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RESEARCH ARTICLE

# Evaluation of *Cordia Dichotoma* gum as A Potent Excipient for the Formulation of Film

Vaibhav Mangalrao Darvhekar*, A. V. Chandewar Chandewar

*Department of Pharmacognosy, P. Wadhwani College of Pharmacy, Yavatmal, Maharashtra, India*

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## ABSTRACT

Films were prepared (viz. CDF1, CDF2, CDF3, CDF4, CDF5) using five parts of 10% w/w of mucilage of gum of *Cordia dichotoma* with different proportions of plasticizers methyl paraben and glycerine. The films were casted on mercury plate. Films prepared with different proportion of gum and 0.2 % w/v methyl paraben, 2.5% w/v of glycerine showed satisfactory drying after 24 h. They were evaluated for qualitative phytochemical analysis followed by mechanical properties like water uptake, tensile strength, folding endurance, and water vapor transmission rate and stability studies also done for plane film. Further, the gum was evaluated for release parameter with model drug diclofenac sodium (0.5% w/w) with same composition of methyl paraben and glycerine. The study found that the CDF3 film shows the best result among other batches of *C. dichotoma.*

**Keywords:** *Cordia dichotoma*, diclofenac sodium, film, natural gum, sustained release drug delivery systems

## INTRODUCTION

Polymers are widely used in medicinal products, from complex formulations to biopharmaceuticals in prescription drug delivery systems. Pharmaceutical coating materials are characterized by mechanical properties,[1,2] permeability,[3,4] and water vapor transport.[5] The coating process and nature of the dosage form did not affect the properties of the free film.[6] Item natural polymers are of interest to their use in drug delivery due to their presence, compatibility, and degradation in natural and physiological conditions (Item).[7] It is widely used in natural resins, varnishes, sealants, bonding medium, waterproofing, and so on. Uses of natural products such as rosin (pinaceae), dammar resin, sandalwood resin, frankincense, and guaiac resin were evaluated.

This paper deals with the evaluation of a natural gum for its use in preparing films for application as drug delivery systems and coating agents. There are several reports about the successful use of natural gums in various pharmaceutical preparations. The gum in the present study is an extract from the berries of *Cordia dichotoma* (Lasuda).

## MATERIALS AND METHODS

Ripe cordia fruits were collected from local habitat and got authenticate by botanist from agricultural college. Methyl paraben, glycerine, and other solvents were purchased from S.D. Fine Chemicals.

### Extraction of Gums from the Fruits of *C. dichotoma*

The gum was isolated from *C. dichotoma* fruit using solvent precipitation method.[8] Ripe fruits of *C. dichotoma* were extracted with water (1:2) by stirring for 3 h. The viscous solution obtained was filtered through Muslin cloth. Ethanol (95%) was added with continuous stirring to the viscous

***Corresponding Author:**
Vaibhav Mangalrao Darvhekar,
E-mail: vaibhav1109@gmail.com

solution obtained in the ratio 1:1 to precipitate out gum present in the fruit.[9] The precipitated gum was transferred to an evaporating dish and treated consecutively with ethanol (95%) to make it free from impurities. The gum obtained was dried in oven at temperature 40–45°C.[10] The dried gum was then size reduced by passing through 60 # sieve and stored in airtight container.

## Qualitative Phytochemical Analysis

The isolated gum was subjected to various phytochemical tests[11-14] as Test for Alkaloids as Dragendorff's test, Mayer's test, Hager's test, Wagner's test, Test for carbohydrates *Molisch test,* Fehlings test (detection of reducing sugars), Test for proteins and amino acids as Biuret's tests, Million's test, Ninhydrin test, Xanthoprotein test, Tests for Steroids such as Salkowski Reaction, Liebermann-Burchard Reaction, Libermann's reaction, Test for Tannins and Phenolic compounds *Test for flavanoids as Ammonia test, Shinoda's/ Paw test*, *Test for saponins Foam test, Libermann-Burchard test*, Test for Gums and Mucilages, and Test for sterols and or triterpenes.

The extracts were refluxed with alcoholic potassium hydroxide until the saponification was complete. The saponification mixture was diluted with distilled water and extracted with diethyl ether. The ethereal extract was evaporated and the unsaponifiable matter was subjected to following tests *Libermann-Burchard test,* Salkowski's reaction, Hesses reaction, Hersch's Sohn's reaction, Test for Glycosides *Borntrager's test, Keller-Killiani test, and* Legal test.[15-17]

## Physical Parameters of Extracted Gums

### *Organoleptic evaluation*

The isolated mucilage was subjected for various organoleptic evaluations which included evaluation of color, odor, shape, taste, and special features such as touch and texture.[18-20] The majority of information on the identification, purity, and quality of the material can be drawn from these observations.

