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Formulation and Evaluation of Medicated Lipstick using Pioglitazone

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ABSTRACT:Pioglitazone is an anti-diabetic medication that takes effect immediately after being taken orally. It was necessary to create a formulation that could function all day and provide sustained release, as well as be taken anyplace without the use of a medium such as water.The medicated lipstick was created with (04 percent w/w) pioglitazone. Preformulation investigations, such as drug characterisation and stability testing, were carried out.Lipstick was evaluated for melting point, Softening point, breaking point, pH, solubility and Percent drug content. Melting point, softening point, breaking point, pH, solubility and percent drug content were found as 64-68ºC, 50-57ºC, 80-110g, 6.6-7.0, methanol, 97-102% respectively.In the future, it will be necessary to conduct a permeation research across the mucosal membrane in order to determine if a medication can be released over an extended period of time.

KEYWORDS: Pioglitazone, medicated lipstick, anti-diabetic.

I. INTRODUCTION

Pioglitazone an antidiabetic drug was used for formulation of medicated lipstick [1, 2]. Lips are supplied with the Blood supply, Nerve supply, Lymphatic Drainage, Muscle supply.Lips are the visible external component of a human or animal's mouth. Lips are flexible and soft, and they provide the aperture of the mouth cavity for food absorption and speech production[3-5].. The dose form is easily administered and removed from the application location. It allows you to halt the supply of medicine by simply releasing the dosage type from your lip skin. Objective of research is formulation and evaluation of translabial drug delivery system of pioglitazone [6].

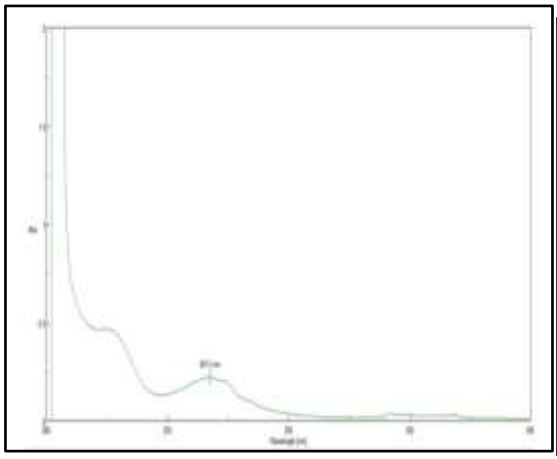

Figure1.Absorbance Maxima of Pioglitazone

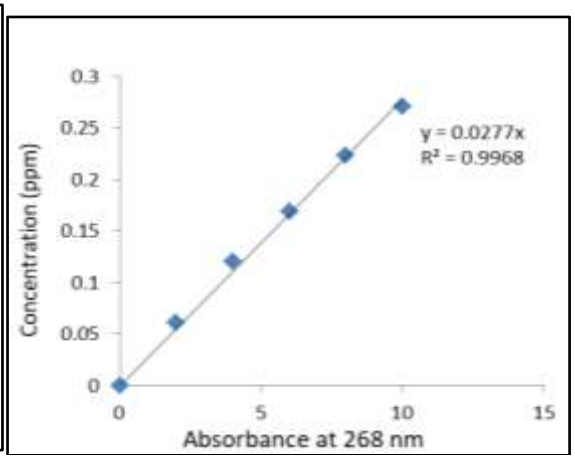

Figure 2. Calibration Curve for Linearity

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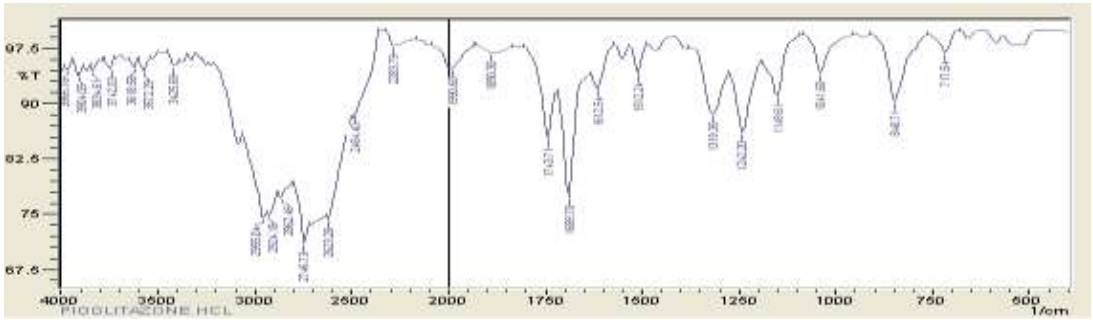

