RESEARCH ARTICLE

Fabrication and Characterization of Novel Liquid Film Forming Solution for Pain Management

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ABSTRACT

The purpose of the current study's is to develop, characterize, and analyze a novel transdermal film forming solution of Tramadol (TMD) in order to maximize drug availability, minimize the frequency of oral side effects, and eliminate the need for frequent dosing. Tramadol is an opiate pain reliever, used to treat moderate to severe pain caused on by both acute and chronic illnesses or injuries. They lessen pain by influencing your brain and nervous system. The preparation of Film Forming Solutions (FFS) for transdermal distribution of TMD involved the use of Eudragit-L100, Hydroxy-Propyl Methyl Cellulose (HPMC E5), and PVA as a film forming polymer, ethyl alcohol as a solvent, PEG 400 as a plasticizer. The pH, viscosity, drying time and drug content was assessed for FFS. They also underwent in-vitro drug release testing. For every test, every formulation produced results that fell within an acceptable range.The formulation F5 was determined to be the best based on the basis of physiochemical evaluation. Formulation gave 76.83% of sustained drug release within 10 hrs. It is further evaluated for SEM analysis and in vivo analgesic study. A film-forming solution formulation may be regarded as an acceptable approach for pain management because the developed formulation exhibited comparable analgesic activity to that of the commercially available traditional formulation.

Keywords: Transdermal, Tramadol Hcl, Eudragit L100, PVA, Analgesic

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INTRODUCTION

The skin provides both local and systemic effects, making it a useful route for drug administration. There are drawbacks to traditional formulations, such as poor patient compliance, permeability, and skin adherence. Semi-solid dosage forms may encourage wound cross-infection because they are applied with the fingers and readily adhere to clothing when in motion. As an alternative, topically a medicated adhesive patches are applied to administer a predetermined dosage of the medication; however, it can be purposefully abused and still leaves drug residues after using it.[1] The new method known as film-forming solution (FFS) can be applied in place of conventional topical and transdermal dose forms. FFS develops as a solution that, when applied, leaves a thin layer on the skin.[2] Like a patch, thin film formed can improve the drug's permeability and contact time.[3]

The resultant film penetrates various layer of skin to produce a therapeutic response, leading to medications controlled release into the systemic circulation. By preventing the drug from entering the systemic circulation in pulses, this continuous delivery lowers systemic toxicity. Additionally, once applied to the skin, FFS is quickly drying, less oily, well-retained, and almost undetectable. it may have better cosmetic qualities than semi-solid formulation.[4] Drugs can be delivered transdermally to avoid the effect of first-pass administration, increase bioavailability, and deliver the drug through the skin at a controlled and predetermined rate.[5] The spray formulation can be used as a patient-complied dosage form, for self-medication, and for quick action. By maximizing drug availability at a smaller dose, it enhances therapy.[6]

Tramadol Hcl (TMD) is a synthetic centrally-acting opioid analgesic drug and SNRI (serotonine/norepinephrine reuptake-inhibitor). It is a strong analgesic that is a member of the narcotics, or opiate, drug class. Usually, it is applied to moderate to severe pain, such as after surgery or in situations involving serious injuries.[7] TMD rapidly diffuses into the systemic circulation through the mucosal membrane and is classified as BCS type-I, which has high solubility and permeability. With a half-life of roughly six hours and a bioavailability of less than 70% when taken orally, the medication requires frequent dosing in order to maintain ongoing pain relief.[8]

Tramadol is available in oral and intravenous formulations. It comes in the form of tablets, capsules and liquid drops which you swallow. It can also be taken by injection, but it is usually only done in hospitals. Tramadol's most frequently reported side effects include nausea, constipation, dry mouth, vomiting, drowsiness, and dizziness. By applying it topically as a film-forming solution, these adverse effects could be reduced. With a significant dose reduction, the film-forming transdermal

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Table 1: Development of Film Forming Solution of Tramadol hydrochloride

