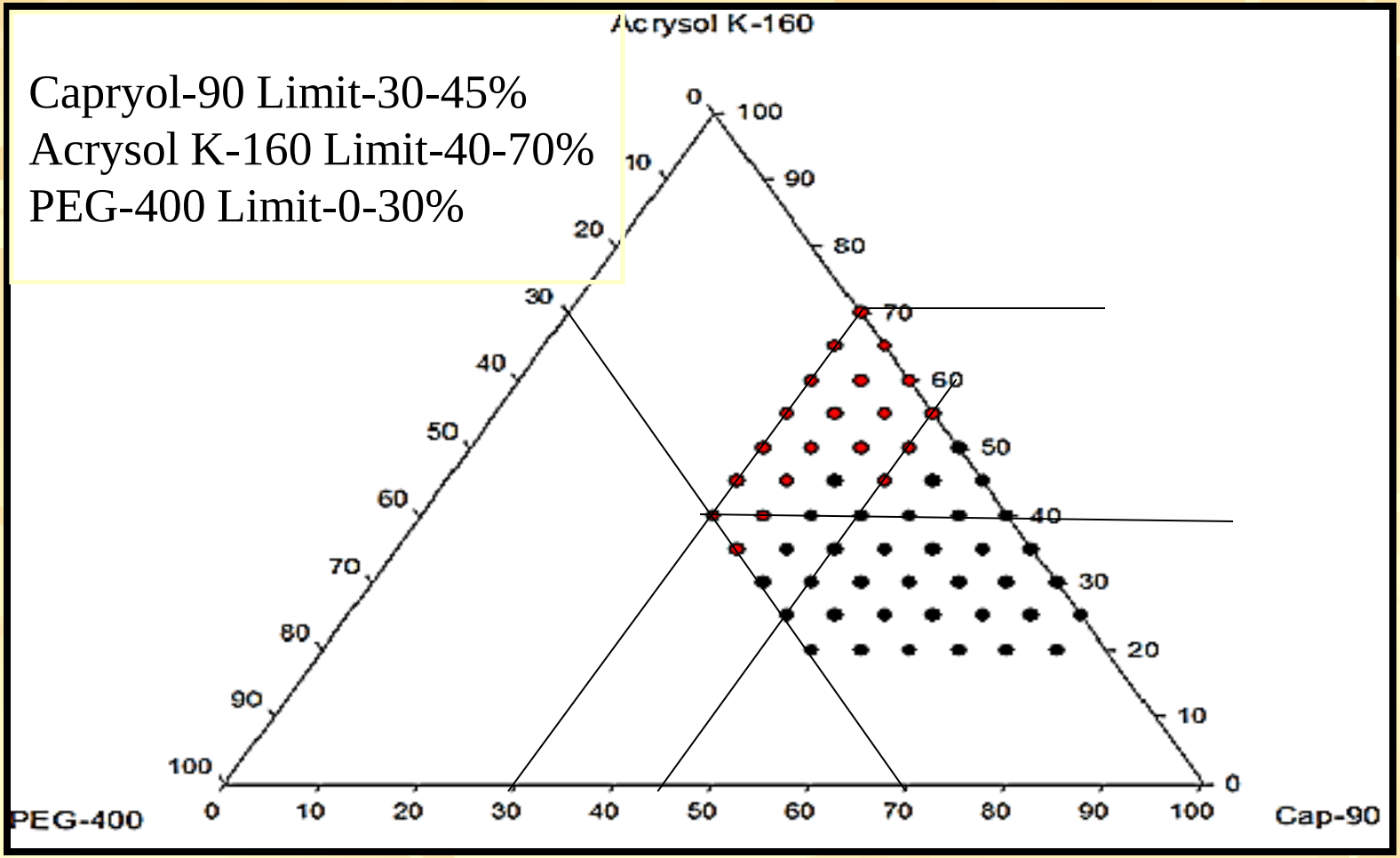
| Sr.No | Oil (%) | S (%) | Co-S (%) |
|---|---|---|---|
| **1** | 30 | 70 | 0 |
| **2** | 30 | 65 | 5 |
| **3** | 30 | 60 | 10 |
| **4** | 30 | 55 | 15 |
| **5** | 30 | 50 | 20 |
| **…….55** | 75 | 20 | 5 |

# Ternary phase diagram without drug in 0.1 N HCl

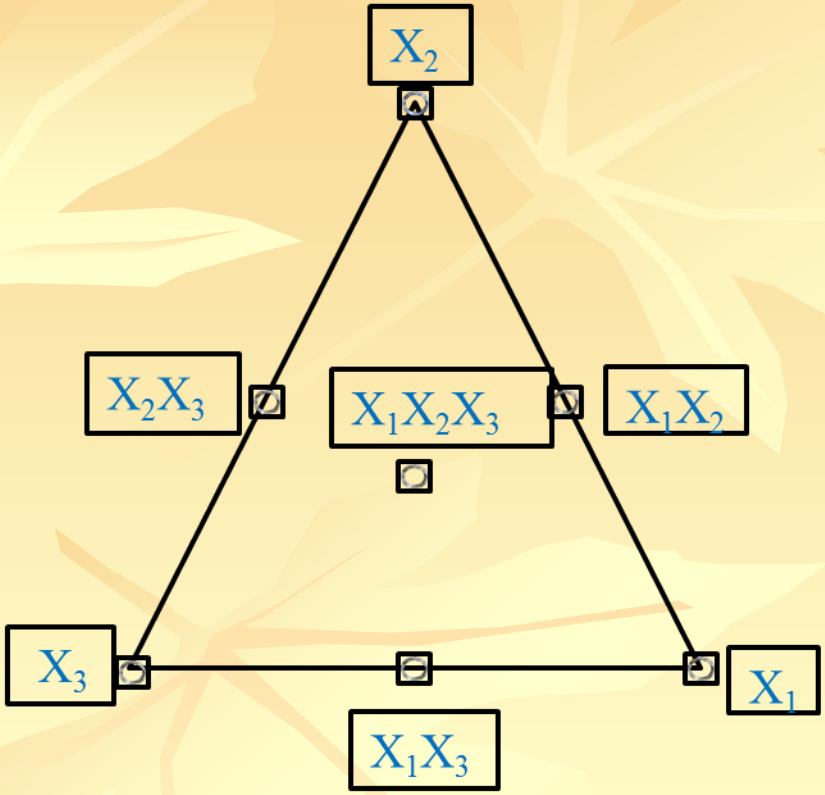


# Ternary phase diagram with Lornoxicam in 0.1 N HCl

Capryol-90 Limit-30-45%
Acrysol K-160 Limit-40-70%
PEG-400 Limit-0-30%



# Simplex lattice design




| Independent variables | | Levels | |
|---|---|---|---|
| | | Low | High |
| $X_1$ | Percentage of Oil (Capryol 90) | 20 | 40 |
| $X_2$ | Percentage of Acrysol K- 160 | 50 | 70 |
| $X_3$ | Percentage of PEG-400 | 10 | 30 |

