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RESEARCH ARTICLE

Formulation and evaluation of Miconazole Nitrate loaded topical microemulsion gel using Carica Papaya Seed oil and Cinnamon oil

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ABSTRACT:- **Aim:** The present investigation was aimed to study the antifungal effect of Miconazole Nitrate along with essential oils like Carica papaya seed oil and Cinnamon oil to be prepared as microemulsion and explore the synergistic antifungal effect. **Method:** Microemulsions were prepared by titrating different ratios of oil to Smix (surfactant + co-surfactant) with water, and the region was determined using a pseudoternary phase diagram. Formulations were characterized for viscosity, pH, drug content, globule size, zeta potential, and stability. Optimized formulations (CPM3 and CCM3) were incorporated into 1% w/w Carbopol gel to form CPM3-G1 and CCM3-G2, which were evaluated for physicochemical properties, drug release, and antifungal activity. **Results:** Drug and physical mixture were characterized by FTIR, which confirmed that no interaction between drug and excipient and other formulation parameters of preparation of microemulsion and microemulsion gel were evaluated which showed better results. In vitro antifungal study confirmed that when Miconazole nitrate is combined with essential oils in the form of microemulsion have shown synergistic antifungal effect compared with drug and oil separately. **Conclusion:** Carica papaya seed oil and Cinnamon oil-based Miconazole nitrate microemulsion were prepared for topical application. CPM3 and CCM3 formulation were taken as an optimized formulation because of high percentage transmittance, less viscous, high drug content and shows topical pH, more in vitro drug released and good stability. In vitro antifungal effects studied on Candida Albicans fungal strain. Microemulsion drug delivery system can improve therapeutic effect of the topical drugs and combination of drug and essential oils in the form of microemulsion showed synergistic activity and give better therapeutic effect for topical drug delivery.

Keywords: Microemulsion, Pseudoternary phase diagram, Miconazole Nitrate, Carica papaya seed oil, Cinnamon oil, Anti-fungal agent.

INTRODUCTION

Drugs known as topical preparations are applied topically to specific body parts. Formulations that solely impact a specific area of the body and are designed to minimize systemic absorption of the drug are referred to by this term. The conventional topical drug delivery techniques basically involve either breaking down the horny layer at the molecular level or assisting or manipulating the skin's barrier function (topical antibiotics, anti-bacterial, emollients, and sunscreen agents) in order to deliver drugs to the viable epidermal and dermal tissues without the use of oral, systemic, or other therapies.

A microemulsion is a good candidate for oral delivery of poorly water-soluble drugs because of its ability to improve drug solubilization. Absorption rate of a drug increases as its thermodynamic activity in the vehicle increases.

Microemulsions are widely used for topical drug delivery, which are optically isotropic and thermodynamically stable systems of water, oil, surfactant, and/or co-surfactant have been investigated as drug delivery systems due to their ability to solubilize poorly water-soluble drugs and to improve topical and systemic availability. It has quick and effective skin penetration and aids in the solubilization of the lipophilic drug moiety.

As a result, it is beneficial when administering topical medications. Transparent, isotropic, and thermodynamically stable mixtures of two immiscible liquids, microemulsions are made possible by the presence of a suitable surfactant, usually in conjunction with a co-surfactant. In addition to the usual advantages of improved drug stability and availability as a result of surfactant solubilization, the microemulsion method significantly affects transdermal dispersion. Additionally, because microemulsion sizes are usually quite small, they are a great way to deliver drugs. Microemulsion hence has great potential for drug delivery through the skin.

Miconazole nitrate, a synthetic imidazole derivative, has a wide range of antibacterial action and can be used to treat fungal infections both locally and systemically. In particular, it is effective against species of Microsporum, Trichophyton, Epidermophyton, and Candida, and having some ability to combat gram-positive bacteria. It indicates that the cell membrane is the main site of action. According to research using Candida Albicans, Miconazole selectively inhibits the uptake of muco-polysaccharides (glutamine) and RNA and DNA precursors (purines) at low concentrations by acting mainly on the yeast cell membrane.

Therefore, the goal of the current study was to investigate the antifungal effect of Miconazole Nitrate in combination with essential oils such as Carica papaya seed oil and cinnamon oil to create a microemulsion gel and examine the advantages of a stronger antifungal effect.

MATERIALS AND METHODS

Materials

The following chemicals and reagents were used in the study. Miconazole Nitrate (Pharma grade, Mahrshee Laboratories, Gujarat) served as the active antifungal drug. Carica papaya seed oil and Cinnamon oil (LR grade, RV Essential, New Delhi) were used as natural antifungal agents. Tween 20 and Tween 80 (LR grade, Thomas Baker Pvt. Ltd., Mumbai) act as non-ionic surfactants for microemulsion stabilization. Propylene glycol and PEG 400 (LR grade, S D Fine Chem. Ltd., Mumbai) were used as co-surfactants and penetration enhancers. Carbopol 934 (LR grade, CDH Pvt. Ltd., New Delhi) served as a gelling agent for microemulsion gel formation. Methanol (LR grade, S D Fine Chem. Ltd., Mumbai) was used as a solvent. Potassium dihydrogen orthophosphate (Thermo Fisher Scientific, Mumbai) and Sodium hydroxide(S D Fine Chem. Ltd., Mumbai) were used for buffer preparation and pH adjustment. All chemicals were of analytical or laboratory reagent grade and used without further purification.

Method of preparation of Microemulsion gel

The drug was first dissolved in the selected oil, followed by the addition of a fixed ratio of surfactant and co-surfactant. The resulting mixture was vortexed continuously for about 15 minutes to ensure proper mixing. Subsequently, the required quantity of demineralised water was added drop wise to the mixture with constant stirring. The process was continued until a clear and transparent liquid was obtained, indicating the formation of a microemulsion. The prepared microemulsion was then incorporated into a 1% w/w Carbopol 934 gel base to obtain the final microemulsion gel formulation suitable for topical application.

Table 1: Formulation development based on Pseudo ternary phase

Formulation Code	Smix ratios	Co-surfactant	Surfactant	Oils	Percent w/w component in formulation			
					Oil %	Smix %	Water %	Drug %
CPM1	1:1	Propylene glycol	Tween80	Carica papaya seed oil	16	64	20	1
CPM2	2:1				30	54	15	1
CPM3	3:1				37	50	13	1
CCM1	1:1			Cinnamon oil	26	55	17	1
CCM2	2:1				25	54	22	1
CCM3	3:1				32	50	18	1

EVALUATION OF MICROEMULSION [10-15]

Percent transmittance: The transparency of the microemulsion was determined by measuring the percentage transmittance at 272 nm against distilled water as blank by using UV spectrophotometer.

$$Percent\ Transmittance = -log_{10}(2\text{-}absorbance)$$

Viscosity measurements: The Rheological behavior of the microemulsion formulation was evaluated using an Ostwald viscometer at a room temperature.

Measurement of pH: The pH of Miconazole Nitrate microemulsion formulations was determined by using digital pH meter. The measurement of pH of each formulation was done in triplicate and average values were calculated.

Percentage Drug content: For the determination of drug content about one ml of each microemulsion formulation was transfer to a 10 ml volumetric flask and dissolved in methanol. It was diluted appropriately and analyzed spectrophotometrically at 272 nm.

Measurement of globule size and zeta potential: The average globule size and zeta potential of the optimized microemulsions were measured using a Malvern Zeta seizer instrument at a temperature 25 °C.

Surface morphology: Surface morphology of the optimized microemulsion formulations CPM3 and CCM3 was determined by using a scanning electron microscope (SEM).

In-vitro diffusion study: In in vitro diffusion study, the diffusion medium used was phosphate buffer pH 6.8. Assembly of diffusion cell for in vitro diffusion studies the diffusion cell was designed as per the dimension given. Diffusion cell with an effective diffusion area of 3.14 cm2 was used for in vitro permeation studies. The egg membrane was mounted on the cell carefully so as to avoid the entrapment of air bubble under the egg membrane. Intimate contact of egg membrane was ensured with receptor fluid by placing it tightly with clamp.

The diffusion cells were placed on the receptor compartment with magnetic stirrer. Then add 1gm of microemulsion to the donor compartment and 200ml of phosphate buffer pH 7.4 to receptor compartment. The speed of the stirrer and temperature was kept constant throughout the experiment. Withthehelpof1mlpipette 1 ml of sample was withdrawn at a time interval of 60 min (0 to 6hrs) from receptor compartment and same volume was replaced with receptor medium in order to maintain sink condition. The samples were appropriately diluted and the absorbance was measured at 272 nm using UV spectrophotometer.

EVALUATION OF MICONAZOLE NITRATE MICROEMULSION GEL [16-20]

Spreadability: Spreadability was performed by using two glass slides of length 7.5 cm. 350 mg of Microemulgel was weighed accurately and it was taken on one glass slide. Another glass slide was placed above it from a height of 5 cm. A weight of 5 gm was kept on the upper slide and after 1 minute, diameter of circle that spread was noted in cm. The observed diameter indicates the type of gel.

Viscosity and Rheological studies: Brookfield digital viscometer (Model LVDV–E, USA) was used for the determination of viscosity and rheological properties of microemulsion based gel using spindle no. 6. 10 gm of sample was taken into a small sample holder and the viscosity of gel was measured at a temperature of 25°C.

Determination of pH: The apparent pH of the gel was determined by pH meter in triplicate at 25±1ºC.

Determination of Percent drug content: For the determination of drug content 1 gm of gel formulation as weighed in 10 ml volumetric flask and dissolved in methanol. It was diluted appropriately and analyzed spectrophotometrically at 272 nm.

In vitro release studies: An In vitro drug release study was performed using diffusion cell. Egg membrane was placed between receptor and donor compartments. Microemulsion gel equivalent to 0.2gm was placed in the donor compartment and the receptor compartment was filled with phosphate buffer pH 6.8. The diffusion cells were maintained at 37 ± 0.5℃ with stirring at 100 rpm throughout the experiment. At fixed time interval, 5ml of sample was withdrawn for every 1,2,4,6,8,10 and 12 hrs, and same volume was replaced with receptor fluid solution in order to maintain sink condition. The collected samples were analyzed by UV spectrophotometer at λ max 272nm.