Ingredients (% w/v)	F 1	F 2	F 3	F 4	F 5	F 6	F 7	F 8	F 9
Tramadol Hcl	3%	3%	3%	3%	3%	3%	3%	3%	3%
Eudragit L 100	1 %	1%	1%	3%	3%	3%	5%	5%	5%
HPMC E 5	1%	3%	5%	1%	3%	5%	1%	3%	5%
PVA	3%	3%	3%	3%	3%	3%	3%	3%	3%
PEG 400	5%	5%	5%	5%	5%	5%	5%	5%	5%
Menthol	5%	5%	5%	5%	5%	5%	5%	5%	5%
Methyl Paraben	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%
Ethanol	qs	qs	qs	qs	qs	qs	qs	qs	qs
Water	qs	qs	qs	qs	qs	qs	qs	qs	qs

Table 2: Physicochemical evaluation of Film Forming solution of Tramadol Hcl

Formulation	Appearance	Viscosity	Ph Value	Drug Content	Drying time
F1	Clear, Transparent	40 ± 2	4.86	96.53%	2 min 15 Sec
F2	Clear, Transparent	49 ± 2	5.23	97.44%	3 min 40 Sec
F3	Clear, Transparent	58 ± 2	4.45	97.72%	5 min 34 Sec
F4	Clear, Translucent	51 ± 2	5.71	96.88%	4 min 12 Sec
F5	Clear, Translucent	57 ± 2	5.16	98.05%	5 min 20 Sec
F6	Clear, Translucent	66 ± 2	4.95	96.46%	6 min 48Sec
F7	Clear, Off white	60 ± 2	4.62	98.25%	6 min 22 Sec
F8	Clear, Off white	68 ± 2	5.08	97.28%	7 min 15 Sec
F9	Clear, Off white	75 ± 2	5.37	96.34%	8 min 50 Sec

solution maintains the same drug efficacy while mitigating the disadvantages associated with the traditional semisolid dosage form. Drugs are delivered directly to the application site by transdermal solution.[6]

The goal of the current study was development and evaluation of film-forming spray containing Tramadol with improved skin retention time on the site, increased bioavailability and reduced side effects for effective pain management and improved patient compliance.

MATERIAL AND METHODS

Materials

Tramadol hydrochloride was acquired from Cipla Limited (Ahmedabad, Gujarat, India). Eudrgait L100, HPMC E5 and PVA were acquired from Yarrow Chemical Pvt. Ltd. (Mumbai, India). PEG 400, menthol, Methyl Paraben and ethanol was acquired from Mumbai, India's Loba Chemie Pvt. Ltd. Every additional chemical and reagent that was used was of analytical quality.

Preparation of the Tramadol Film-Forming Spray Solution (TMD-FFS)

The FFSS containing TMD was formulated using 3 filmforming polymers viz., PVA, Eurdragit L 100 and HPMC E5 and with other excipients as shown in table 1. To make the polymeric solutions, the polymer was added with solvent and was stirred to get clear solution. The plasticizer (PEG 400) and preservative (Methyl Paraben) were added to this transparent polymeric solution and swirled. The drug (3% w/v) was added to the resulting clear solution and dissolved while being constantly stirred to produce a clear drug in polymeric solution. Menthol was added to this dropwise while being continuously stirred after being dissolved in a small amount of the solvent. As indicated in Table 1, approximately nine distinct formulations were created by varying the concentration of three distinct film-forming polymers.

Evaluation of Tramadol Film-Forming Solution (TMD-FFSS)

Appearance

The Film Forming solution was assesed for its physical properties such as colour and its clarity by the visual inspection against the black & white background.[9]

Viscosity

Viscosity was measured by using Brookfield viscometer using spindle number 6. Spindle was rotated at speed of 100 rpm at temperature of 25±1°C. Before measuring the sample was equilibrated for about 10 min.[10]

pH Determination

The pH of the formulation is evaluated to remove any irritation to the skin. It is less likely that a formulation will irritate skin if its pH is comparable to that of the skin.[11] pH was determined using pH meter digital one and dipping electrode in the solution.[12]

Drug Content

To ascertain the drug distribution in the TMD-FFS-formed film, the drug content was examined. After cutting and dissolving the film in 5 milliliters of buffer solution of pH 7.4 phosphate. The volume was made to 10 milliliters (first dilution). PBS (pH 7.4) was used to make up the volume after 1 ml of this dilution was transferred into a second 10 mL volume flask.[13] A UV-visible spectrophotometer set to 240 nm was used to spectrophotometrically estimate the drug content.