### Bulk density

Loose Bulk Density (LBD) and Tapped Bulk Density (TBD) were determined. A quantity of 2 g of powder from each formula, previously lightly shaken to break any agglomerates formed, was introduced into a 10 ml measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 s intervals. The tapping was continued until no further change in volume was noted. LBD and TBD were calculated using the following formula.[21,22]

LBD = Weight of the powder/Volume of the packing

TBD = Weight of the powder/Tapped volume of the packing

### Compressibility Index

The compressibility of the granules was determined by Carr's Compressibility Index.

Carr's compressibility index (%) = ([TBD-LBD] × 100)/TBD

Or it can be expressed as Carr's Index relates the poured density of the material to the tapped density and was calculated using the following relationship: [21,22]

$$Carr's\ Index = \frac{Tapped\ density - Poured\ density}{Tapped\ density} \times 100$$

### Hausner's ratio

It is the ratio of tapped density to bulk density.[22]

$$Hausner's\ ratio = \frac{Tapped\ density}{bulk\ density}$$

### Angle of Repose (θ)

This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane.

The powders were allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.[21,22]

$$\text{Tan}\theta = h/r$$
$$\theta = \tan\text{-}1\ (h/r)$$

Where, θ = angle of repose
h = height of the heap
r = radius of the heap
The lower the angle of repose, the better the flow properties, when granules are placed in the hopper and allowed to slide down into the die for compression. It forms a pile. The angle of repose may be calculated by measuring the height (h) of the pile and the radius of the base (r) with ruler. The angle of repose shows in between 30 and 40°C which is considered as passable flow of granules.

**Loss on Drying (LOD)**

10 g of extracted gums was heated in a hot air oven (GallenKamp, England) at 105°C. LOD was the difference between the initial weight and the final weight of the sample expressed as a percentage.[23,24]

$$\%\text{LOD} = \text{initial weight-final weight/initial weight} \times 100$$

**Solubility Test**

A 1.0 g of powdered gum was weighed and suspended in the respective solvents and was agitated for 24 h over a magnetic plate. A 1.0 mL from the supernatant was filtered and dried at 50°C. The gain in weight of previously tarred porcelain was taken as the amount of solute in the filtrate and this was used to calculate the solubility of the substance in 100 ml of the solvent.[25,26]

**pH**

The pH of 1% suspension was determined using digital pH meter 3310 (Genway) at 25°C.[27]

**Viscosity**

Rheological studies of dried mucilage were carried out using concentration (1% w/v) prepared in distilled water. The viscosities were measured using an Oswald's viscometer.[28]

**Swelling Index (SI)**

SI of mucilage was determined by accurately weighed 1 g of mucilage powder and was transferred into a 25 mL glass Stoppard measuring cylinder. The initial bulk volume was noted. Then, 25 mL of water was added and mixture was shaken thoroughly every 10 min for 1 h. It was then allowed to stand for 3 h at room temperature. Then, the volume occupied by mucilage was measured. The same procedure was repeated thrice and the mean value was calculated. SI is expressed as a percentage and calculated according to the following equation.[29]

$$\text{Swelling index (SI)} = V_2\text{-}V_1 V_1 \times 100$$

Where: V1 is initial volume of powder before hydration.
$V_2$ is volume of swollen powder after (3 h) hydration.

**Ash Values**

Ash values such as total ash, acid insoluble ash, and water soluble ash were determined according to Indian Pharmacopoeia. The following procedures were used for the determination of ash values.[30]

***Total ash***

About 3 g of sample was accurately weighed and taken in a silica crucible, which was previously ignited and weighed. The powder was spread as a fine, even layer on the bottom of the crucible. The crucible was incinerated gradually by increasing temperature to make it dull red hot until free from carbon. The crucible was cooled and weighed. The procedure was repeated to get constant weight. The percentage of total ash was calculated with reference to air dried sample.[31]

***Acid insoluble ash***

The ash obtained as described above was boiled with 25 mL of 2N HCL for 5 min. The insoluble ash was collected on an ash less filter paper and washed with hot water. The insoluble ash was transferred into a silica crucible, ignited, and weighed. The procedure was repeated to get a

constant weight. The percentage of acid-insoluble ash was calculated with reference to the air-dried sample.[32]

## Fourier Transform-infra Red (FTIR) Analysis

Pure drug sample, extracted mucilage, and the physical mixture of drug with excipient in the ratio 1:1 were subjected to IR spectral studies using FTIR spectrophotometer.[33] A physical mixture of drug and isolated mucilage was mixed with desirable quantity of potassium bromide. 100 mg of this mixture was compressed to form a transparent pellet using hydraulic press at 15 tons pressure. It was scanned from 4000 to 400$^{cm-1}$ in a FTIR-8400 Shimadzu, JAPAN.[34] The individual spectra of the drug and mucilage were performed.