In vitro antifungal studies: Sterile Sabourd Dextrose Agar plates were prepared, by pouring the sterile agar into sterile Petri dishes under aseptic conditions. 0.1 ml of the test organism (Candida Albicans) was spread on agar plates. 5 mm diameter holes were made in the agar plates using a sterile bore. 500µg/ml drug, 30µl of formulations (CPM3 & CCM3) 20µl of essential oils (CPO & CO) and 60mg of gels (CPM3-G1 & CCM3-G2) were added into each hole separately. The plates were maintained at +4˚C for 4 hrs to allow the diffusion of solution into the agar medium. All the plate-containing Candida Albicans were incubated at 28˚C for 48 hrs. zones of inhibition of microbial growth around the well were measured and recorded after the incubation time.

Ex-vivo skin permeation studies: Ex-vivo drug permeation study was conducted using a Franz diffusion cell containing 150 ml of phosphate buffer (pH 6.8) using an excised goat skin. The goat's skin was obtained from a local slaughter house within 15 min after the goat was sacrificed. After removing the hairs, the skin was stored on ice-cold phosphate buffer (pH 6.8). The skin was immediately immersed in Ringer's solution. The freshly excised skin was mounted on the diffusion cell, and gel containing an equivalent dose of 20 mg microemulsion gel was placed on it. Throughout the study, the buffer solution in the chamber was maintained at 37±1°. At predetermined time intervals (1, 2, 4, 6, 8, 10, 12hrs), 1 ml of the samples was withdrawn at a pre-determined time interval and replaced with an equal amount of phosphate buffer. The samples were appropriately diluted and filtered and absorbance was measured spectrophotometrically at 272 nm using UV/Vis Spectrophotometer, taking phosphate buffer (pH 6.8) as the blank.

RESULTS AND DISCUSSION

The Miconazole nitrate melting point was found to be 178℃ by Theil's method and 180.27℃ by DSC method which complied with standard monographs, thus indicating the purity of the drug. FTIR analysis confirmed that there was no chemical interaction between the drug and excipients such as Carica papaya seed oil and Cinnamon oil. For formulation development, a pseudoternary phase diagram was constructed using Tween 80 and propylene glycol at Smix ratios (1:1, 2:1, and 3:1) to identify the microemulsion region. Increasing the surfactant ratio expanded the microemulsion zone. Based on this, suitable proportions of oil, Smix, and water were selected for formulation. The prepared microemulsions were clear, transparent, and stable, with % transmittance above 90%, confirming Nanometric droplet size. The viscosity ranged from 13–15 cps, showing Newtonian flow, while pH values (5.9–6.5) were within the skin-compatible range.

The drug content was uniform (93–98%), and zeta potential values indicated stability without aggregation. The globule size (around 70 nm) and SEM images confirmed smooth, spherical droplets. No phase separation was observed after centrifugation, confirming good physical stability. In vitro drug release studies revealed sustained release for 12 hours, with 95.86% release from CPM3 and 93.98% from CCM3. The release followed zero-order kinetics with a Non-Fickian mechanism. Carica papaya seed oil-based formulation showed slightly higher release than Cinnamon oil-based formulation.

Stability studies indicated no significant changes, confirming formulation stability. Optimized microemulsions (CPM3 and CCM3) were converted into 1% Carbopol 934-based gels (CPM3-G1 and CCM3-G2). These gels showed good spreadability, suitable viscosity, and pH (6.4–6.6) compatible with skin. The optimized formulations CPM3, CCM3, CPM3-G1, and CCM3-G2 showed higher antifungal activity with inhibition zones of 24 mm, 27 mm, 21 mm, and 23 mm respectively, compared to 19 mm for the pure drug, 13 mm for Carica papaya seed oil, and 16 mm for cinnamon oil. This indicates a strong synergistic effect enhancing antifungal efficacy. Ex-vivo permeation showed sustained drug release with percentage cumulative drug release values of 81.98 % for CPM3-G1 and 79.96 % for CCM3-G2, confirming prolonged retention and controlled release. The drug content was above 93%, and the gels exhibited sustained release over 12 hours, following zero order kinetics. Stability studies showed no major changes during storage.