$$Y = b_1X_1 + b_2X_2 + b_3X_3 + b_{12}X_1X_2 + b_{23}X_2X_3 + b_{13}X_1X_3 + b_{123}X_1X_2X_3$$

# Simplex lattice design

**Independent variable**

- $X_1$ = Capryol-90
- $X_2$ = Acrysol K-160
- $X_3$ = PEG-400

**Dependent variable**

- $Y_1$= Globule size (nm)
- $Y_2$= *In-vitro* Drug release at 10 min.

# Batches of Simplex lattice design

| Batch code | Coded value | | | Uncoded value | | |
|---|---|---|---|---|---|---|
| | $X_1$ | $X_2$ | $X_3$ | $X_1$(%) | $X_2$(%) | $X_3$(%) |
| F1 | 1 | 0 | 0 | 40 | 50 | 10 |
| F2 | 0 | 1 | 0 | 20 | 70 | 10 |
| F3 | 0 | 0 | 1 | 20 | 50 | 30 |
| F4 | 0.5 | 0.5 | 0 | 30 | 60 | 10 |
| F5 | 0.5 | 0 | 0.5 | 20 | 60 | 20 |
| F6 | 0 | 0.5 | 0.5 | 30 | 50 | 20 |
| F7 | 0.33 | 0.33 | 0.33 | 26.67 | 56.67 | 16.66 |

# Evaluation parameters

| Pre- optimized formulation evaluation | Optimized formulation evaluation |
|---|---|
| % Transmittance | Cloud-point measurement |
| Physical robustness to dilution | Centrifugation test |
| Emulsification time | Viscosity measurement |
| Determination of Globule size and PDI | Heating cooling cycle |
| *In-vitro* drug release study | Short term stability study |
| Drug content | |

# 1. % Transmittance

| Batch | % Transmittance |
|---|---|
| F1 | 99.33 ± 0.15 |
| F2 | 99.45 ± 0.30 |
| F3 | 99.70 ± 0.13 |
| F4 | 99.12 ± 0.08 |
| F5 | 99.51 ± 0.21 |
| F6 | 99.61 ± 0.22 |
| F7 | 99.75 ± 0.07 |

- All Batch shows % T above 99% indicating that formulation were Self-Nano emulsifying without precipitation.

# 2. Physical robustness to dilution

| Batch | Water | | | 0.1 N HCl | | | 6.8 pH Phosphate buffer | | |
|---|---|---|---|---|---|---|---|---|---|
| | 100 | 500 | 1000 | 100 | 500 | 1000 | 100 | 500 | 1000 |
| F1 | N | N | N | N | N | N | N | N | N |
| F2 | N | N | N | N | N | N | N | N | N |
| F3 | N | N | N | N | N | N | N | N | N |
| F4 | N | N | N | N | N | N | N | N | N |
| F5 | N | N | N | N | N | N | N | N | N |
| F6 | N | N | N | N | N | N | N | N | N |
| F7 | N | N | N | N | N | N | N | N | N |

N= No sign of precipitation or phase separation

# 3. Emulsification time

| Batch | Emulsification time (sec) |
|---|---|
| **F1** | 49 ± 2 |
| **F2** | 70 ± 2 |
| **F3** | 37 ± 2 |
| **F4** | 54 ± 2.5 |
| **F5** | 47 ± 3 |
| **F6** | 42 ± 2.5 |
| **F7** | 46 ± 1.5 |