Drying Time

By applying the formulation to a glass slide or hand arm and measuring the amount of time needed for the formed film to dry, the amount of time needed to prepare film and was dry and determined. A digital stopwatch was utilized to record the drying time.[14]

Evaluation and of TMD-FFS Film

Appearance of Film

Table 3: Physicochemical evaluation of Tramadol HCl formed film from F1 to F9

Formulation	Film Appearance	Outward stickiness	Thickness (mm)	Folding Endurance	Tensile Strength (kg/cm^2)	Mucoadhesive flexibility of film*	Water washability*
F1	Uniform, Shiny and transparent	Non Sticky	0.15 ±0.02	45± 2	2.16 ± 0.03	+	+++
F2	Uniform, Shiny and transparent	Non Sticky	0.16 ±0.01	52± 2	2.35 ± 0.03	+	+++
F3	Uniform, Shiny and transparent	Less Sticky	0.18 ±0.02	58± 2	2.84 ± 0.03	++	++
F4	Uniform, shiny and translucent	Less Sticky	0.16 ±0.04	53± 2	2.50 ± 0.03	+	+++
F5	Uniform shiny and translucent	Less Sticky	0.17 ±0.02	60 ± 2	3.25 ± 0.03	++	++
F6	Uniform, shiny and translucent	Medium Sticky	0.19 ±0.01	66 ± 2	3.76 ± 0.03	+++	++
F7	Non Uniform, Dull and opaque	Medium Sticky	0.18 ±0.02	62 ± 2	2.91 ± 0.03	++	++
F8	Non Uniform, Dull and opaque	Medium Sticky	0.19 ±0.01	68 ± 2	3.54 ± 0.03	+++	+
F9	Non Uniform, Dull and opaque	Highly Sticky	0.21 ±0.02	73 ± 2	3.95 ± 0.03	+++	+

Here + = Poor, ++ = Moderate, +++ = Good

Table 4: % Cumulative drug release for formulation F1 to F9

	% Drug Release								
Time	F 1	F 2	F 3	F 4	F 5	F 6	F 7	F 8	F 9
0	0	0	0	0	0	0	0	0	0
0.5	22.01± 0.11	19.34± 1.2	18.25±2.1	16.59± 2.2	10.58± 0.8	17.66± 0.9	15.14± 0.9	13.10± 1.1	11.96± 1.2
1	27.24± 0.5	25.52± 1.2	21.66±1.1	20.2± 1.3	13.22± 0.2	21.73± 1.1	20.65± 2	17.41± 3	14.10± 1
2	38.36± 1.1	34.40± 2	29.14±3	28.04± 2.5	23.53± 1.5	24.25± 1.6	27.18± 1.7	25.86± 1.8	20.72± 1.8
3	46.59± 1.2	42± 1.3	37.93±1.4	38.32± 1.5	32.45± 1.6	30.66± 1.7	36.26± 1.65	32.82± 1.25	25.17± 1.35
4	55± 2.1	53.29± 2.5	46.73±2.6	47.94± 2.8	41.73± 3.1	36.29± 1.8	45.11± 1.9	38.49± 2.1	31.34± 3.2
5	62.93± 2.2	57.89± 2.11	52.36±3.12	55.73± 3.18	50.93± 2.19	41.62± 2.65	54.22± 2.78	43.69± 2.28	36.63± 3.28
6	68.25± 2.3	63.12± 2.65	59.01±2.98	61.10± 2.58	58.11± 2.39	47.23± 2.49	60.59± 2.95	49.48± 2.93	41.68± 3.35
7	71.69± 3.1	69.35± 4.29	66.18±5.21	68.17± 4.19	65.31± 1.39	55.48± 3.29	66.77± 4.23	56.35± 3.31	47.88± 2.35
8	78.13± 2.8	74.47± 3.18	73.89±2.81	74.19± 2.98	71.4± 3.18	61.62± 1.98	71.17± 3.09	61.27± 3.18	53.67± 1.98
9	83.68± 2.9	80.95± 4.35	78.27±3.75	77.00± 4.38	73.61± 3.35	67.03± 3.38	76.35± 2.95	65.15± 3.45	59.57± 3.98
10	88.05± 3.2	83.62± 4.2	79.25±5.2	81.59± 5.12	76.83± 6.22	72.24± 5.62	78.82± 3.62	69.09± 3.91	64.15± 3.19

Film prepared was examined visually for appearance, clarity and transparency after drying.

