



ICPPS 2014

Proceeding

The 1st International Conference
on Pharmaceutics & Pharmaceutical Sciences

Proceeding

The 1st International Conference on Pharmaceutics & Pharmaceutical Sciences

Drug Delivery Systems:
From Drug-Discovery, Pre-formulation, Formulation and Technological Approaches for
Poorly Soluble Drugs and Protein



Organized by :

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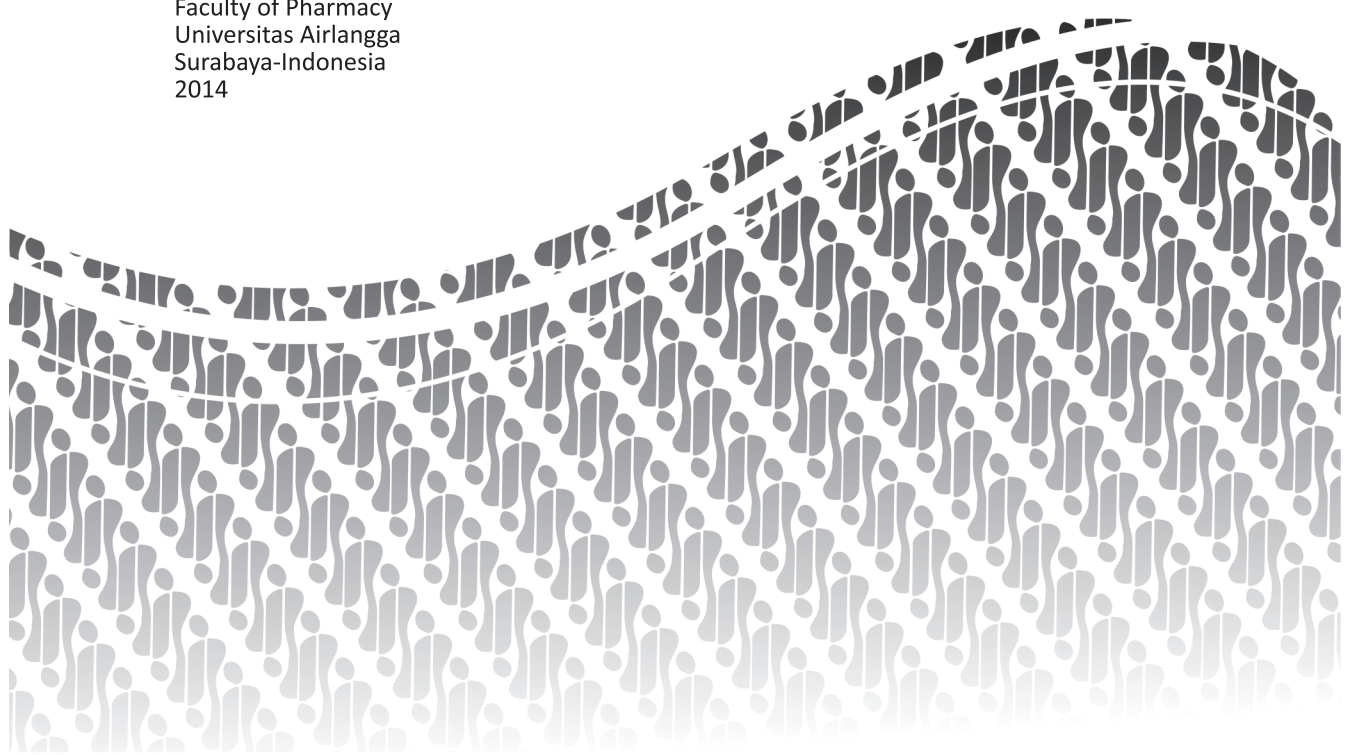
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PREFACE From Chairman

It is our pleasure to present you the proceedings of The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS) organized by The Faculty of Pharmacy Universitas Airlangga Surabaya Indonesia.

The proceeding was produced based on papers and posters presented at The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS), held in Surabaya, Indonesia, 14-15 November 2014.

The proceeding clearly reflects broad interest, from the participants that coming from all around the world.

The papers presented were pharmaceutics and biopharmaceutics; requirements on how to evaluate molecules in discovery and their appropriateness for selection as potential candidate; their development in context of challenges and benefits, together with associated time and cost implications and also requirements to progress through pre-clinical and clinical.

In this an opportunity, I would like to express my appreciation to the editorial team of the proceeding who have been working hard to review manuscripts, and making the first edition of this proceeding be possible.

I would like also to thanks to all invited speakers and presenters who participated in The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS) and your contribution to this proceeding.

Finally, I hope this proceeding will give contribution to the Pharmaceutics and Pharmaceutical Sciences research.