# 4. Determination of Globule size and PDI

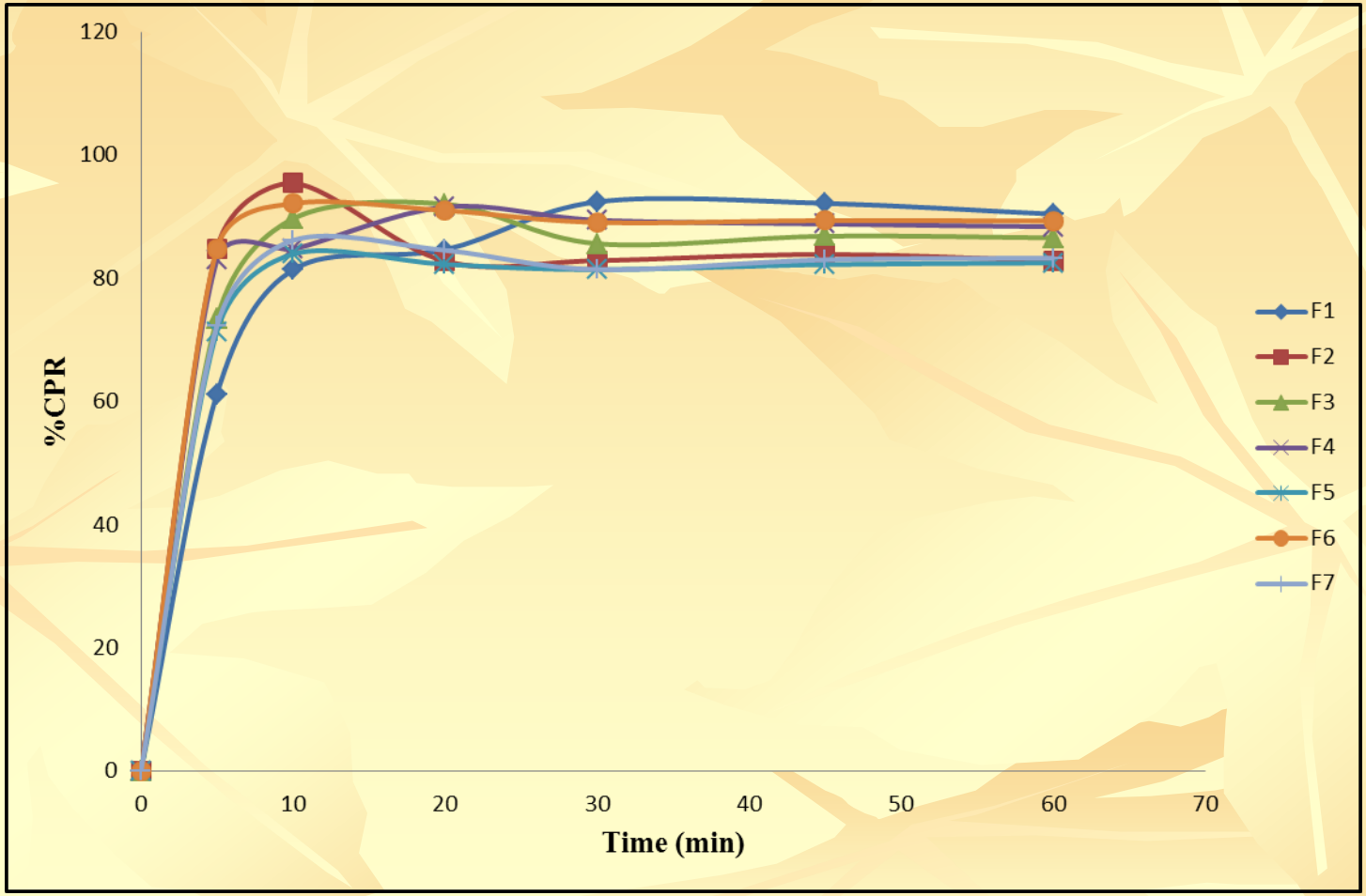
| Batch | Globule size(nm) | PDI |
|---|---|---|
| **F1** | 22.10 | 1.15 |
| **F2** | 10.66 | 0.65 |
| **F3** | 12.62 | 1.197 |
| **F4** | 12.50 | 1.60 |
| **F5** | 15.11 | 0.86 |
| **F6** | 12.44 | 1.19 |
| **F7** | 14.66 | 2.082 |

# 5. *In-vitro* drug release study

| Time (min) | % CPR | | | |
|---|---|---|---|---|
| | F1 | F2 | F3 | F4 |
| 0 | 0 | 0 | 0 | 0 |
| 5 | 61.22 | 84.85 | 73.42 | 83.01 |
| 10 | 81.41 | 95.46 | 89.68 | 84.76 |
| 20 | 84.66 | 82.81 | 92.08 | 91.59 |
| 30 | 92.43 | 82.89 | 85.66 | 89.48 |
| 45 | 92.19 | 83.91 | 86.88 | 88.84 |
| 60 | 90.44 | 82.87 | 86.60 | 88.39 |

| Time (min) | % CPR | | |
|---|---|---|---|
| | F5 | F6 | F7 |
| 0 | 0 | 0 | 0 |
| 5 | 71.39 | 84.85 | 72.31 |
| 10 | 83.96 | 92.14 | 86.17 |
| 20 | 82.30 | 91.03 | 84.57 |
| 30 | 81.44 | 89.10 | 81.47 |
| 45 | 82.26 | 89.40 | 83.04 |
| 60 | 82.52 | 89.32 | 83.31 |

# Comparison of *In-vitro* drug release profile



# 6. Drug Content

| Batch | % Drug Content |
|---|---|
| **F1** | 99.18 ± 0.32 |
| **F2** | 99.05 ± 0.57 |
| **F3** | 99.08 ± 0.73 |
| **F4** | 99.28 ± 0.83 |
| **F5** | 101.05 ± 0.82 |
| **F6** | 98.97 ± 0.25 |
| **F7** | 99.64 ± 0.18 |