Outward Stickiness

The stickiness was determined by lightly placing a cotton-piece onto the dried film without putting any pressure on it.[15] The quantity of cotton fibers retained on the film's surface was used to gauge the degree of stickiness. For highly sticky, medium sticky and less sticky cotton retained adherence was noted down. If there is no adherence it is considered as non-sticky.

Thickness

The film formed after applying and drying of solution was peeled off and a micrometer was used to measure its thickness.[14]

Folding Endurance

This demonstrates how brittle the film is. A strip of the formed film (approximately 2×2 cm2) was folded

repeatedly at the same spot until it broke out in order to measure the folding endurance of the film. The folding endurance value is determined by the number of times the film could be folded in the same position without becoming broken.[16]

Tensile Strength

Tensile strength was measured using universal tensile test-apparatus (International Equipments, Mumbai, India) by using formula. [10]

$$Tensile\ Strength = \frac{Load\ at\ Break}{(Original\ Width)\ (Original\ Thickness)}$$

Muco-adhesive Flexibility and Water Washability of Film

In order to evaluate the film's dermal adhesion, the volunteer's palm was rotated for approximately ten minutes in an anticlockwise direction, with sporadic palm opening and closing, following eight minutes of film forming solution application. The film's nature was closely examined for any fractures, removals, or separations during the 600-minute study. Water washability of the film was also examined after 600 minutes.[6]

In vitro Diffusion Study

The Tramadol film-forming solutions were subjected to in-vitro drug diffusion studies using a Franz diffusion cell and cellulose membrane. A phosphate buffer solution (PBS) pH 6.8 was taken to soak the cellulose membrane for the entire night in order to pre-activate it. The cell's donor and receptor compartments were separated by the membrane. To guarantee that the whole membrane surface stayed in contact with the buffer, the FFSS was put in donor compartment and PBS was put in the receptor compartment. At predetermined intervals (0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 hours), samples were taken from the receptor compartment, and each time, the volume was maintained by addition of PBS and diffusion was determined at 240 wavelength in UV.[10]

Scanning Electron Microscopy (SEM)

A scanning electron microscope was employed to ascertain the films' microstructure. Film samples spent two weeks enclosed in an airtight desiccator filled with silica gel and SEM analysis was done.[10]

In vivo Analgesic Activity

The anmals were approved as per Institute animal ethical committee. The animals used in the experiment were kept in separate cages and regularly provided with food and water. Each of the three groups consisted of six male albino rats. The best Tramadol Hcl medicated FFS formulation (F5) was given to the test group, blank (non-medicated) FFS was given to the control group, and the commercially available standard formulation was given to the third group. 0.6%v/v aceticacid solution 10ml/kg was given ip and writhes were counted for 20 mts and % activity was reported.[17]

RESULTS AND DISCUSSION

Evaluation of Film Forming Solution

pH, viscocity, drug content and film formation time were reported and the results are shown in Table 2.

Appearance

Based on the visual observations all formulations were found to be clear. The observations for F1 to F9 formulations are to be shown in Table 2.

pH Value

For topical formulations, the pH value is an important parameter because a pH value that deviates from the normal range of 4 to 6 can irritate the skin. All of the formulations had pH values between 4.45 and 5.71, which is thought to be appropriate for reducing the risk of irritation when applied topically. The pH values of every formulation were within a reasonable range. Table 2 displays the recorded pH values for formulations F1 through F9.