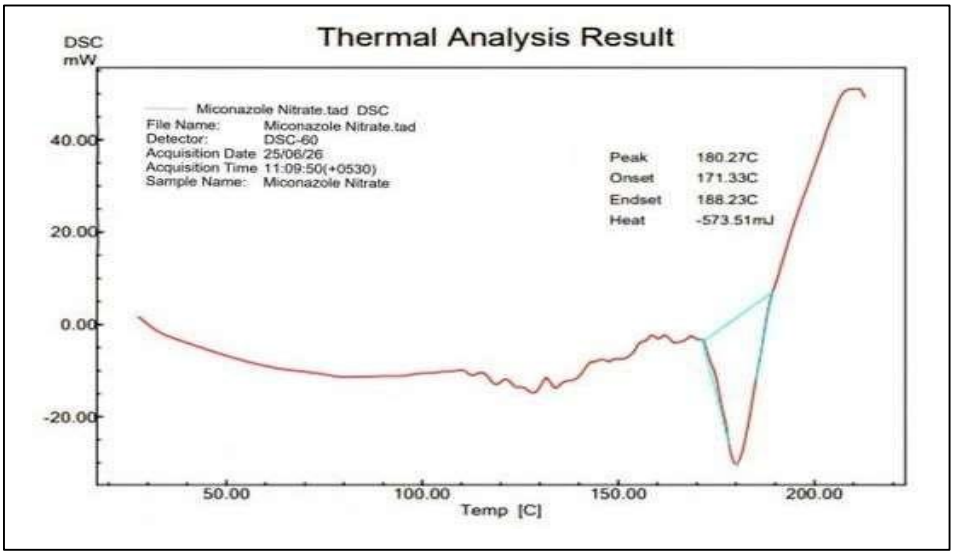


Fig.1: DSC Thermograph of Miconazole nitrate

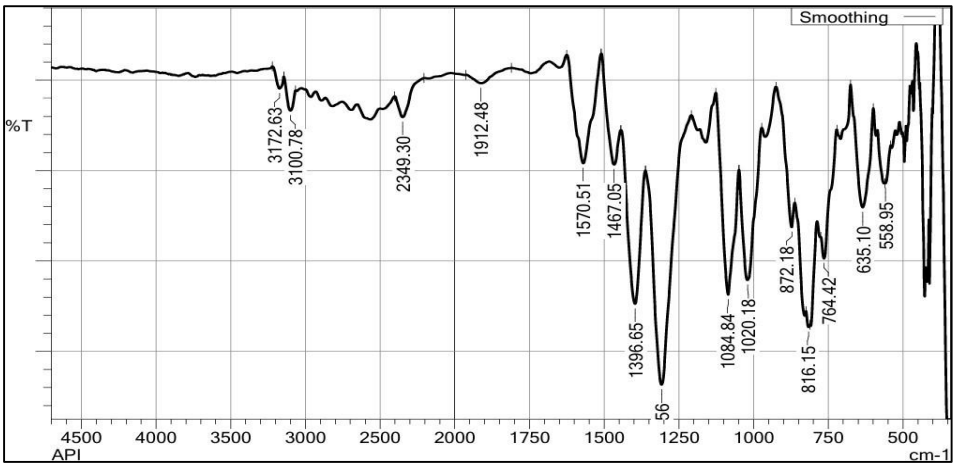


Fig.2: FTIR spectra of Miconazole Nitrate

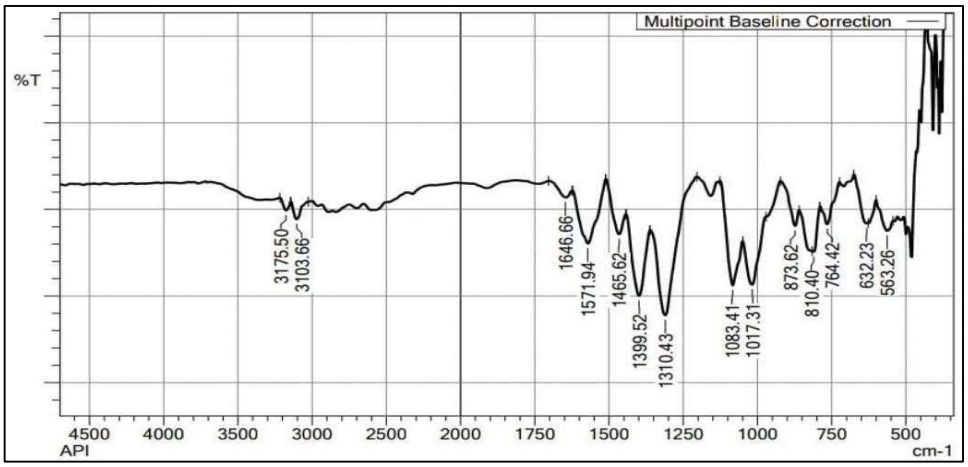


Fig.3: FTIR spectra of mixture of Miconazole Nitrate and Carica papaya seed oil

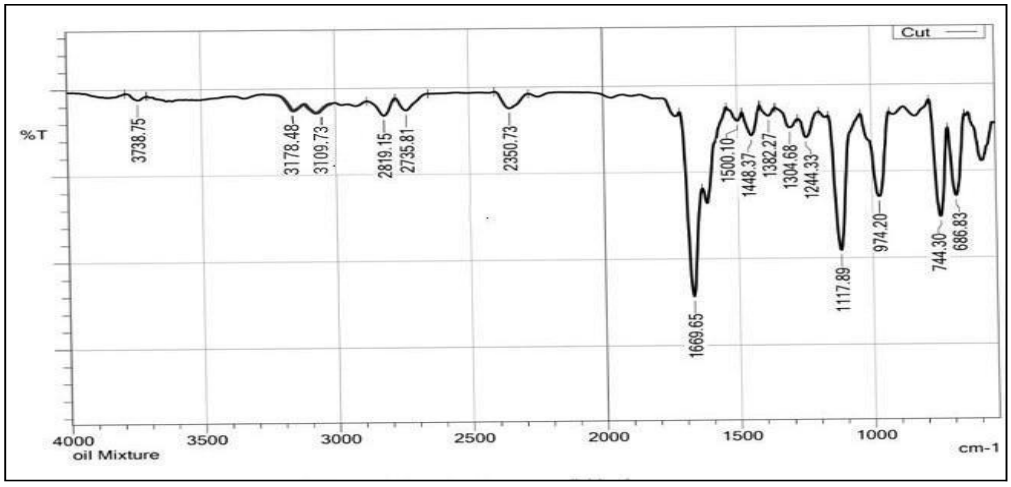


Fig.4: FTIR spectra of mixture of Miconazole Nitrate and Cinnamon oil

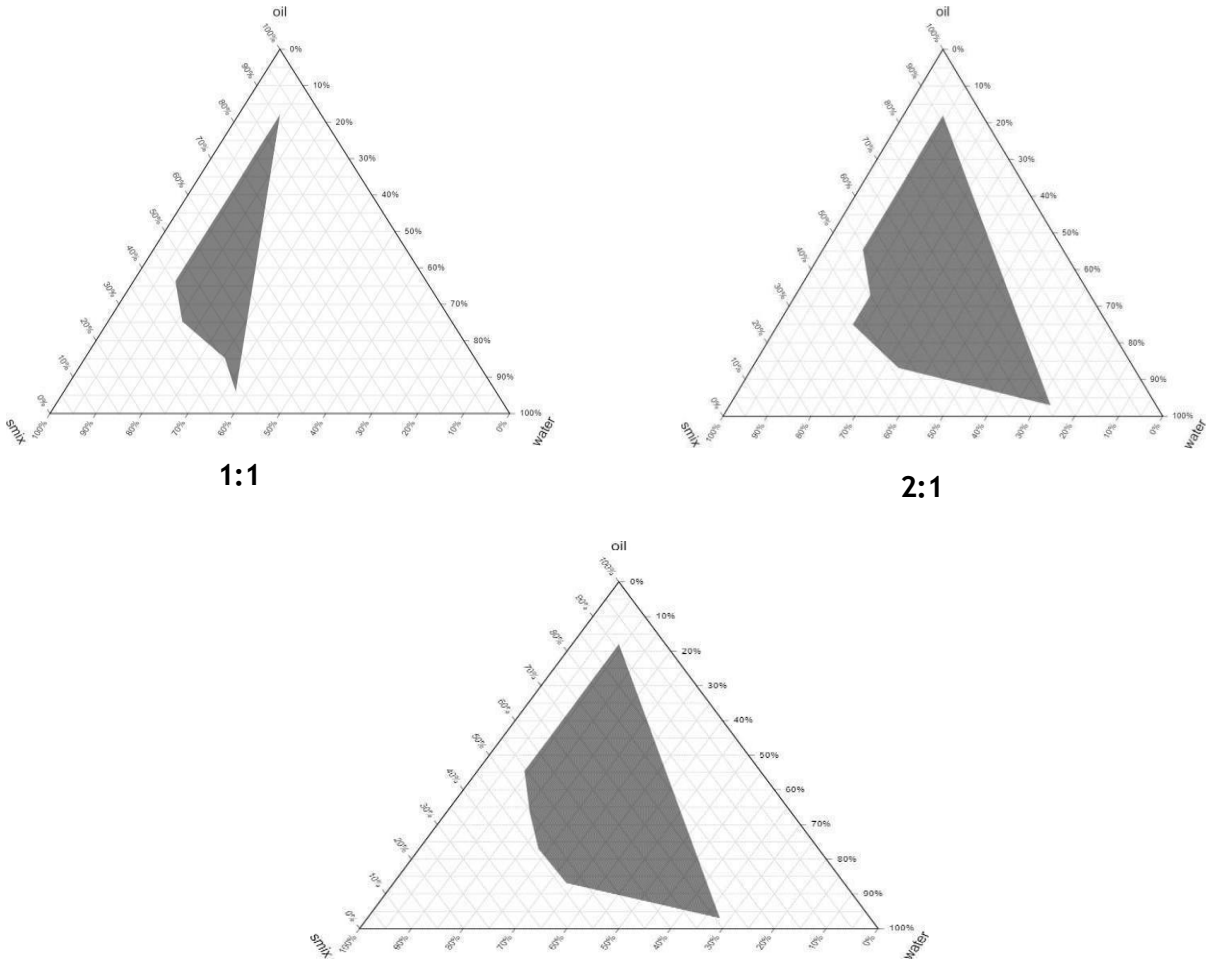


Fig.5: Pseudoternary phase diagram of Carica papaya seed oil, Tween 80, Propylene glycol contains different Smix ratio (1:1, 2:1 and 3:1)

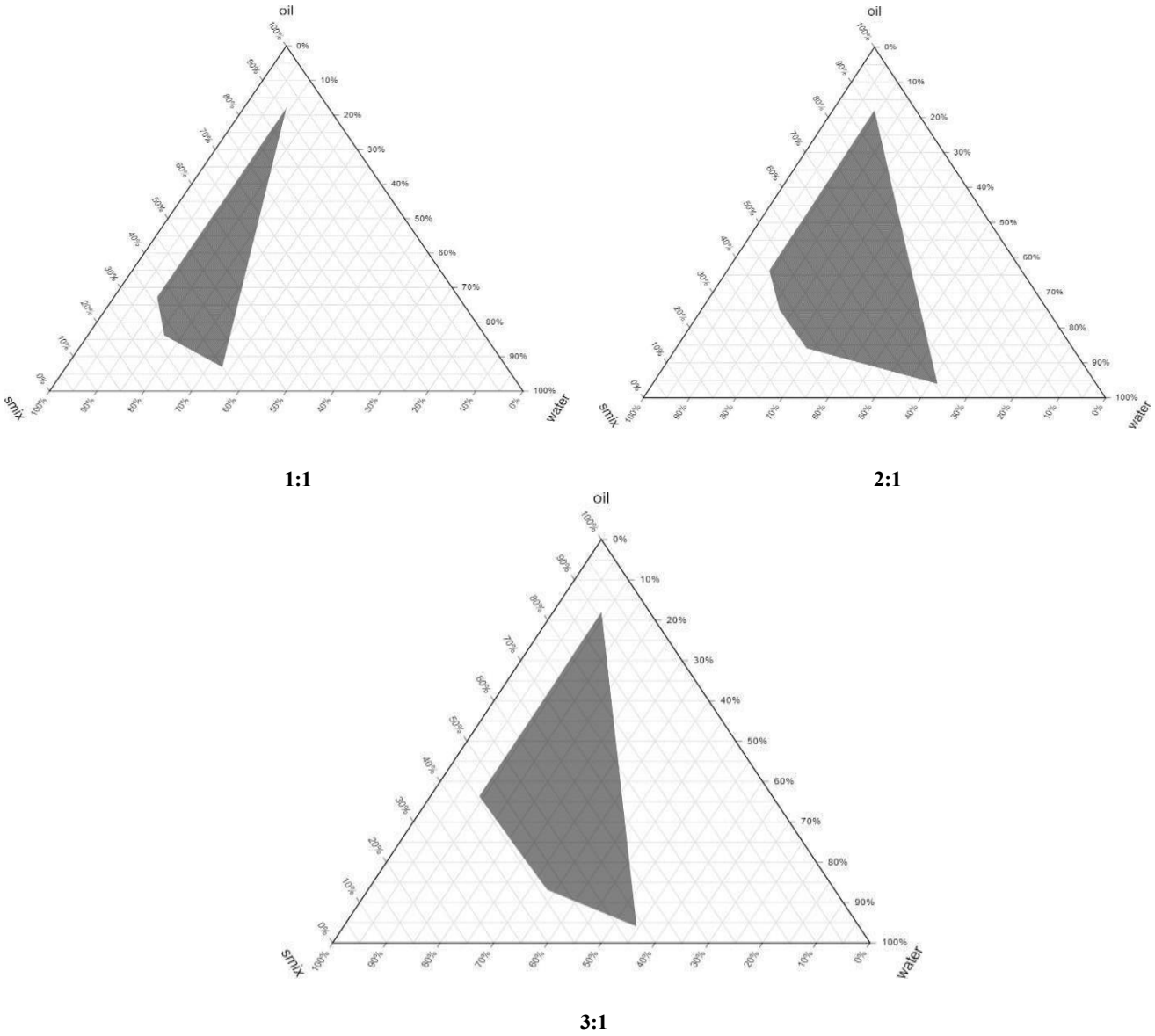


Fig.6: Pseudoternary phase diagram of Cinnamon oil, Tween 80, Propylene glycol contains different Smix ratio (1:1, 2:1 and 3:1)