Mean ± S.D, n=3

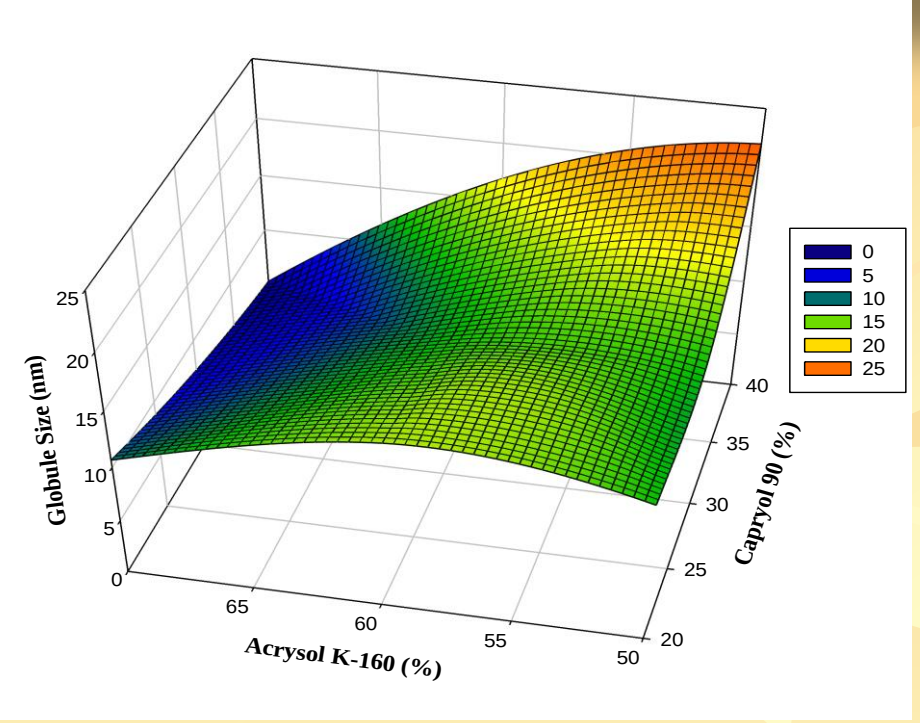
# Statistical analysis

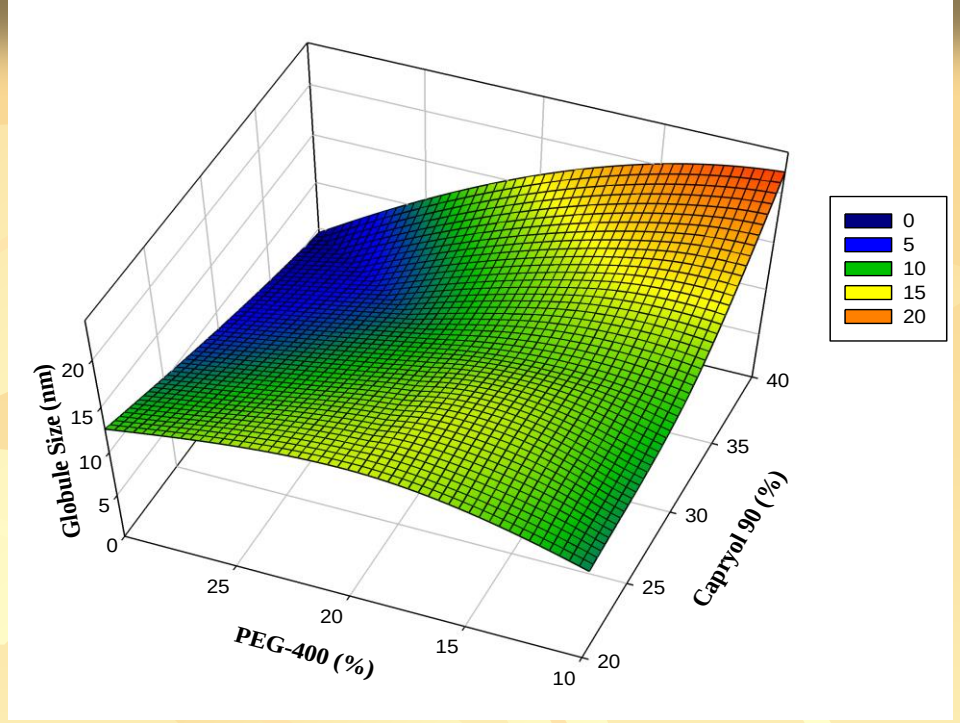
| Batch | $X_1$ (Capryol -90) | $X_2$ (Acrysol K-160) | $X_3$ (PEG-400) | $Y_1$ (Globule size)(nm) | $Y_2$ (*In-vitro* drug release at 10 min.) (% CPR) |
|---|---|---|---|---|---|
| **F1** | 1 | 0 | 0 | 22.10 | 81.41 |
| **F2** | 0 | 1 | 0 | 10.66 | 95.46 |
| **F3** | 0 | 0 | 1 | 12.62 | 89.68 |
| **F4** | 0.5 | 0.5 | 0 | 12.50 | 84.76 |
| **F5** | 0 | 0.5 | 0.5 | 15.11 | 83.96 |
| **F6** | 0.5 | 0 | 0.5 | 12.44 | 92.14 |
| **F7** | 0.33 | 0.33 | 0.33 | 14.66 | 86.17 |
| ***F8** | 0 | 1 | 0 | 10.58 | 95.68 |

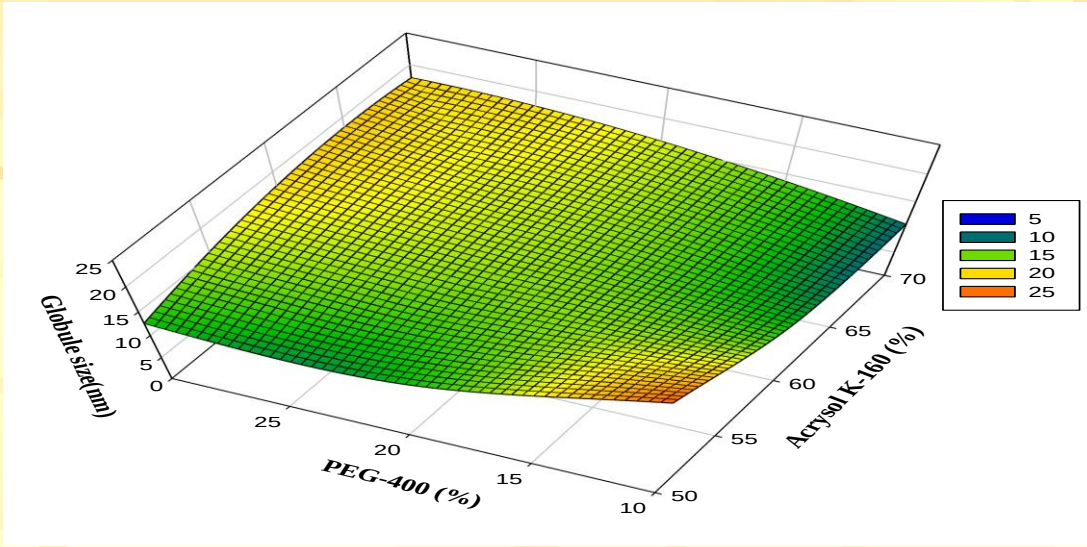
# Results of regression analysis Y (Globule size)

| | Full Model | |
|---|---|---|
| $Y_1$ (Globule size) | Co-efficient | p-value |
| b1 | 22.1 | 0.0016 |
| b2 | 10.62 | 0.0023 |
| b3 | 12.62 | 0.0028 |
| b12 | -15.44 | 0.0109 |
| b13 | -19.68 | 0.0089 |
| b23 | 13.96 | 0.0120 |
| b123 | 51.24 | 0.0241 |

| Source of variation | DF | SS | MS | F | Significant-F value | $F_{tab}$ |
|---|---|---|---|---|---|---|
| Regression | 7 | 1627.47 | 232.496 | 72655.11 | < 0.05 | 236.77 |
| Residual | 1 | 0.0032 | 0.0032 | | | |
| Total | 8 | 1627.47 | | | | |