Chairman,

Dra. Esti Hendradi, MSI., Ph.D., Apt

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CHARACTERIZATION OF DOSAGE FORM AND PENETRATION DICLOFENAC SODIUM WITH MICROEMULSION SYSTEM IN HPMC 4000 GEL BASE (Microemulsion W/O with ratio use of surfactant Span 80 – Tween 80 : Cosurfactant Ethanol 96% = 6:1)

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INTRODUCTION

Diclofenac is NSAID that has activated as anti-inflammation, analgesic and antipyretics (Schuelert, 2011). Diclofenac sodium has partition coefficient of 13.4 (Hasan et.al.2005) which means diclofenac sodium has a partition in oil a higher amount than in the water. By usage two phases to diclofenac sodium like emulsion, diclofenac sodium can dispersed in the initial phase oil and water. But emulsion has thermodynamically unstable (Allen, 1997). So that, needed a system more stable for dispersion of diclofenac sodium to produce a more effective preparation, namely microemulsion system.

The characteristics of microemulsion are stable in thermodynamics, transparent, low viscosity, and have high solubilisation so that it can increase bioavailability drugs in the body (Santos et al., 2008). To overcome the low viscosity of microemulsion by adding hydroxy propyl methyl cellulose (HPMC). The aim of this study was to observe characterization dosage form and penetration of diclofenac sodium in microemulsion system which contained ratio surfactant Span 80-Tween 80 an cosurfactant ethanol= 6:1.

METHODS

Material

Diclofenac sodium (PT. KIMIA FARMA), soybean oil (Sime Draby Edible Product Limited), Span 80 and Tween 80 (Croda), ethanol 96% (Merck), HPMC 4000 (Cosmetic Grade) (Dow Chemical Pacific), aquadem (PT Widatra Bhak-

ti), propyleneglycol (BASF SE, Germany).

Preparation of Microemulsion and emulsion
 The composition of microemulsion and emulsion system in table 1.

Preparation of Emulsion

Emulsion was made by mixing Span 80 and soybean oil as oil phase. As water phase was aquadem and Tween 80. Diclofenac sodium was added in the water phase and oil phase was 2% and 3%, respectively. Mixed the system using magnetic stirrer 500 rpm for 30 minutes.

Preparation of Microemulsion

Span 80, Tween 80, soybean oil, surfactant and cosurfaktant were mixed using magnetic stirrer 100 rpm for 15 minutes. Added aquadem and mixed 100 rpm, 15 minutes. Then, added diclofenac sodium into the system mixed at 150 rpm for 60 minutes.

Table 1. Formula of microemulsion and emulsion W/O type of diclofenac sodium

Material	Concentration (%) (b/b)	
	Microemulsion	Emulsion
Diclofenac sodium	5.00	5.00
Span 80	38.00	7.70
Tween 80	12.83	2.86
Etanol 96%	8.47	-
Soybean oil	33.74	64.41
Aquadem	1.95	20.03



Material	Concentration (%) (b/b)
HPMC 4000	1.5
Propyleneglycol	5
Aquadem	93.5

Table 2. Componen HPMC 4000 gel

Preparation of Microemulsion and emulsion diclofenac sodium in HPMC gel

The concentration of diclofenac sodium of Microemulsion and emulsion in HPMC gel was made 1%. Weigh the microemulsion or emulsion that contained 1% diclofenac and added in to HPMC gel and mixed.

Evaluation

Organoleptic Evaluation

Organoleptic evaluation carried out visually includes examining the color, odor, and consistency. The evaluations performed on microemulsion and emulsion of diclofenac sodium.

Determination of Droplet Size Distribution

Examination of the size and distribution of the microemulsion droplet size was performed with a submicron Delsa™ Nano Particle Size and Zeta Potential Dynamic Light Scattering. The droplet of emulsion of diclofenac sodium was determined using microscope.

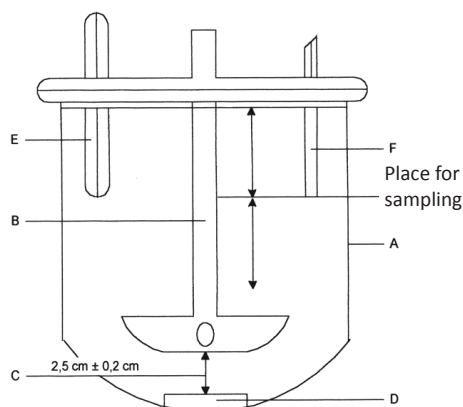
Determination of conductivity

Determination of conductivity was measured using conductometer to microemulsion and emulsion preparation.