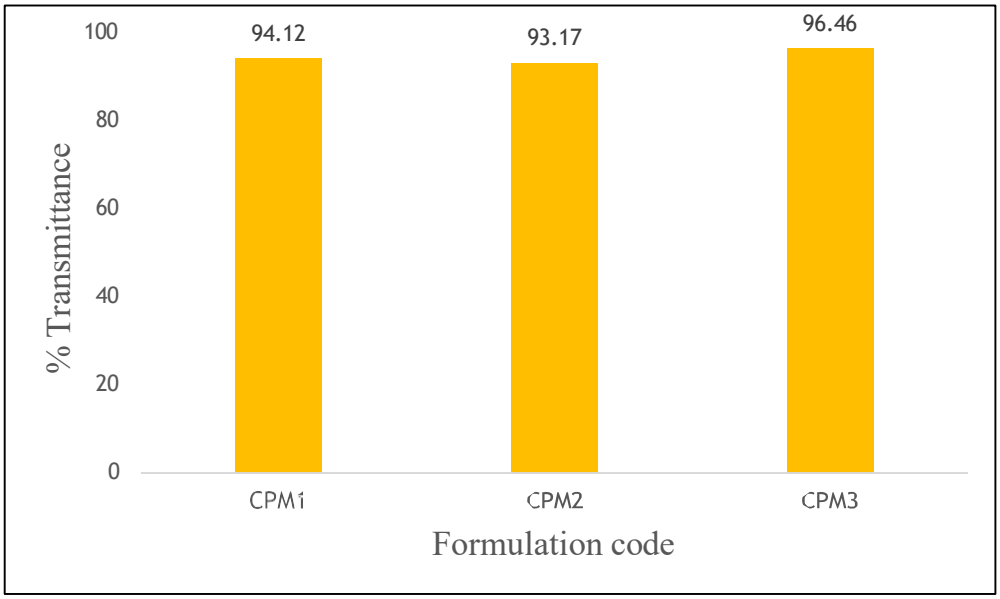


Fig.7: Percent Transmittance of CPM1-CPM3

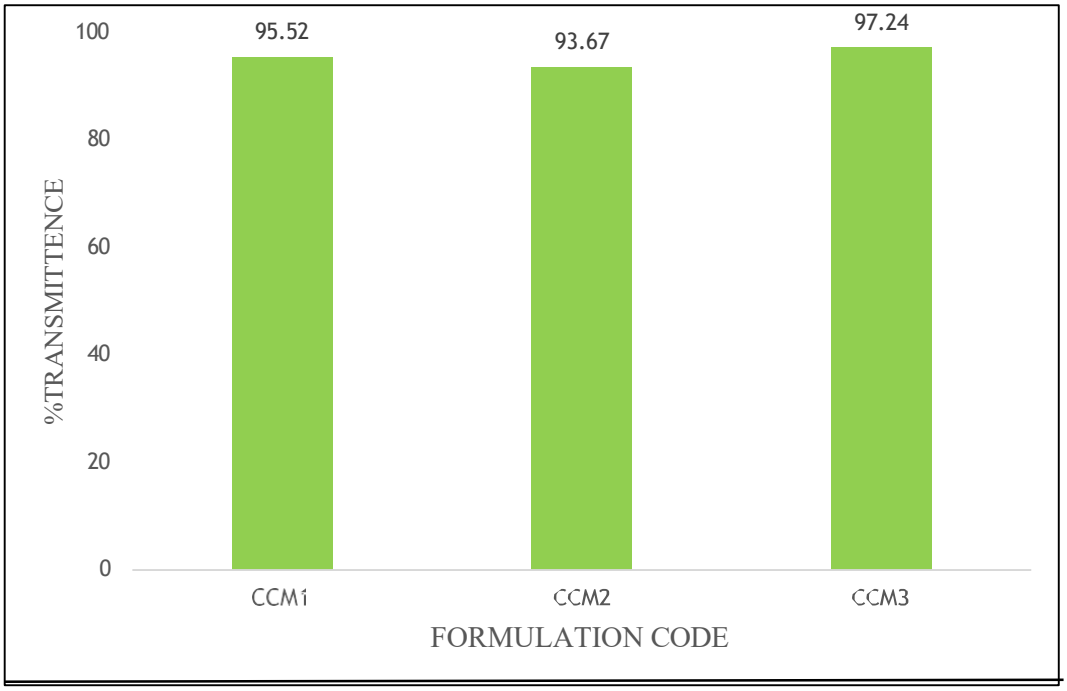


Fig.8: Percent Transmittance of CCM1-CCM3

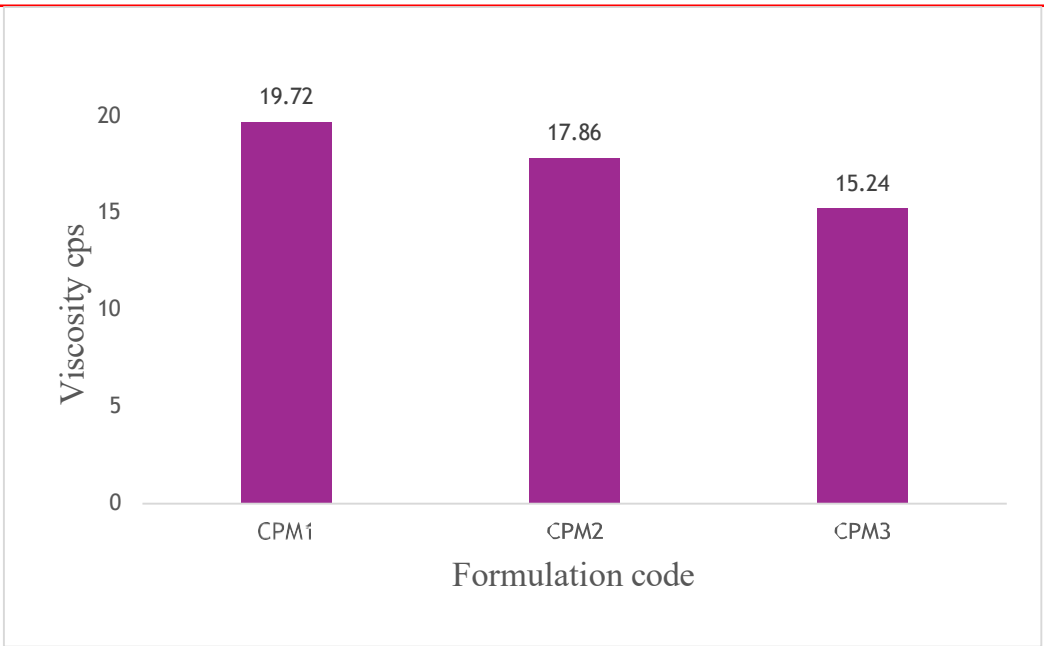


Fig.9: Viscosity of CPM1-CPM3

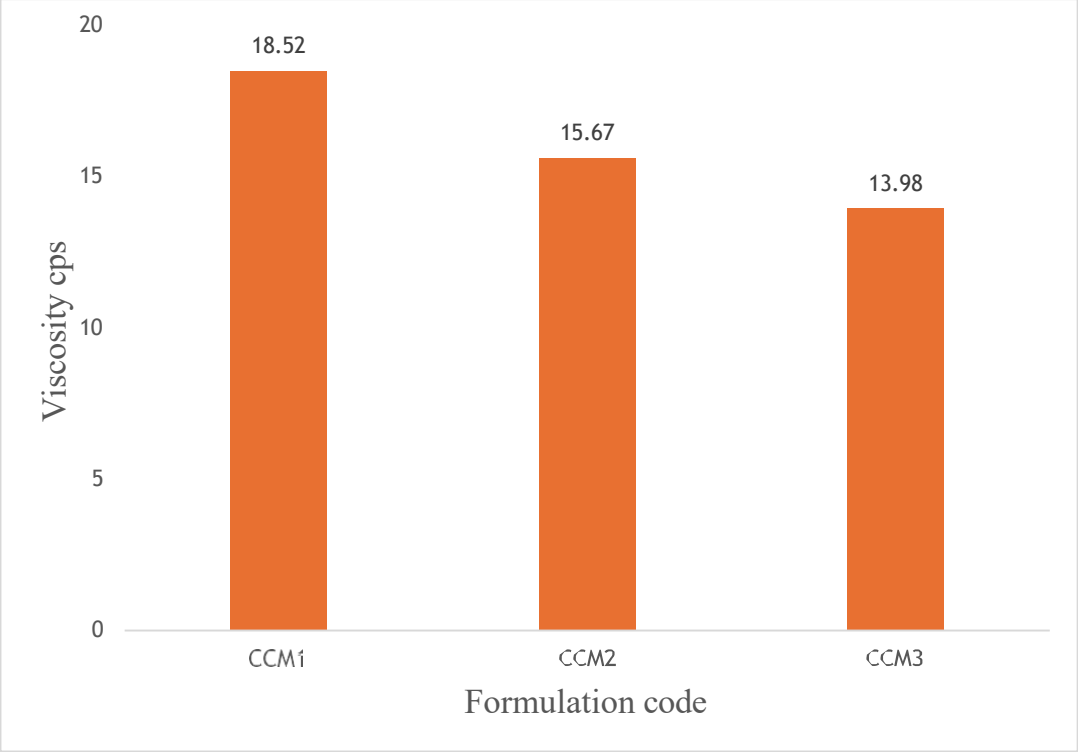


Fig.10: Viscosity of CCM1-CCM3

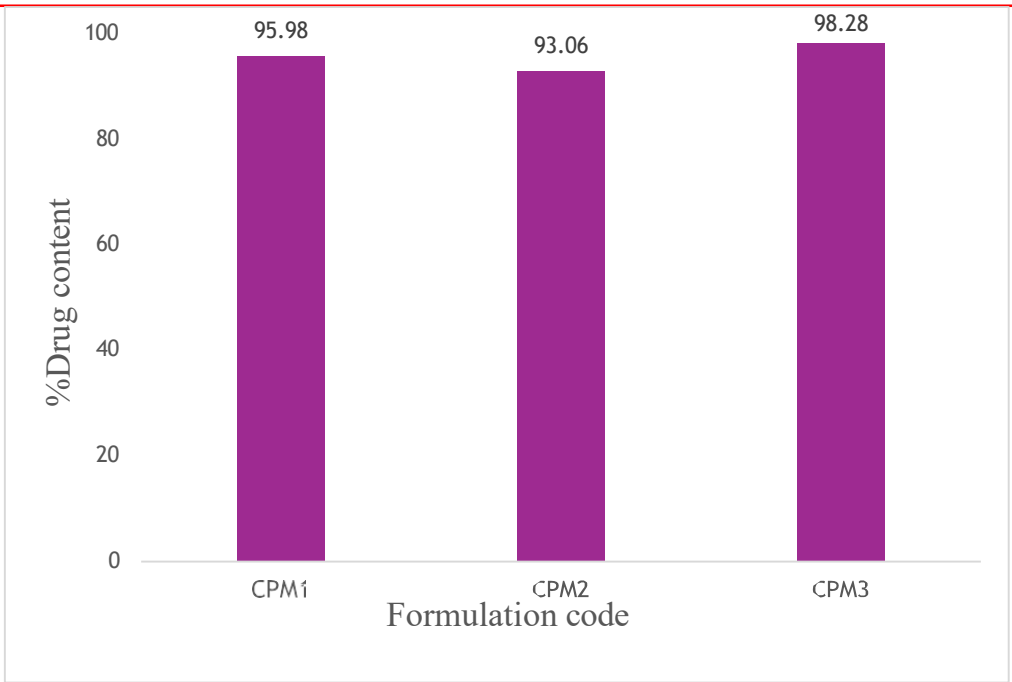


Fig.11: Percent Drug content of CPM1-CPM3

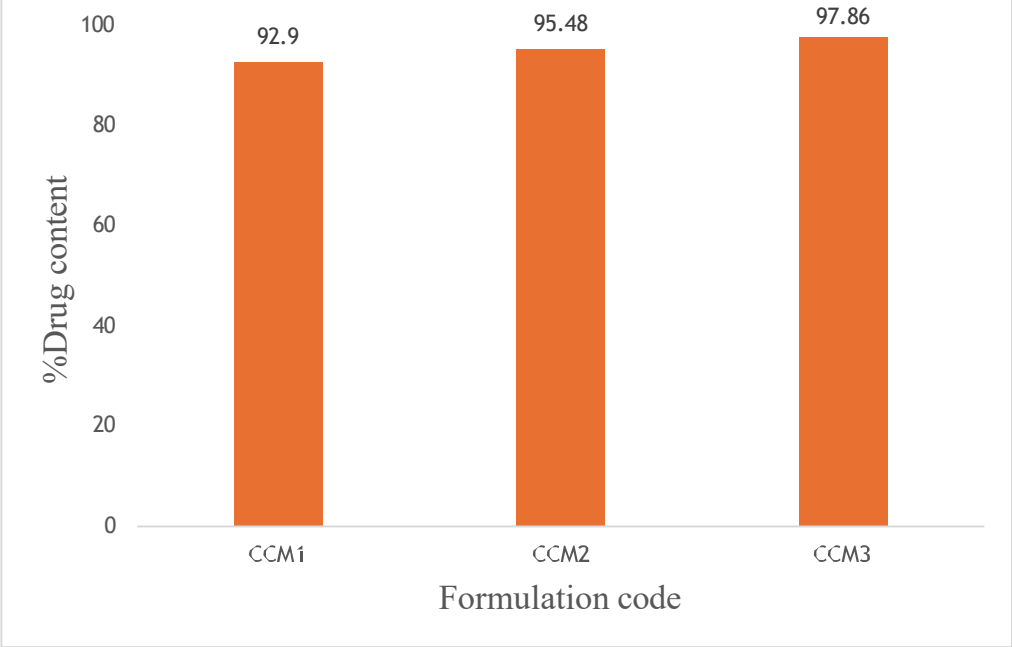
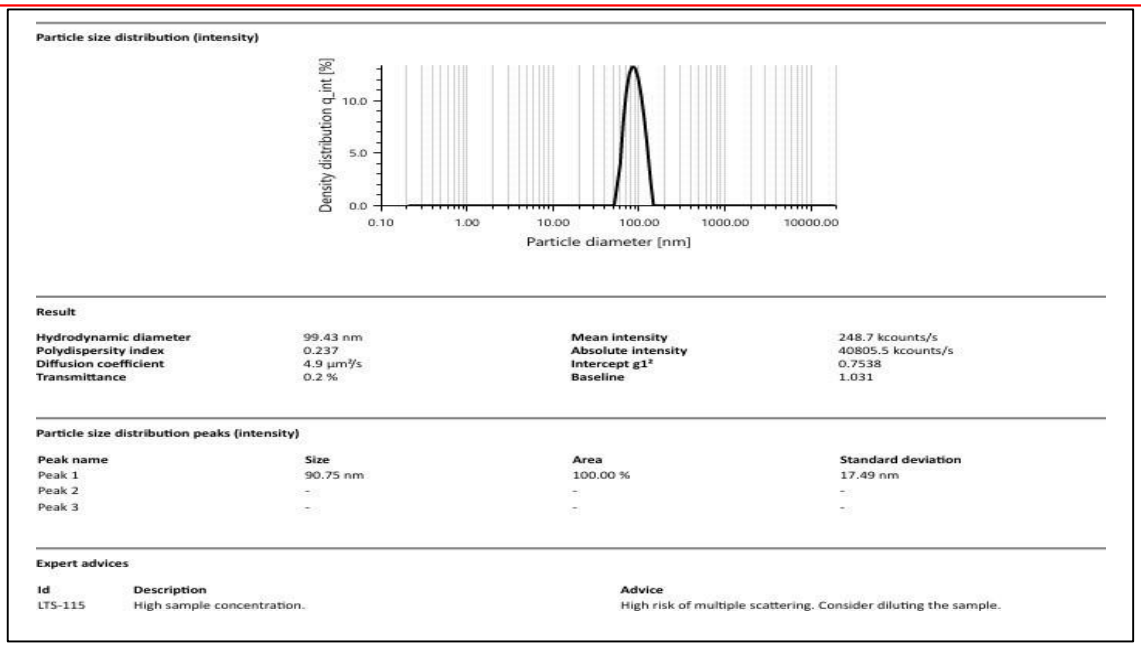


Fig.12: Percent Drug content of CCM1-CCM3



Particle size distribution (intensity)

Result

Hydrodynamic diameter	99.43 nm	**Mean intensity**	248.7 kcounts/s
Polydispersity index	0.237	**Absolute intensity**	40805.5 kcounts/s
Diffusion coefficient	4.9 µm²/s	**Intercept g1²**	0.7538
Transmittance	0.2 %	**Baseline**	1.031