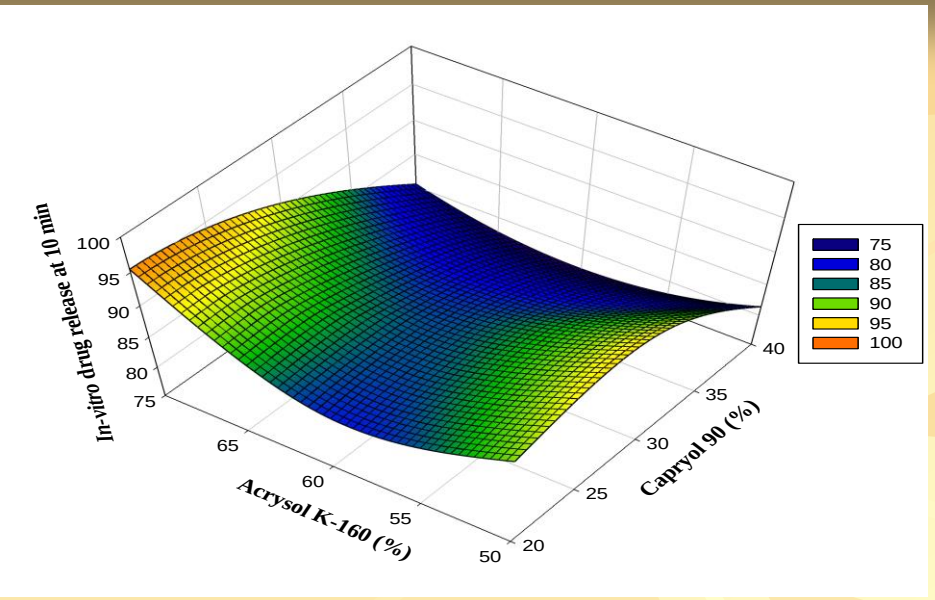



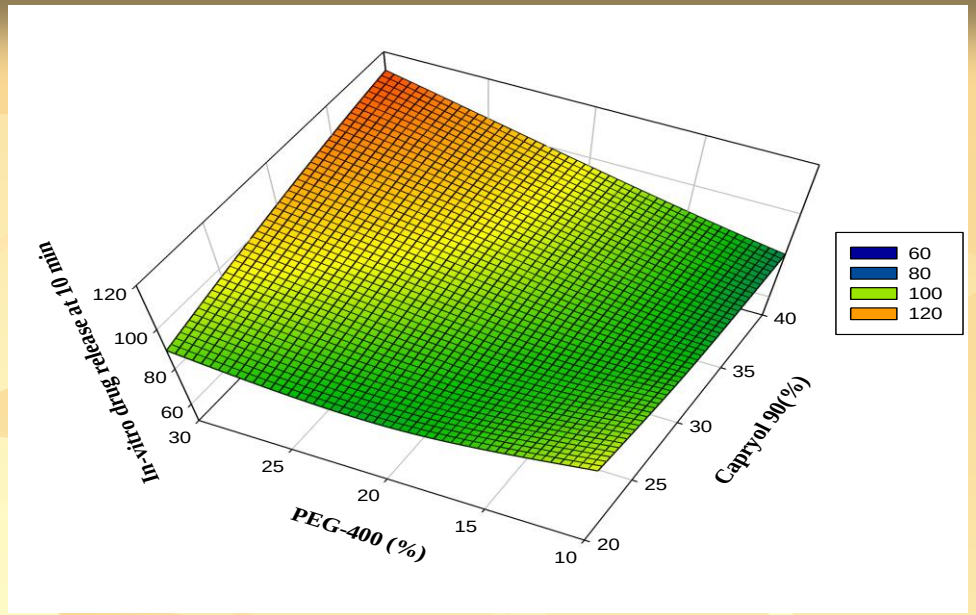

$$Y_1 = 22.1X_1 + 10.62X_2 + 12.62X_3 - 15.44X_{12} - 19.68X_{13} + 13.96X_{23} + 51.24X_{123}$$

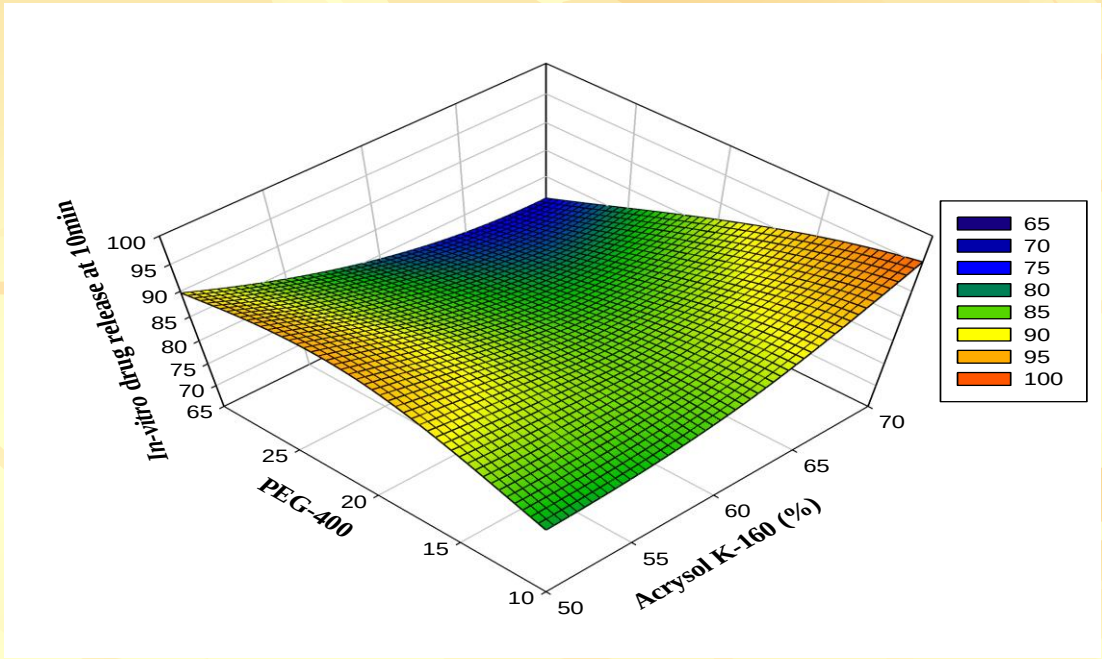
# Results of regression analysis Y2 (*In-vitro* drug release at 10 min.)

