EFFECT OF MENTHOL AS PENETRATION ENHANCER TO DICLOFENAC SODIUM MEMBRANE-TYPED TRANSDERMAL PATCH CHARACTERIZATION

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INTRODUCTION

Inflammation is a non-specific immune response that occurs in reaction to any type of bodily injury. The cardinal signs of inflammation can be explained by increased blood flow, elevated cellular metabolism, vasodilatation, release of soluble mediators, extravasation of fluids and cellular influx1.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are drug class which commonly used to treat inflammation. Diclofenac sodium is one of the drug class of non steroidal anti-inflammatory drugs (NSAIDs) are widely used to relieve pain and inflammation. Absorption of sodium diclofenac in oral delivery is very fast but only about 60% of which reaches the systemic circulation, this is because first-pass metabolism that occurs in the liver2. Half-life of diclofenac sodium was also very brief about 2 hours and a few other side effects such as gastrointestinal disorders (ulcers in the stomach) and the reaction idionsynchratic. One way to overcome this problem, given by way of diclofenac sodium transdermal. Diclofenac sodium is not absorbed through the skin as perfect hydrophilic can be seen from log P of sodium diclofenac of 4.42,

Absorption of sodium diclofenac into the skin can be improved by the addition of enhancers such as menthol. Adding one or more excipients could change dosage form characteristics. This study was aimed to determine effect of menthol to patch characteristics when it added to diclofenac sodium membrane-typed patch.

METHODS

Material

Diclofenac sodium (Aarti Drugs Limited), alginate sodium (Sigma-Aldrich), hydroxypropil methylcellulose E-15 (ILE Pharmaceutical), propylenglycol (Bratachem), L-menthol (Bratachem), ethanol 96% (Bratachem), and aquades

Preparation of patch

Patches were made using formula in Table 1. Dose of diclofenac sodium in dosage is 100 mg/50 cm2 patch. Sodium alginate were dissolve in water:ethanol (80:20) and stirred constantly to make alginate sodium 9%. Diclofenac sodium previously dissolved in same solvent and were added with alginate sodium 9%, and stirred homogenously. The mixture were poured into mold and it dried on 45°C for an hour. HPMC E-15 were dissloved in water to made 20% concentration. Propylenglycol were added and stirred constantly. Menthol were dissolved in ethanol, previously, and were added to HPMC E-15 and propylenglycol, and stirred. This mixture were poured on to alginate sodium and dried on 40°C for an hour

Table 1 Formulation of diclofenac sodium membrane-typed patch

Composition	Function	Weight (mg/ 12,56 cm^2)	
		FI	FII
Diclofenac sodium	Active ingredients	25,2	25,2
Alginate sodium 9%	*Drug reservoir*	1308,4	1308,4
HPMC E15 20%	*Rate-controlling membrane*	1280	1280
Propylenglycol	*Plastisizer*	53,3	53,3
Menthol	*Enhancer*	26,7	-
Weight Total		2693,6	2666,9

Organoleptic evaluation
Organoleptic evaluation were observed on patch characteristic, odor, and consistency.

Moisture content evaluation
The films were weighed and kept in a desiccator contain- ing calcium chloride at room temperature for 24 hours. Values for the percentage of moisture content, calculated as the percentage of difference between the constant final and initial weight with respect to the initial weight.

Surface homogeneity
Surface homogeneity were observed using Scanning Electron Microscope (SEM) FEI INSPECT S50 om magnification x1000.

Stabilty evaluation
Stability evaluation were performed 12 weeks (1,3,6,12 weeks), regarding to change of organoleptic, moisture content, and concentration of active ingredient (diclofenac sodium).

Statistical analysis
The results were expressed as arithmetic mean ± SD. The statistical analysis was performed using Anova one-way. The data was considered significant at p>0.05.

RESULTS
Organoleptic evaluation
As menthol added, there were only odor difference on patches. Their color and elasticity remain same.

Figure 1. Diclofenac sodium membran-typed patch with and without menthol (left and right, re spectively)

The results of evaluation of diclofenac sodium membrane-typed patch were summarize on Table 2.

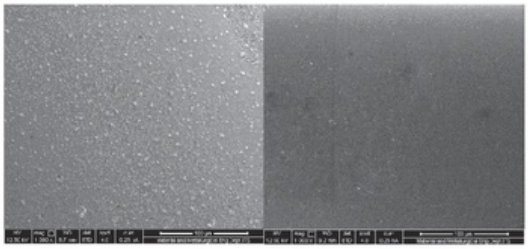

Figure 2. Scanning electrone microscope photograph of diclofenac sodium membrane-typed trans dermal patch with (left) and without (right) menthol on magnification x 1000.

The results of evaluation of diclofenac sodium membrane-typed patch were summarize on Table 2.

Table 2. Evaluation of diclofenac sodium membrane-typed patch

Week Observation	Type of evaluation	Formula I	Formula II
0	Organoleptic (colour, odor, consistency)	Transparant, mentholic odor, elastic	Transparant, no mentholic odor, elastic
	% Moisture content	42.84 ± 9.08	47.48± 2.41
	% Diclofenac sodium content	100.70 ± 0.85	102.02 ± 0.59
1	Organoleptic (colour, odor, consistency)	Transparant, mentholic odor, elastic	Transparant, no mentholic odor, elastic
	% Moisture content	29.15 ± 2.93	26.76 ± 6.37
	% Diclofenac sodium content	97.67 ± 1.55	96.68 ± 0.62
3	Organoleptic (colour, odor, consistency)	Transparant, mentholic odor, elastic	Transparant, no mentholic odor, elastic
	% Moisture content	20.83 ± 1.02	26.88 ± 2.17
	% Diclofenac sodium content	96.17 ± 4.42	95.13 ± 3.28
6	Organoleptic (colour, odor, consistency)	Transparant, no mentholic odor, elastic	Transparant, no mentholic odor, elastic
	% Moisture content	19.89 ± 0.65	21.02 ± 1.39
	% Diclofenac sodium content	97.21 ± 5.70	97.21 ± 0.71
12	Organoleptic (colour, odor, consistency)	Transparant, no mentholic odor, elastic	Transparant, no mentholic odor, elastic
	% Moisture content	22.27 ± 2.63	21.61 ± 0.39
	% Diclofenac sodium content	99.46 ± 0.62	99.03 ± 0.62

CONCLUSION

Menthol as penetration enhancer did not gave difference on diclofenac sodium membran-typed transdermal patch characterization.

ACKNOWLEDGMENT

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