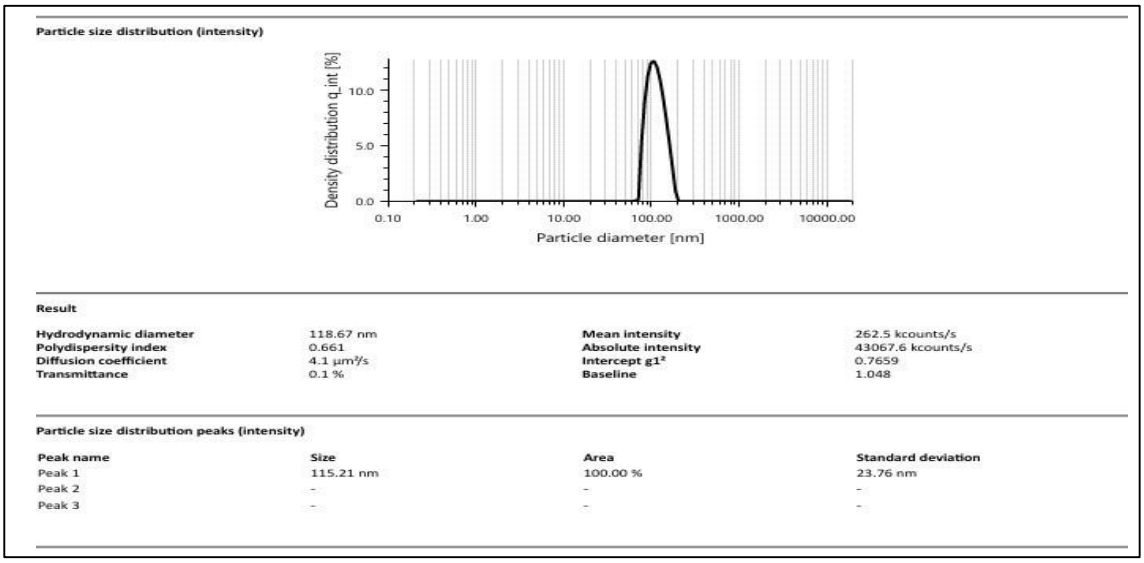
Particle size distribution peaks (intensity)

Peak name	Size	Area	Standard deviation
Peak 1	90.75 nm	100.00 %	17.49 nm
Peak 2	-	-	-
Peak 3	-	-	-

Expert advices

Id	Description	Advice
LTS-115	High sample concentration.	High risk of multiple scattering. Consider diluting the sample.

Fig.13: Globular size of CPM3



Particle size distribution (intensity)

Result

Hydrodynamic diameter	118.67 nm	**Mean intensity**	262.5 kcounts/s
Polydispersity index	0.661	**Absolute intensity**	43067.6 kcounts/s
Diffusion coefficient	4.1 µm²/s	**Intercept g1²**	0.7659
Transmittance	0.1 %	**Baseline**	1.048

Particle size distribution peaks (intensity)

Peak name	Size	Area	Standard deviation
Peak 1	115.21 nm	100.00 %	23.76 nm
Peak 2	-	-	-
Peak 3	-	-	-