| | Full Model | | Reduce Model | |
|---|---|---|---|---|
| Y2 (*In-vitro* drug release at 10 min.) | Co-efficient | p-value | Co-efficient | p-value |
| b1 | 81.41 | 0.0012 | 81.41 | 2.70E-06 |
| b2 | 95.57 | 0.0007 | 95.57 | 9.83E-07 |
| b3 | 89.68 | 0.0011 | 89.68 | 2.22E-06 |
| b12 | -14.92 | 0.0311 | -15.10 | 0.0015 |
| b13 | 26.38 | 0.0183 | 26.18 | 0.0005 |
| b23 | -34.66 | 0.0134 | -34.84 | 0.0002 |
| b123 | -3.75 | 0.6108 | - | - |

| Source of variation | DF | SS | MS | F | Significant-F value | $F_{tab}$ |
|---|---|---|---|---|---|---|
| Regression | 6 | 63085.916 | 10514.31 | 582799.2729 | 0.001002688 | 19.33 |
| Residual | 2 | 0.0360821 | 0.018041 | | | |
| Total | 8 | 63085.952 | | | | |

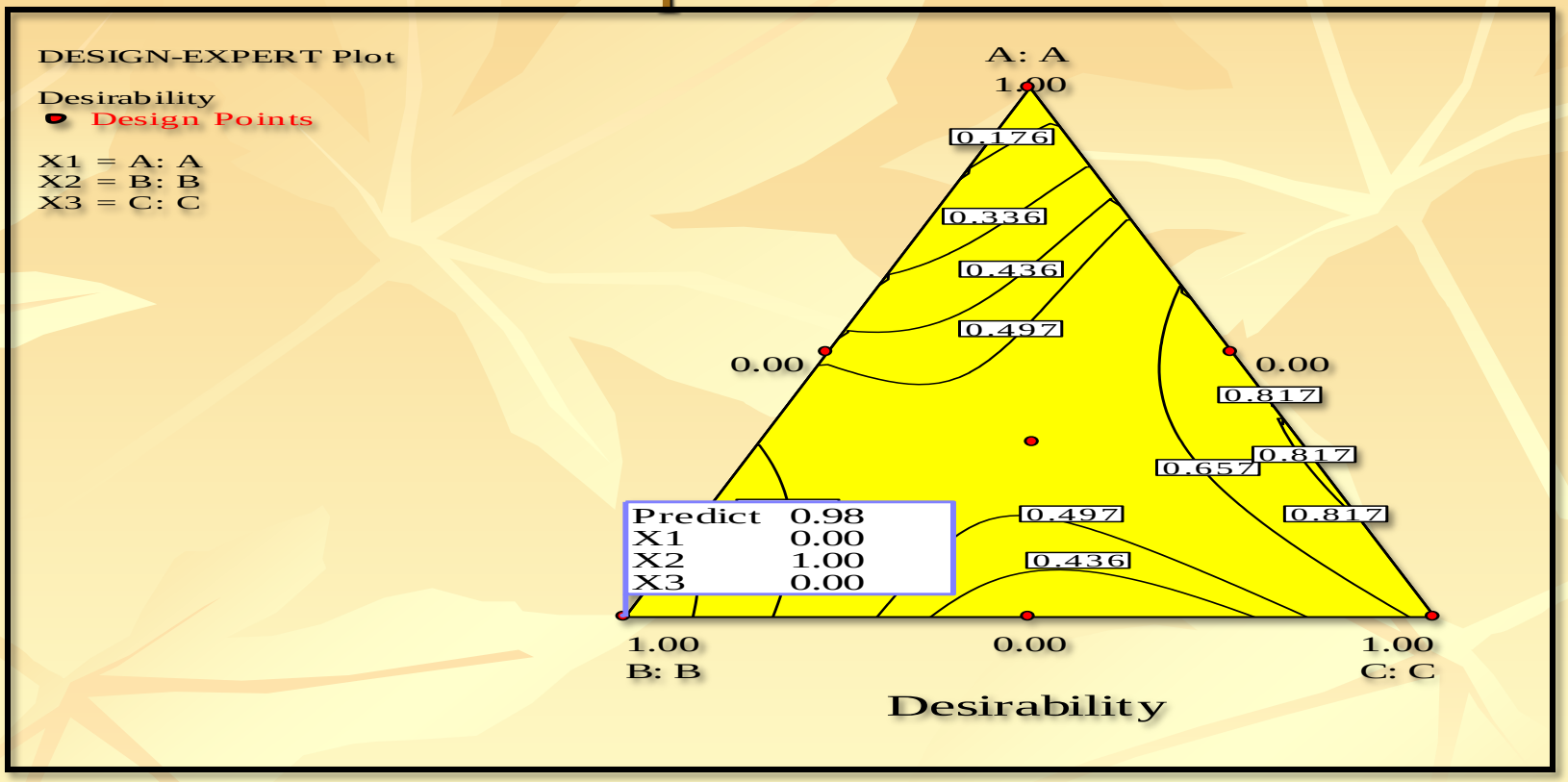



$$Y_2 = 81.41X_1 + 95.57X_2 + 89.68X_3 - 15.10X_{12} + 26.18X_{13} - 34.84X_{23}$$

# Statistical optimization using Design Expert 6.0.8




| Response | Constraints | | Goal |
|---|---|---|---|
| | Minimum | Maximum | |
| **Globule-size (nm) ($Y_1$)** | 10 | 25 | Minimize |
| ***In-vitro* drug release at 10 min.($Y_2$)** | 80 | 95 | Maximize |