Figure 3. IR spectrum of Pioglitazone

II. MATERIALS AND EQUIPMENTS

Pioglitazone, Carnauba wax, Beeswax, Castor oil, Cetyl alcohol, Lanoline, K-35 M polymer and K-15 polymer were purchased from chemical supplier.Analyticalbalance(ModelAUY220 Shimadzu,japan), pH meter(GMPH, Labindia), UV spectrophotometer (UV1800 Shimadzu, Japan), FT-IR (FTIR 8400S Shimadzu,japan) and Differential Scanning Colorimeter (SW930,MettlerToledo) were used.

Table 1. Comparison of Organoleptic Properties of Pioglitazone HCL with the Reported Standards

Identification Test	Observation	Standard as per IP	Inference
Appearance	Almost White powder	A white or almost white powder	Complies as per IP
Colour	white	A white or almost white powder	Complies as per IP
Odour	Odourless	Odourless	Complies as per IP

Table 2 UV absorbances of Pioglitazone at 268nm

Sr. No.	Concentration (ppm)	Absorbance of 268 nm
1.	0	0
2.	2	0.0608323
3.	4	0.120019
4.	6	0.1685
5.	8	0.222906
6.	10	0.270574

Table 3 IR spectrum of Pioglitazone

Sr. No.	Reference peak(cm^{-1})	Observed Peak(cm^{-1})	Functional group
1	3500-3100	3425	Amine N-H Stretch
2	3500-3100	2955	O-H Stretch Phenol
3	1250-1392	1319	C-N Stretch
4	1600-1700	1689	C=O Stretch
5	600-700	717	C-S Stretch
6	1000-1300	1242	C-O Stretch

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III. EXPERIMENTATION

Characterization of Pioglitazone:

Organolepticproperties

The received sample of Pioglitazone was examined for its appearance, colour and odour and compared with standard values.

Melting Point

Melting point apparatus was used to determine the melting point (PMP-D, Veego). The melting point was determined by injecting a little amount of substance into a capillary attached to a calibrated thermometer, and the assembly suspended in the paraffin bath was given steady heat. The temperature at which the medication melted was measured.

Absorbance Maxima

Solution of Pioglitazone was prepared in methanol. Absorbance maxima were determined by analyzing this solution using UV-Visible Spectrophotometer in the range of 200-400nm.

Calibration Curve

Stock solution of Pioglitazone was prepared in methanol. From stock solution different diluted solution in concentration range of 0-10µg/ml were prepared. The absorbance of each solution was measured at λmax 268nm using diluent as a blank and standard curve was plotted between concentration (µg/ml) on X-axis and absorbance on Y-axis.

FTIR of Pioglitazone

The FT-IR spectrum of Pioglitazone HCL was obtained at 4000cm^{-1} resolution at potassium bromide (KBr) powder for authentication and to examine the main peaks using an FT-IR spectrophotometer (FT-IR 8400S, Shimadzu). The discovered peak was compared to the stated IR spectrum's principle peaks, and the sample was verified.

Formulation Method:

Pioglitazone (0.4%w/w) is mixed with the polymer (mixture A). Base was prepared by heating all ingredients of base together and was maintained at 40-45˚C and mixture A was added with continuous stirring. These was transferred to lipstick mold and solidified to form lipstick and stored in suitable container.