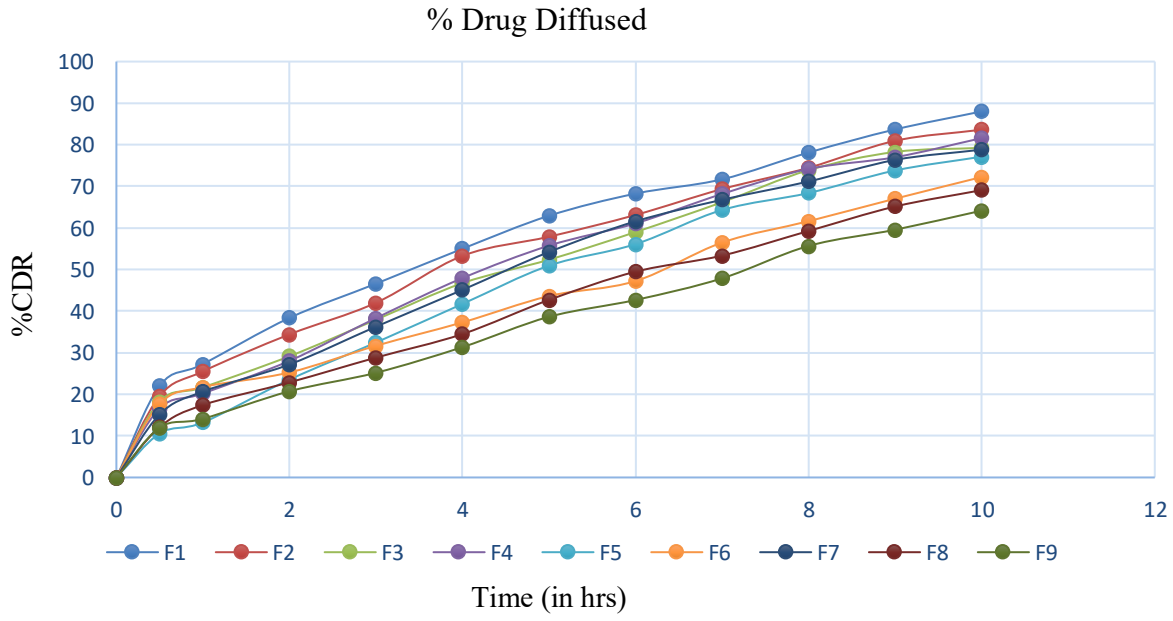

Figure 1: Graphical representation of % cumulative drug release for formulation F1 to F9

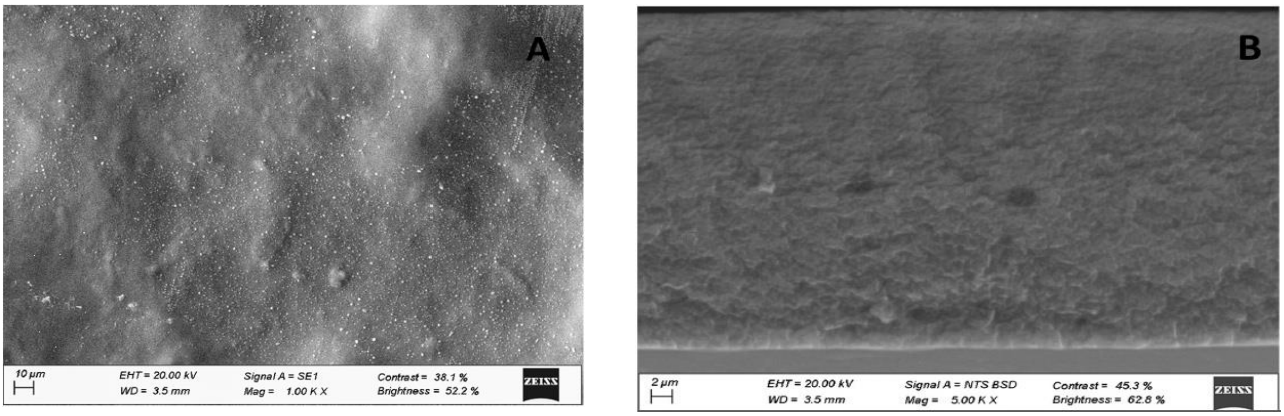

Figure 2: SEM photographs of Selected Eudragit-HPMC dried film: A: Morphology of Surface, B: Morphology of transversal section

Table 5: Evaluation of Analgesic activity of F5: FFS formulation

Treatments	Analgesic activity	
	No. of writhes[a]	Analgesia %
Control (Blank FFS)	74 ± 4	–
Standard formulation	31 ± 2[b]	58.10
Test formulation (F5 - TMD-FFS)	28 ± 1[b]	62.16

Note; a is X ± SEM, *n* is 6, b is $p < 0.05$ vs. control

Viscosity

When creating polymeric films, viscosity is one of the most important rheological factors to take into account. The topical FFS's physical properties, application, use, and in-vivo performance are all impacted by its viscosity. For in situ topical FFS, a desired and favored flow characteristic is medium viscosity. Table 2 displays the observed viscosity values for formulations F1 through F9.