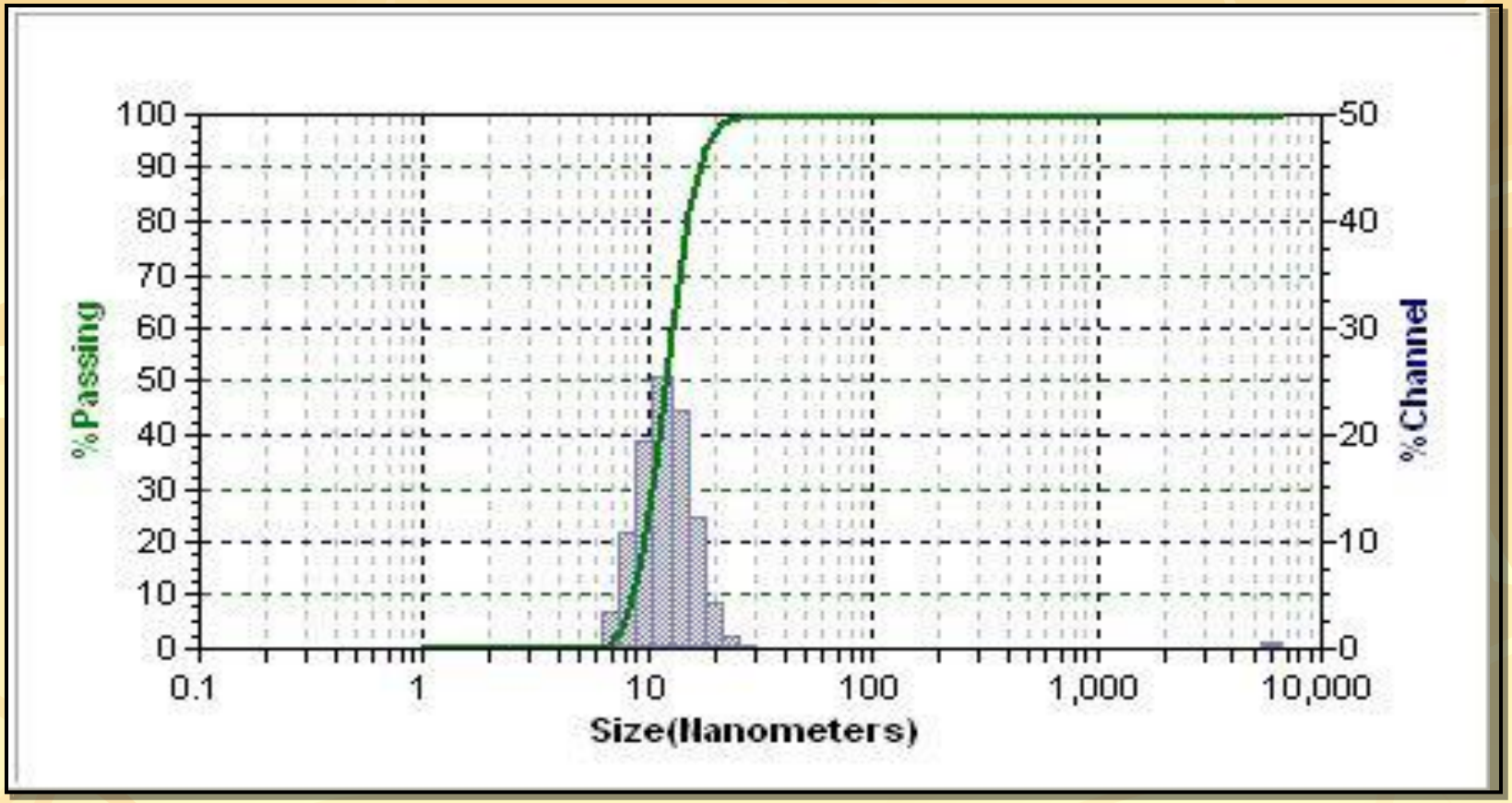
# Mathematical model validation using check point batch

| | Coded value | | | Uncoded value | | | Predicted value | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | $Y_1$ (globule size nm) | $Y_2$ (*In-vitro* drug release at 10 min.) |
| **Check point formulation** | 0.6 | 0.4 | 0 | 32 | 58 | 10 | 13.80 | 83.45 |

| Response | Experimental value | Predicted value | % Bias |
|---|---|---|---|
| **Globule size (nm)** | 13.25 | 13.80 | -4.15 |
| ***In-vitro* drug release at 10 min.** | 85.75 | 83.45 | 2.68 |