Evaluation of lipstick:

1. **Melting point**:

It determination is essential since it indicates the safe storage limit. The melting point of formed lipstick was evaluated using the capillary tube method. The capillary was filled and kept in the capillary apparatus, and the product was first observed to be gently milted. The product was entirely melted after being observed on occasion. The melting point ratio was recorded in all formulations after the aforesaid method was repeated three times.

2. **BREAKING POINT:**

The breaking point test was used to measure the lipstick's strength. The lipstick was placed horizontally in a socket an inch from the support's edge. The weight was gradually increased by a set value (10 gm) every 30 seconds, with the weight at which it broke being regarded the breaking point.

3. **SOFTENING POINT:**

The softening point is the temperature at which a material softens beyond some arbitrary softness. This test is conducted to check the stability of lipstick at high temperature. As per the national standard requirement, the minimum softening point of lipstick should be 55 ℃.

4. **Percent assay for drug content:**

The formulation equivalent to 1g was mixed in methanol and shaked for 15 min similarly blank was prepared using drug free lipstick. Absorbance was taken at λmax of pioglitazone and percent drug content was determined.

IV. OBESERVATIONAL RESULT

Characterization of Pioglitazone:

Organoleptic Properties

Comparison of Organoleptic Properties of Pioglitazone with the Reported Standards is given in Table No.1

Melting point

The melting point was found to be at 183°C which is similar to melting point mention in IP which was 183-184˚C this study indicates purity of the sample and the sample provided in Pioglitazone HCL and for further conformation more test is carried out.

Absorbance Maxima

The UV spectrum of Pioglitazone HCL was obtained in Methanolwhich shows absorbance maximum (λ max) at 268 nm. Figure 1 represents absorption maxima.

Calibration Curve

Linearity was taken for concentration 0-10ppm. Figure 2 represents calibration curve for linearity with correlation coefficient R^2=0.9968 and equation of line as y=0.0277x.UV absorbance of Pioglitazone at 268nm is given in Table 2.

FTIR of Pioglitazone

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The Fourier transform infrared spectroscopy (FTIR) spectrum of Pioglitazone HCL was studied. Figure 3 represents IR spectrum of Pioglitazone with detailed explanation regarding functional group given in Table 3.

Table 4 Evaluation of Lipstick for melting point, pH, softening point, breaking point and Percent drug content

Sr. No.	melting point (*)	Softening point	breaking point (*)	pH	Percent Drug Content
1	68.0	55.40	55.50	6.6	102.12%
2	64.0	52.00	81.04	6.9	97.87%
3	68.0	57.00	106.57	6.7	100.70%
Mean	66.66	54.66	80.66	6.733	100.23%

Results for evaluation of lipstick:

The formulated medicated lipstick was evaluated for melting point, Softening point, breaking point pH and Percent drug content. The mean melting point was found to be 66.66 ^{0}C. The mean softening point was found to be 54.66^{0}C.The mean breaking point was found to be 80.66 g.The average pH of lipstick was found to be 6.733.The mean percent of pioglitazone was found to be 100.23%.Evaluation of Lipstick for melting point, pH, softening point, breaking point and Percent drug content are given in Table 4.

CONCLUSION

TLDDS offers an excellent route for systemic delivery of drugs, for drugs that undergo high first-pass metabolism, thereby offering greater bioavailability or increased therapeutic efficiency, more uniform plasma level and longer duration of the action of drugs. As a drug-delivery system it permits localized, systemic and site-specific action of drugs to the oral cavity for a longer period of time [7]. The delivery system offers direct access to target a disease or various lip diseases or disorder. Medicated lip formulations offer feasible and attractive benefits for systemic drug delivery and offer an interesting area of research for pharmaceutical scientists to design Medistick with diverse effects. As the drug delivered via Translabial route can bypass hepatic first-pass metabolism, in the future medicated lipsticks may be used in the treatment of epilepsy, Parkinson's disease, Alzheimer's disease and angina. Albeit, to date no commercial formulation is available on the market for the systemic delivery of drugs in these diseases using labial skin as a delivery platform. However, it is a promising platform for the systemic delivery of drugs and intensive research exploring a Nanoformulation approach may be the future of Tranlabial drug-delivery systems.

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