Drug Content

A content uniformity test was conducted to ensure that the drug was distributed uniformly throughout the films. According to Table 2, the drug content for every formulation falls between 96.34% and 98.25%. This suggests that the drug was distributed uniformly throughout the formed film..

Drying Time

The formulations were found to dry between 2 minutes 15 seconds and 8 minutes 50 seconds. The drying time increases in tandem with the polymer's concentration. For topical application, the optimized formulation F5 demonstrated promising results. Results were given in table 2.

Evaluation of the TMD-FFS Film

The test for Outward stickiness, Thickness, Folding Endurance, Tensile Strength, Mucoadhesive flexibility and Water washability of filmwas done and shown in table 3.

Film Appearance

Appearance of dry film was noted by organoleotic studies and the results were given in table 3.

Outward Stickiness

The outward stickiness was shown in table 3. Batch F1 & F2 shows no stickiness while formulation batch F3-F5 shows low stickiness, F6-F8 shows medium stickiness and F9 shows High stickiness. Outward stickiness of all the formed films is to be shown in Table 3.

Thickness

Thickness was found in range of 0.16 ±0.01 mm to 0.21 ±0.02 mm .

Tensile Strength and Folding Endurance

The maximum stress a material can withstand before it breaks. Tensile testing is the most common way to test the mechanical properties of films. Folding endurance of all films varied from 45±2 to 73±2.

Mucoadhesive flexibility and Water Washability of Film

F1, F2, and F4 were found with poor dermal adhesion flexibility of film, easy water washability, low viscosity and filmformation in less time due to lower HPMC and Eudragit concentration. In contrast, F6, F8, and F9 had higher concentrations of HPMC and Eudragit, as well as a more mucoadhesive film that was challenging to remove with water. Batches F3, F5, and F7 demonstrated water washability and moderate mucoadhesive properties. Table 3 lists the outcomes of the water washability and mucoadhesive flexibility tests.

In -Vitro Diffusion Study

All of the prepared formulations of film-forming solutions underwent in vitro diffusion studies for ten hours. The Tramadol diffusion study data obtained for F1 to F9 formulations were tabulated in Table 4. Figure 1 is the graphical representations of % cumulative drug release for the formulation F1 to F9. The total amount of Tramadol Hcl released from batches F1 to F9 were varied from 88.05 % to 64.15%. While selected formulation F5 Here as the level of concentration of Eudragit RS100 and HPMC E5 is increased Tramadol diffusion was found to be reduced.

On the basis of physiochemical characterization formulation F5 was found to be best. As per results obtained F5 have a Medium viscosity and suitable drying time. Its dried film was observed with low outward stickiness and moderate mucoadhesive flexibility and water washability. It showed 76.83±6.22% of sustain drug release after a period of 10 hrs. The formulation with good physicochemical properties, "F5", was therefore chosen for SEM analysis and analgesic research based on the physicochemical evaluations.

SEM Analysis

For morphological analysis of its surface and transversal section, scanning electron microscopy was used to view the chosen FFS optimal formulation (F5, dried film). The produced showed smooth surface and free from cracks. Fogure 2, a and B showed the SEM images.

In vivo Analgesic Activity

When formulation F5's in-vivo analgesic activity was analyzed, it demonstrated superior analgesia (62.16%) compared to the standard, which demonstrated 58.10% analgesia shown in Table 5.

CONCLUSION

Prepared formulations were screened by physicochemical characterization. Based on the results, formulation F5 was identified as the most effective. It produced a transparent, homogeneous solution that formed a clear, flexible, and easily washable film after application. It also showed superior analgesic effects compared to existing commercial products. The topical Tramadol film-forming solution offers several advantages over current dosage forms, including ease of use, strong adhesion, prolonged retention, controlled release, and effectiveness. Nevertheless, further research and clinical studies need to establish the formulation to prove its better efficacy in the treatment of pain.

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