Fig.14: Globular size of CCM3

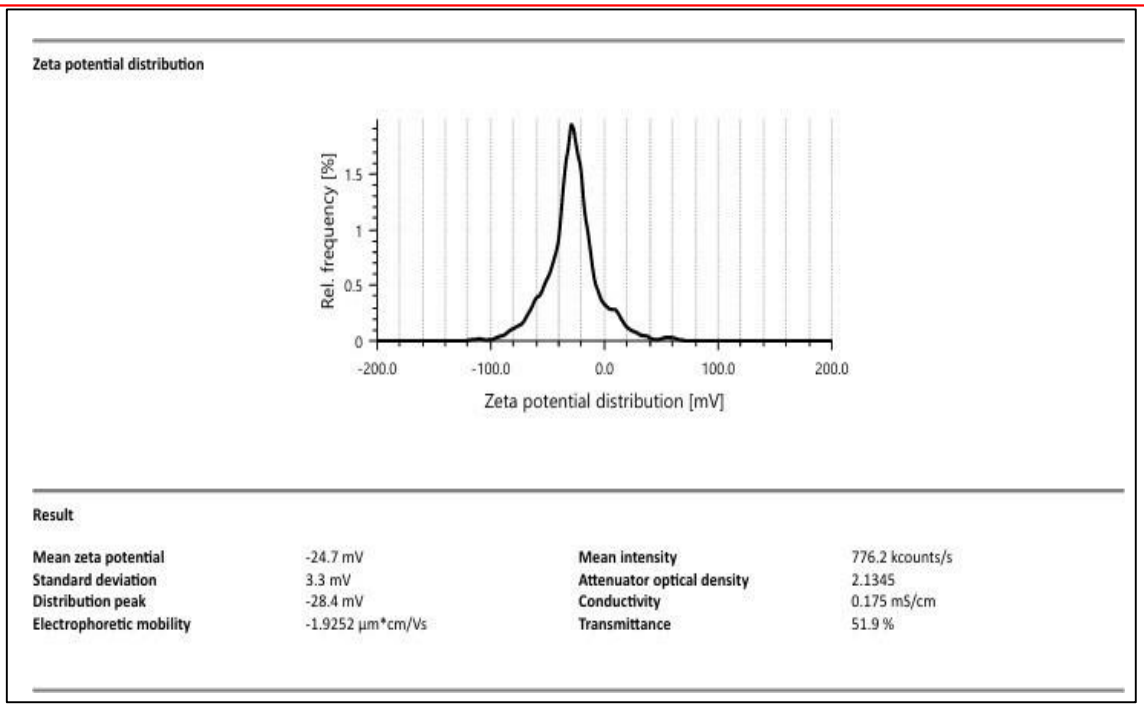


Fig.15: Zeta potential of CPM3

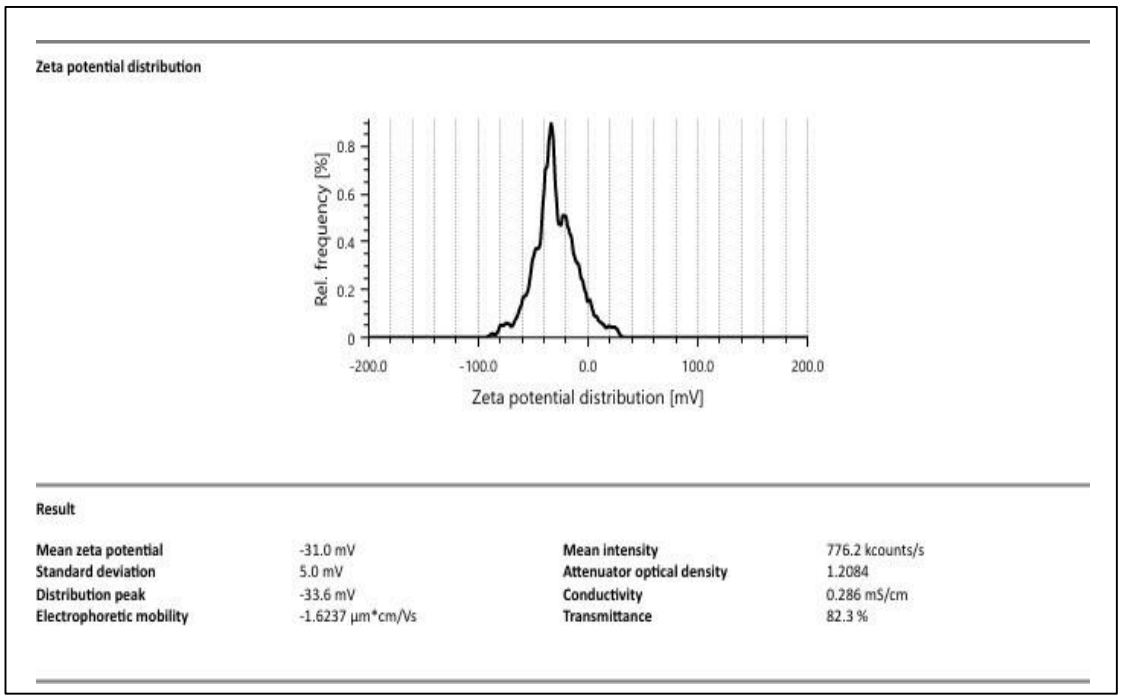


Fig.16: Zeta potential of CCM3

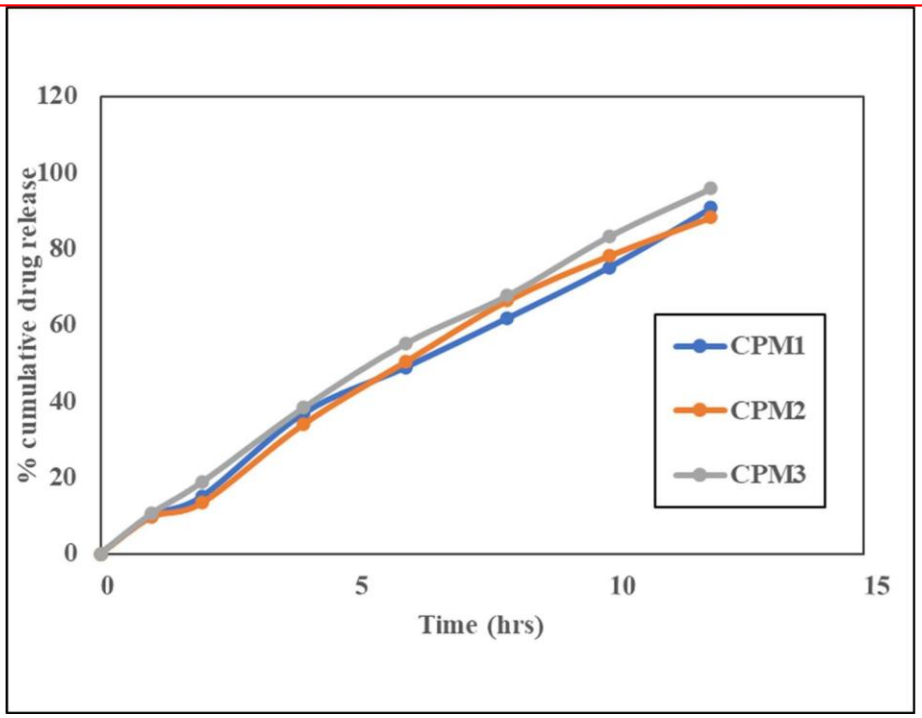


Fig.17: Comparison of Percent Cumulative Drug Release of CPM1-CPM3

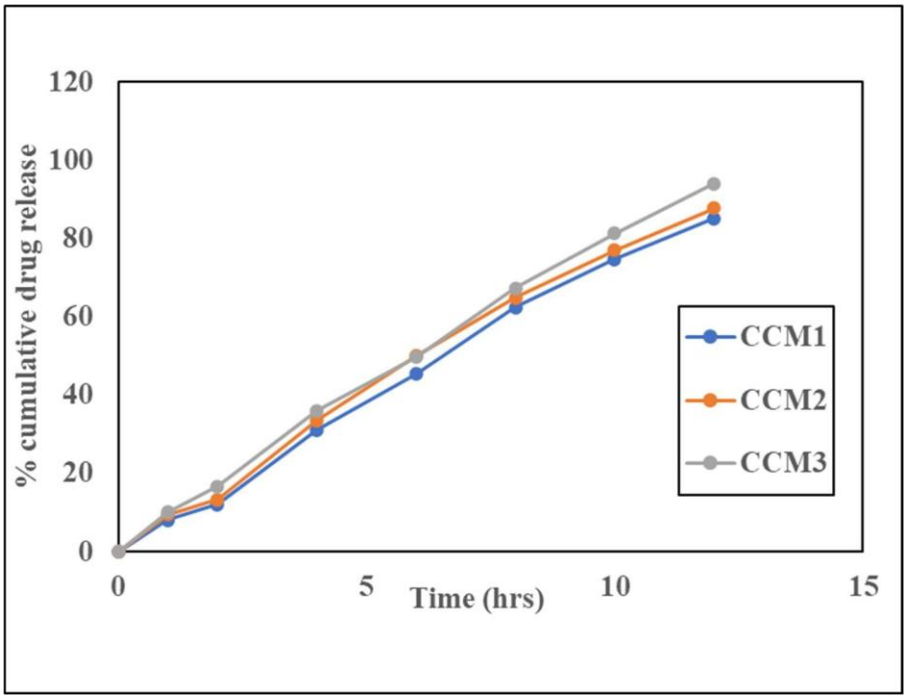


Fig.18: Comparison Cumulative Drug Release of CCM1-CCM3

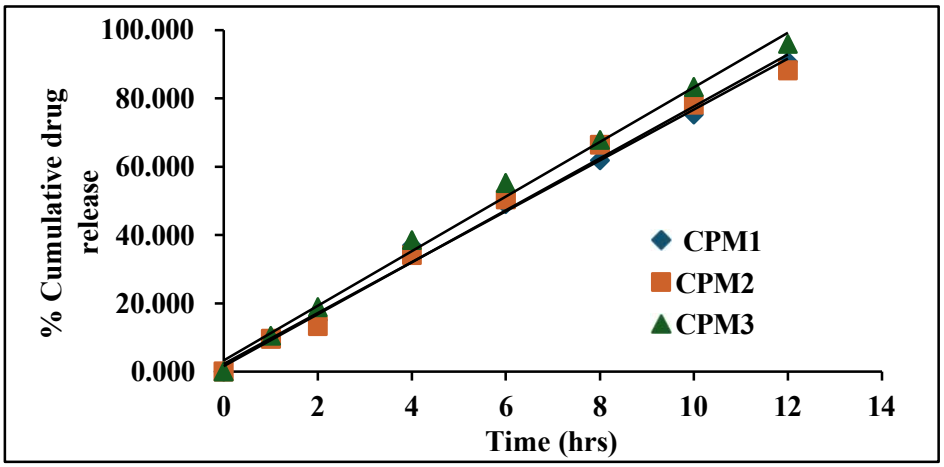


Fig.19: Zero order release kinetic profile of CPM1-CPM3

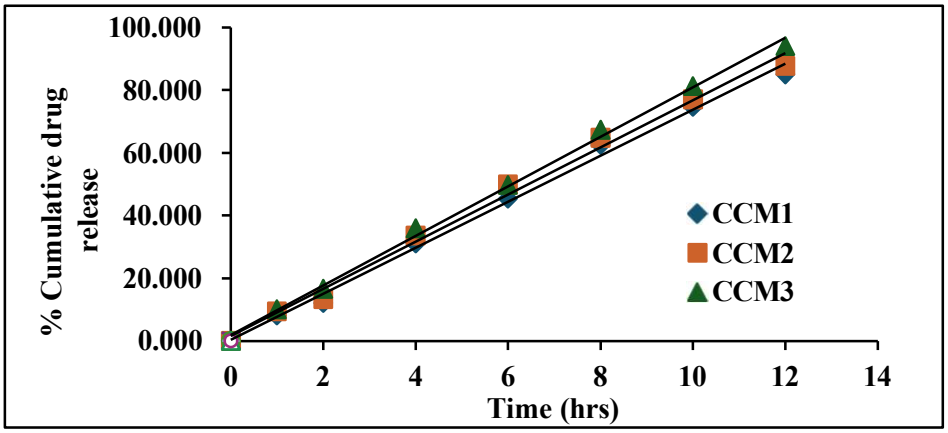


Fig.20: Zero order release kinetic profile of CCM1-CCM3

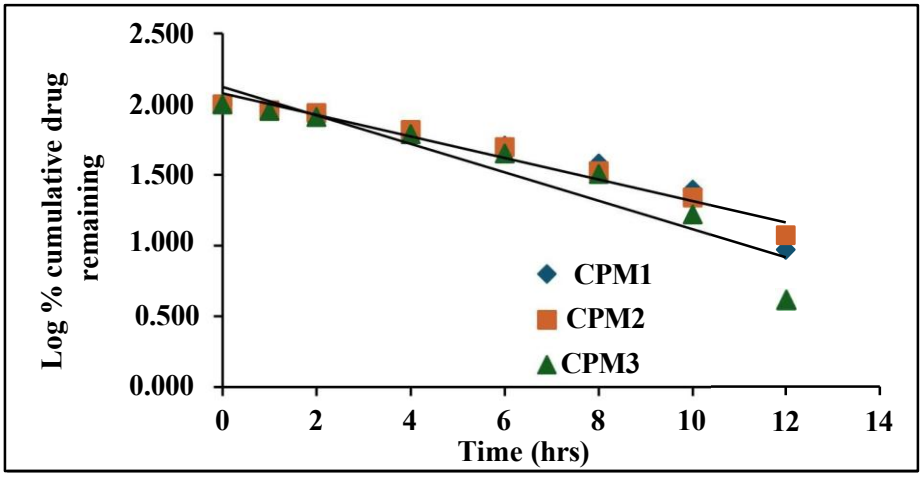


Fig.21: First order release kinetic profile ofCPM1-CPM3

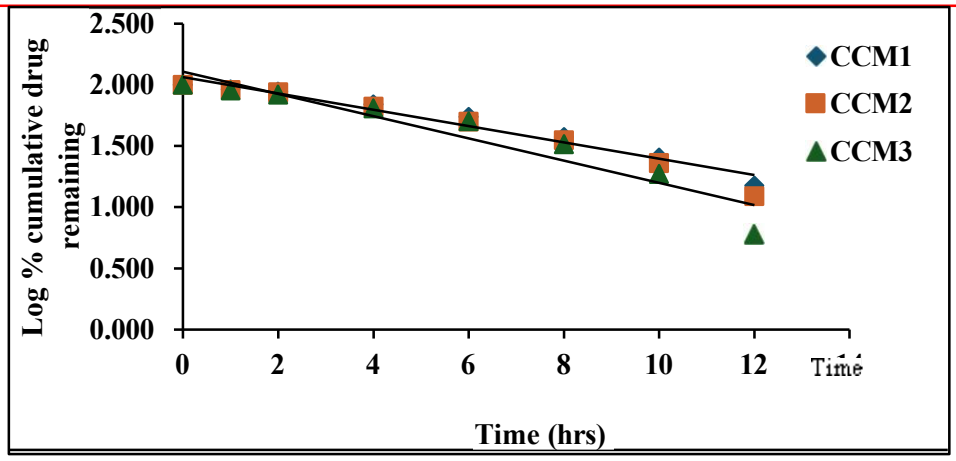


Fig.22: First order release kinetic profile of CCM1-CCM3

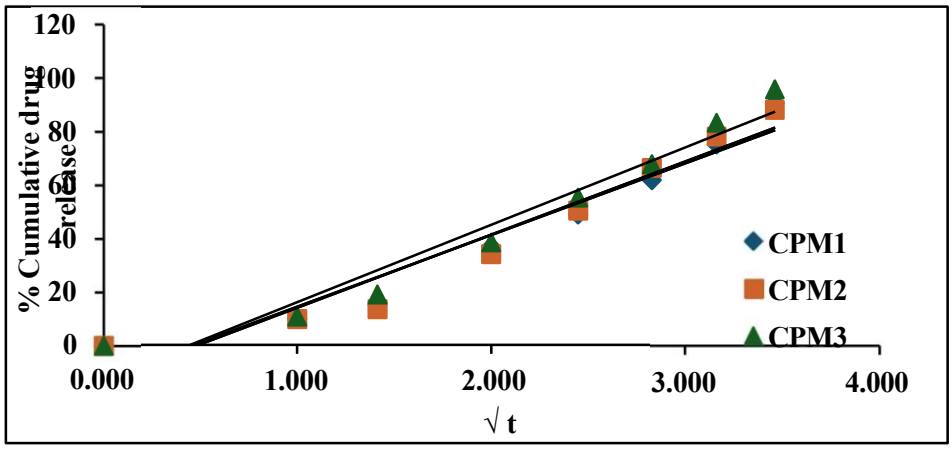


Fig.23: Higuchi release kinetic profile of CPM1-CPM3

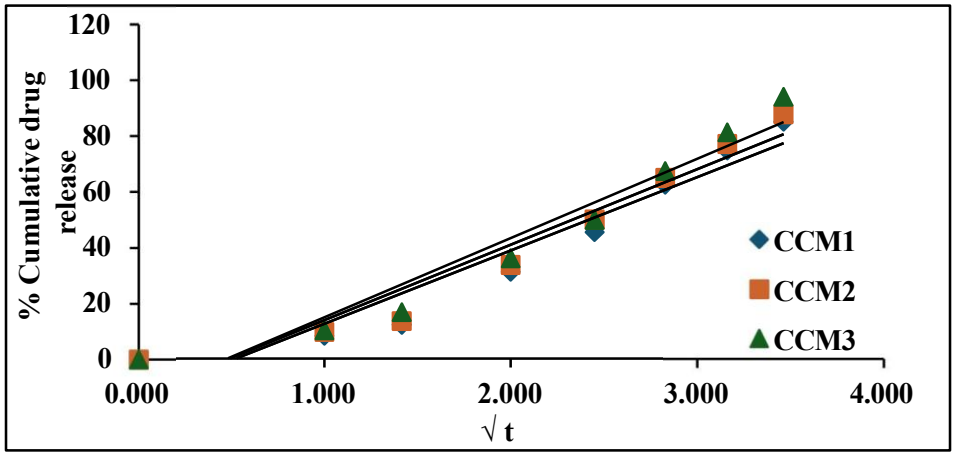


Fig.24: Higuchi release kinetic profile of CCM1-CCM3