Penetration of diclofenac sodium from the preparation

The penetration of diclofenac sodium from microemulsion gel through Wistar rat skin membrane was determined by dissolution test for 8 h. The gel microemulsions of diclofenac sodium (in cell diffusion) were placed respective in the dissolution chamber (Figure 1). All in vitro penetration were performed at 100 rpm, with each medium of dissolution (phosphate buffer saline pH 7.4 ± 0.05 at temperature 37 ± 0.5°C) was 500 mL. The samples withdrawn at different time intervals were analyzed for drug con-

tent using Spectrophotometer Double Beam UV-VIS Recording UV 160 A (Shimadzu). The result was analyzed by statistic programmed of using Independent sample t-Test with degree of confident 95% (α = 0.05).



- A :Diffusion chamber contain PBS pH 7.4
- C: Distance from paddle to diffusion membrane
- D: Diffusion cell
- E: Thermometer
- F: Sample holder

Figure 1. Apparatus 5-paddle Over Disk (TheUnited States Pharmacopeia Convention, 2002)

Penetration of diclofenac sodium was calculated using equation 1

$$J = \frac{dM}{S \cdot dt} \quad (1)$$

Where

J : flux

M : mass of compound (gram)

S : surface area of barrier/membrane (cm²)

t : time (minute/hour)

RESULTS AND DISCUSSION

The appearance system of microemulsion and emulsion shown in Figure 2 and Table 3. In this figure showed that microemulsion was clear and the emulsion was not clear.

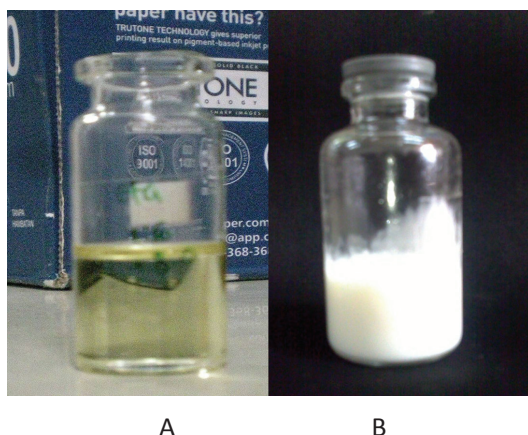


Figure 2. The appearance of microemulsion (A) and emulsion (B)

Table 3. The organoleptics, droplet size and conductivity microemulsion and emulsion of diclofenac.

Observation	Microemulsion of diclofenac sodium	Emulsion of diklofenac sodium
Organoleptics		
Consistency	Transparent fluid	Viscous liquid
Color	Yellow	White
Smell	No smell	No smell
Droplet size	117.2617 nm	1.04 μ m
Conductivity	0.40 \pm 0.01 μ S	0.92 \pm 0.01 μ S

The droplet size of microemulsion smaller compared with the droplet of emulsion of diclofenac. The results of conductivity test showed both of microemulsion and emulsion of diclofenac 0,40 \pm 0,01 μ S and 0,92 \pm 0,01 μ S, respectively. It means both the emulsion type were W/O.

Table 4. The spread diameter and pH of microemulsion and emulsion of diclofenac.

Observation	Microemulsion of diclofenac sodium	Emulsion of diklofenac sodium
Spread diameter	7.7 \pm 0.2 cm	12.73 \pm 0.2 cm
pH	6.33 \pm 0.02	6.33 \pm 0.02

Each data represents the mean \pm S.D. of 3 determinations

The data of spread diameter of microemulsion of diclofenac was lower than emulsion of diclofenac but the pH of two preparations were same. In this research the penetration of diclofenac from emulsion preparation was not done because the stability of emulsion of diclofenac only 2 hours. The flux of diclofenac from microemulsion preparation shown in table 5.

Table 5. Flux of diclofenac from microemulsion preparation

Replication	Flux of diclofenac sodium (μ g/cm ² /minutes)
1	0.24
2	0.18
3	0.24
Mean \pm SD	0.22 \pm 0.03
% KV	16.25 %

The permeability of rat skin to diclofenac shown in table 6.

Table 6. The permeability of rat skin to diclofenac sodium

Replications	Permeability of rat skin to diclofenac sodium (cm/minute)
1	2.18 \times 10 ⁵
2	1.63 \times 10 ⁵
3	2.21 \times 10 ⁵
Mean \pm SD	2.01 \times 10 ⁵ \pm 3.27 \times 10 ⁶
% KV	16.25 %



CONCLUSION

1. Characteristics of microemulsion system in gel base HPMC 4000 showed thicker consistency than emulsion system in gel base HPMC 4000. Different system gave no effect on pH but gave effect on spread diameter of zero load.
2. Penetration flux in microemulsion system in gel base HPMC 4000 was 0.22 ± 0.03 $\mu\text{g}/\text{cm}^2/\text{minute}$ and permeability of membrane was $2.01 \times 10^{-5} \pm 3.27 \times 10^{-6}$ cm/minute .

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