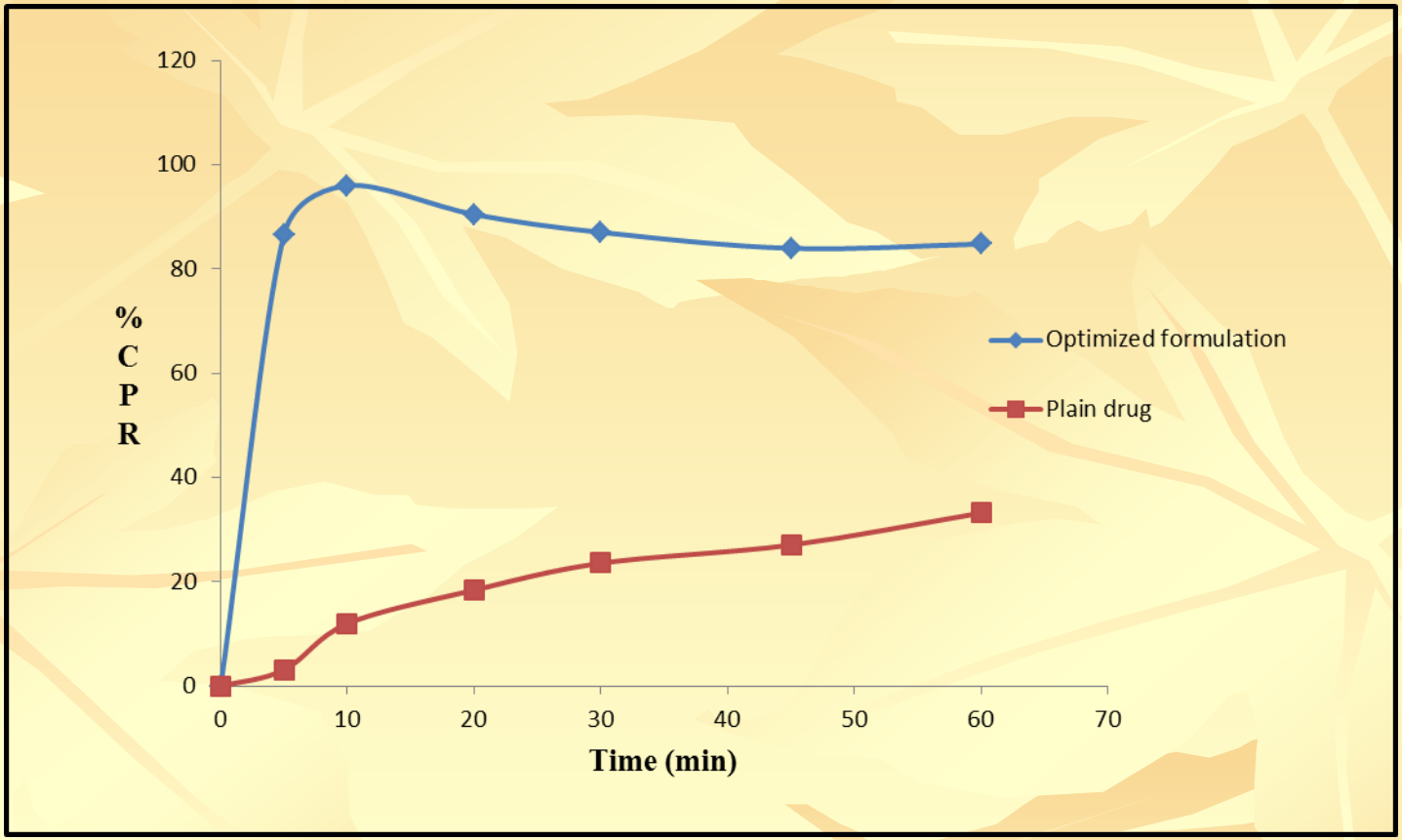
# Optimized formulation evaluation

| Parameter | Result |
|---|---|
| **Globule size** | 10.27 nm |
| **PDI** | 0.23 |
| ***In-vitro* drug release at 10 min.** | 96.03 (% CPR) |
| **Cloud point** | 80-82 $^{o}$C |
| **Centrifugation test** | No phase separation or precipitation |
| **Viscosity measurement** | 172 cps |
| **Heating cooling cycle** | No phase separation |

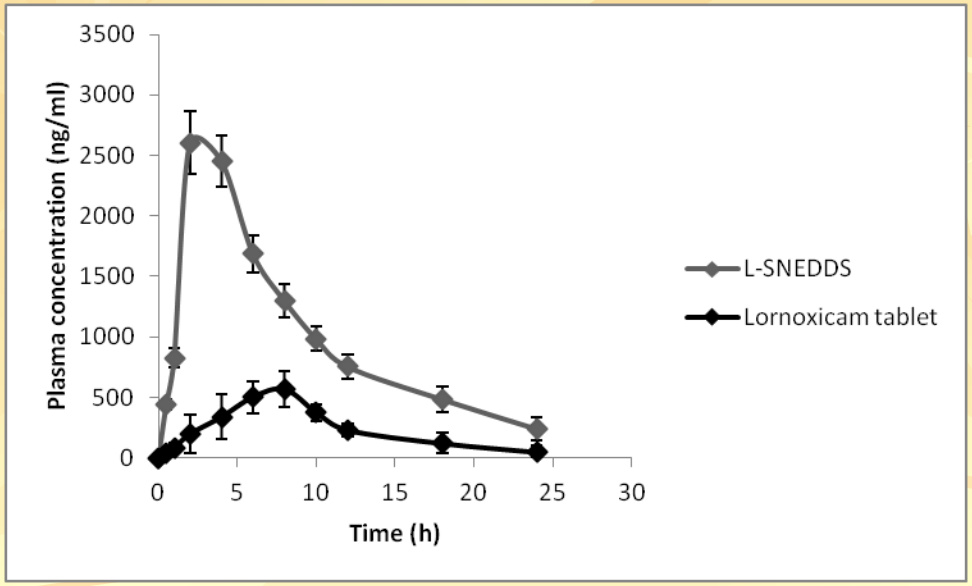



Particle size and size distribution of optimized formulation

# *In-vitro* Drug release comparison with plain drug



# *In-vivo* Drug release comparison with marketed formulation




- After estimation of pharmacokinetics parameters, SNEDDS formulations that rely on their own self-emulsifying capabilities showed enhanced absorption of lornoxicam with $C_{max}$ 2604.54±259.19 ng/ml compared with that of lornoxicam tablet with $C_{max}$ 564.45±148.32 ng/ml.
- The pharmacokinetic study results revealed that preparation of L-SNEDDS can significantly modify its pharmacokinetic profile and can increase its. This was due to the fact that lornoxicam is a lipophilic drug with poor aqueous solubility, and the preparation of this drug as a SNEDDS enhanced its solubility and tissue permeability which leads to shortening in the onset of action.

# Short term stability study

| Parameter | A-1 | B-1 | % Bias |
|---|---|---|---|
| **% Transmittance** | 99.59 ± 0.25 % | 99.48 ± 0.26 % | -0.110 |
| **Emulsification time** | 69 ± 4 Sec | 71 ± 3 Sec | 2.81 |
| **Drug content** | 99.39 ± 0.85 % | 98.95 ± 0.52 % | -0.444 |
| **Viscosity** | 172 ± 5 % | 168 ± 3 % | -2.380 |
| ***In-vitro* dissolution** | *f1* (dissimilarity value) =1.40<br>*f2* (similarity value) =76.61 | | |

*A-1 is denoted for formulation before stability and B-1 is denoted for formulation after short term stability study

*Mean ± S.D (n=3)

# Conclusion

- In the present study, L-SNEDDS was prepared for the delivery of lornoxicam and characterization done by SEM, DSC, and GSD revealed no interaction. In-vitro drug release study demonstrated faster and excellent drug release profile of SNEDDS compared with powdered drug. The pharmacokinetic study showed significant improvement in bioavailability in terms of $C_{max,}$ indicating L-SNEDDS would be promising dosage form.

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