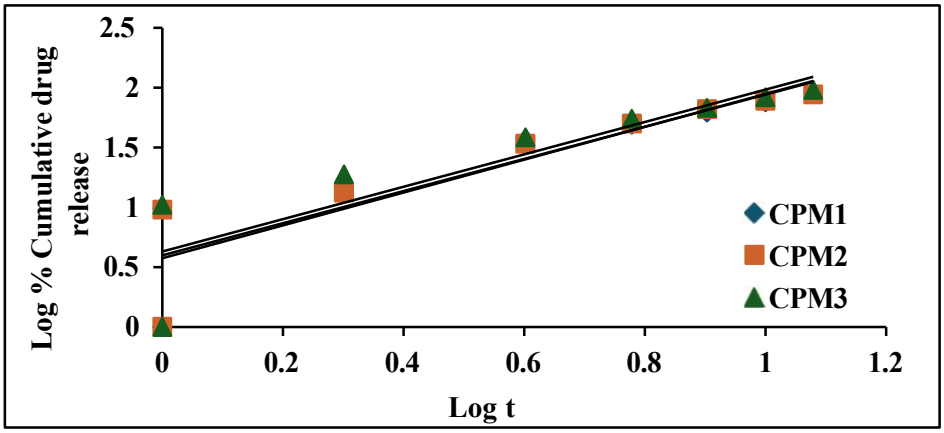


Fig.25: Peppas release kinetic profile of CPM1-CPM3

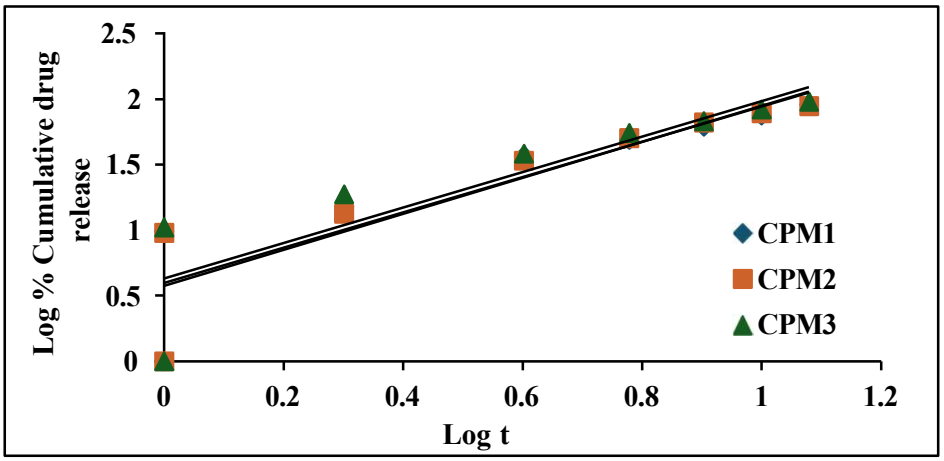


Fig.26: Peppas release kinetic profile of CCM1-CCM3

Table no. 2: Intermediate stability studies at 30ºC±2ºC and 65±5% RH

Parameter	Duration in months					
	0		3		6	
	CPM3	CPM3	CPM3	CCM3	CTM3	CCM3
Drug content	96.64	98.80	95.91	97.58	94.46	96.14
%CDR	95.86	93.98	94.02	92.68	93.02	91.56

Table No 3: Report of Antifungal activity against *Candia Albicans*

Sl. No.	Samples	Quantity Used	Zone Of Inhibition in mm	Sensitivity
1.	Miconazole Nitrate	500µg/ml	19	Sensitive
2.	CPM-3	30µl	24	Sensitive
3.	CCM-3	30µl	27	Sensitive
4.	CPM-3 GEL	60mg	21	Sensitive
5.	CCM-3GEL	60mg	23	Sensitive
6.	Carica papaya seed oil	20µl	13	Sensitive
7.	Cinnamon oil	20µl	16	Sensitive

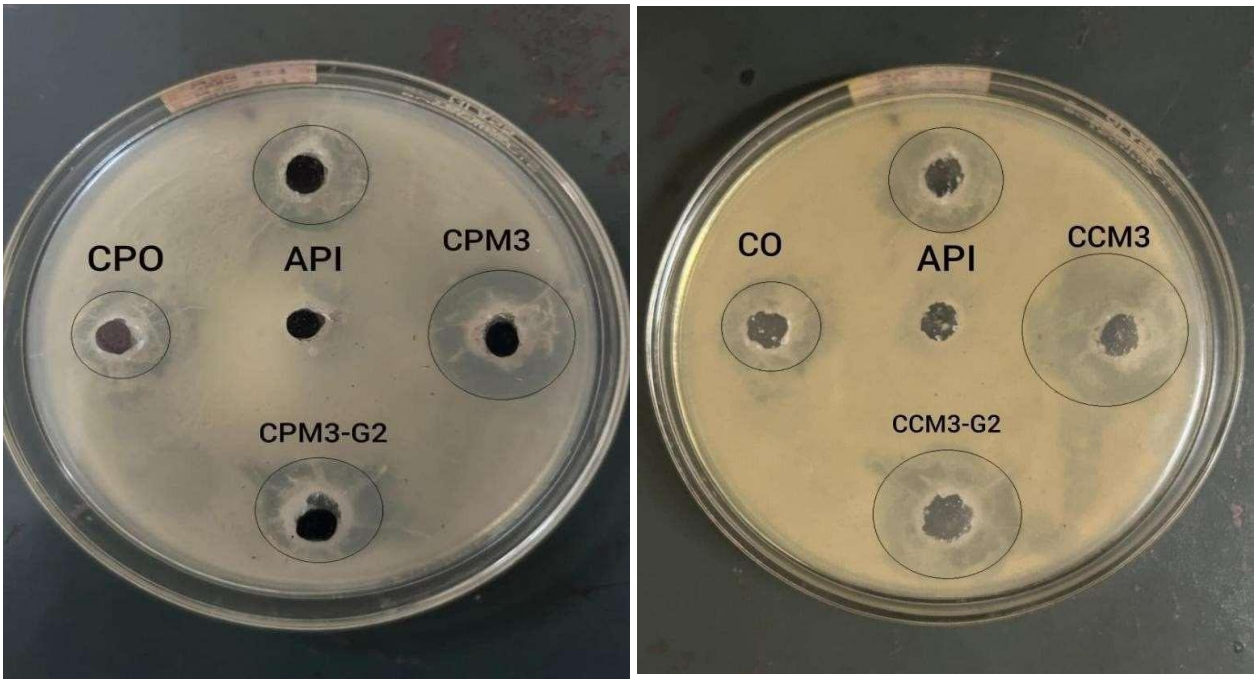


Fig.27: The antifungal activity against *Candida Albicans* using Agar well diffusion method.

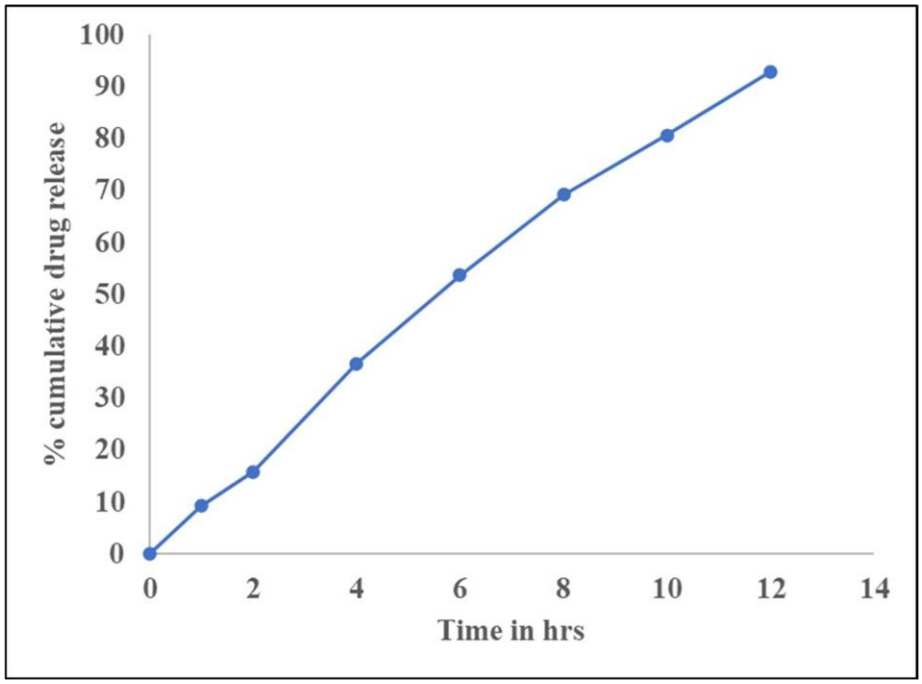


Fig.28: Percent Cumulative Drug Release of CPM3-G1

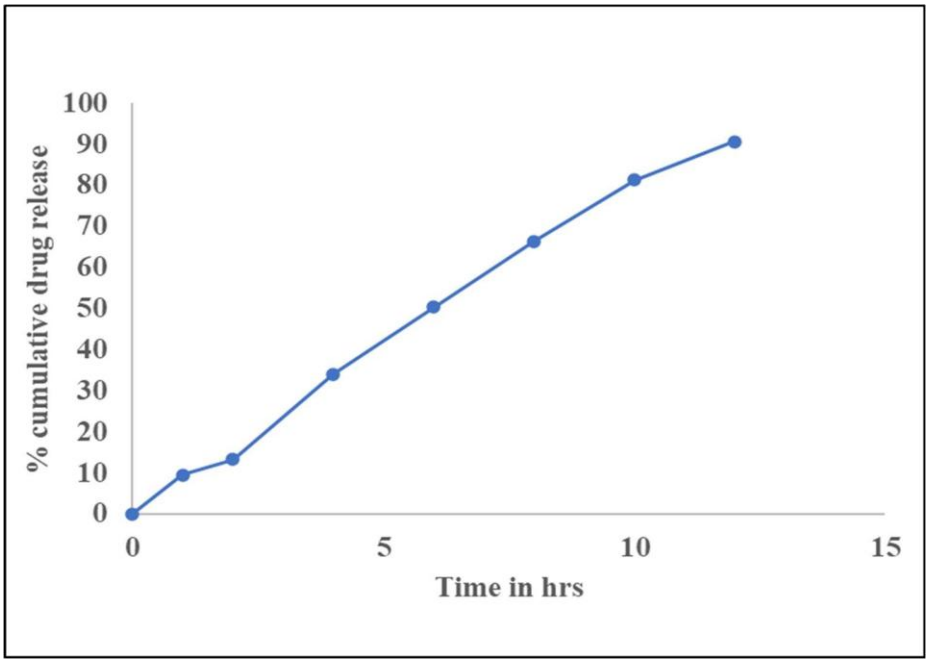


Fig.29 Percent Cumulative Drug Release of CCM3-G2

Table No. 4: Drug permeation study of CPM3-G1 and CCM3-G2

Time (hrs.)	Percentage Drug permeated	
	CPM3-G1	CCM3-G2
0	0	0
1	10.68	9.65
2	24.23	20.54
4	40.72	38.77
6	54.92	52.45
8	67.19	65.63
10	78.45	75.48
12	89.98	88.95

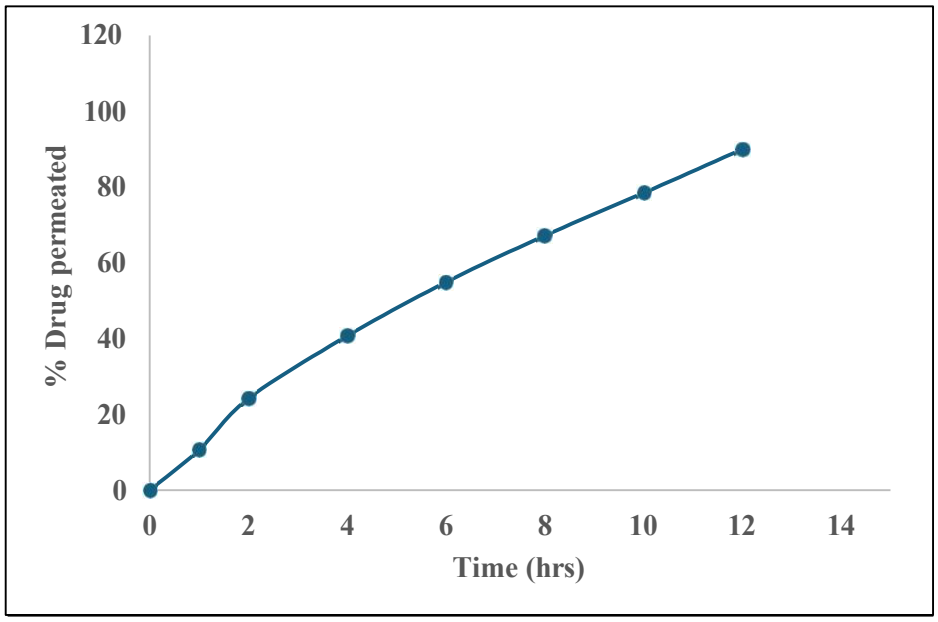


Fig.30: *Ex-vivo* drug permeation profile of CPM3-G1

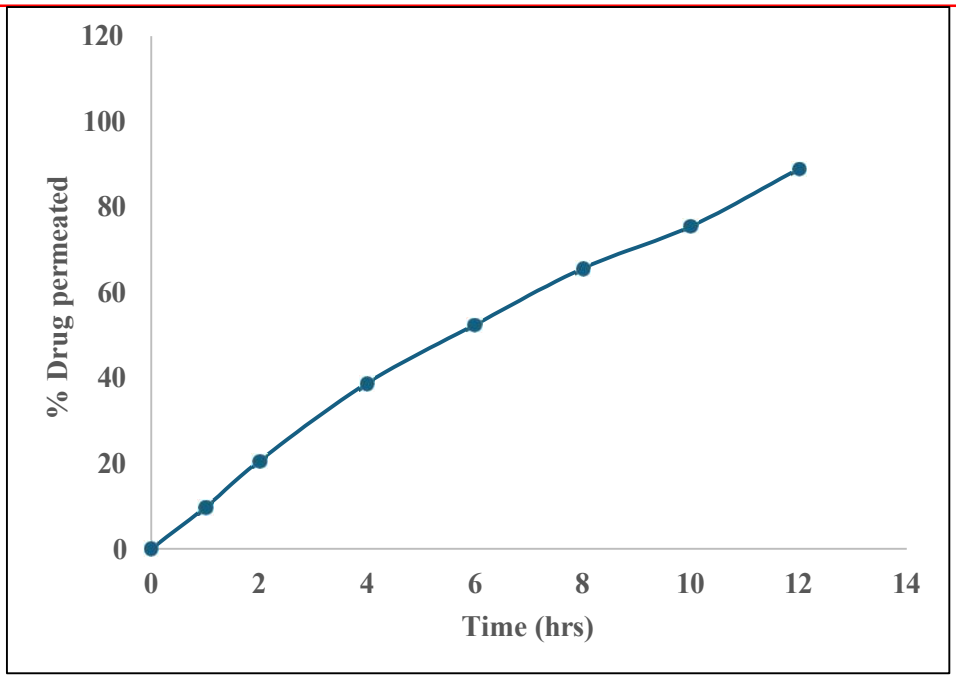


Fig.31: *Ex-vivo* drug permeation profile of CCM3-G2

CONCLUSION

The prepared Microemulsion and gel formulations FTIR analysis confirmed no significant interaction between the drug and excipients. Pseudo-ternary phase diagrams were successfully constructed, and microemulsions were prepared by titrating various oil-to-Smix ratios with water. Among all, formulations CPM3 and CCM3 were optimized due to their high transmittance, suitable viscosity, high drug content, and pH values around 6.4, with better drug release profiles. These were selected for stability testing and gel preparation using 1% w/w Carbopol 934. The resulting gels showed good spreadability, appropriate pH, high drug content, and acceptable viscosity. In vitro drug release studies indicated that CPM3-G1 and CCM3-G2 provided sustained drug release over an extended period. The optimized microemulsion and gel formulations showed superior antifungal activity against *Candida Albicans* compared to the pure drug and oils, indicating a synergistic effect. Enhanced inhibition zones confirmed improved drug penetration and efficacy. Ex-vivo permeation studies revealed sustained drug release and prolonged retention, supporting effective topical delivery.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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