## Film Casting Evaluations for the Extracted Gum

The films were prepared on the mercury substrate by solvent casting method[35] with extracted *C. dichotoma* gum. The plasticizer, glycerine, was added to 5 mL of distilled water and kept for stirring on a magnetic stirrer. To this solution, the weighed quantity of polymer was added and stirred till it gets dissolved completely. Then the weighed quantity of excipients like the methyl paraben was then added to the solution. In case of air entrapment, the air bubbles were removed by sonication (Oscar sonicator). The homogenous solution was then casted on a petri plate and dried at 40°C in hot air oven for 20 h.[35]

## Evaluation of Mechanical Properties of Film

### *Thickness of the film*

The thickness of films was measured with the help of micrometer screw gauge at different strategic locations like four corners and center of the each film. Mean SD is calculated. The standard range for film thickness should not be <5%. This is essential to assure uniformity in the thickness of the film.[35,36]

### *Folding endurance*

It is measured manually for the prepared film. A film was repeatedly folded at 180° at the same place till it breaks. This test was performed on three films of each formulation and mean ± SD was calculated.[35,36]

### *Tensile strength*

Tensile strength is the maximum stress applied to a point at which the film specimen breaks. Tensile strength of the optimized batch formulation was evaluated by a digital tensile strength tester. The test was carried out in triplicates and the average value was noted.[35,36]

### *Water uptake*

The water uptake was determined by drying the films at 60°C with a current of air, after which the films were subjected to desiccation over calcium chloride at 40°C for 24 h. These samples were weighed and exposed to 70% relative humidity at room temperature. This relative humidity was achieved using saturated solutions of sodium chloride. After equilibration under this humidity, films were weighed for determining the increase in weight; and percent water uptake was calculated.[35,36]

### *Determination of piercing load*

The apparatus used for hardness determination was employed with a slight modification. The test was carried out by placing the film between two metal dies with an aperture diameter of 2 mm in both dies. While the two dies hold the film in position, the increments of weights were added on to the wooden plate. The needle moves down across the film as and when the piercing load value is exceeded. The procedure was carried out on 5 films selected at random and the mean values for piercing load were recorded.[34]

### *Surface pH*

Film was soaked in 2 mL of distilled water for 15 min. Surface pH of films was determined using pH paper.[34]

***Scanning electron microscopic (SEM)***

The SEM is used to identify the particle size and the surface morphology of the prepared films. The film is placed on the covered glass slide and then dried by applying vacuum, later it was coated with gold to a thickness of 100A using VEGAS TESCAN Vacuum evaporator and the image was captured for the prepared film. The surface topography of the prepared film was observed by optical microscopy using a calibrated eyepiece micrometer, and photographs were taken at ×400 magnification with a digital camera (Olympus, 8.1 megapixel, Japan).[37]

***Stability studies of films***

Stability test was conducted for 30 days at different temperatures: 4, 45, and 60°C. At specific intervals of time (Day 5, 10, 15, 20, 25, and 30), films were taken out to assay their drug content, appearance, and texture.[37,38]

## Evaluation of Mechanical Properties of Drug-loaded Films Containing Extracted Gum

The drug-loaded films were evaluated as same for plane film of gum.

## Study of *in vitro* Drug Release Kinetics

The *in vitro* diffusion data studies were analyzed for establishing kinetics of drug diffusion. The model fitting was done using an in-house program developed by Zero order (cumulative % drug release vs. time), First order (log cumulative % drug remaining vs. time), Higuchi (cumulative % drug release vs. square root of time), and Peppas (log cumulative % drug release vs. log time), were tested. Three different films formulations of three different herbal gum films were processed for the prediction of release profiles. Diclofenac sodium was used as the model drug. All above-mentioned formulations were subjected for the mathematical modeling for the prediction of the release profiles. The relevant data on the film formation as well as diffusion of the active agents from the films have been fitted into various equations for the mathematical modeling. This modeling gives an overall idea on the drug release kinetics and possible mechanism of drug release characteristics. The drug release profile obtained from the *In vitro* release from various formulations was mathematically treated with various models to predict how a delivery system might function and gives valuable insight into its *in vivo* behavior. All the formulations were subjected to *in vitro* release studies. The results obtained of *in vitro* release studies were attempted to fit into various mathematical models available in the software to fit the release studies. In this software, various models such as Zero order kinetics (cumulative percentage amount of drug release versus time), First order kinetics (log cumulative percentage of drug remaining to release versus time), Higuchi (fraction of drug release, Mt/Mi, versus square root of time), and Peppas (log fraction of drug released, log Mt/Mi, versus log time) were applied to assess the kinetics of drug release from prepared films. Most suited model for drug release was predicted on the basis of regression coefficient, that is, nearer the value of regression coefficient toward 1, greater the suitability of best fitted release mechanism.[8,10,38]

**Table 1:** Relationship between % compressibility and flowability

| Percent compressibility | Type of flow |
|---|---|
| 5–15 | Excellent |
| 12–16 | Good |
| 18–21 | Fare-passable |
| 23–25 | Poor |
| 33–38 | Very poor |
| >40 | Extremely poor |

**Table 2:** Values of Hausner ratio and comment

| Values | Comment |
|---|---|
| <1.25 | Good flow |
| >1.5 | Poor flow |
| Between 1.25–1.5 | Added glidant normally improves |

**Table 3:** The relationship between angle of repose and powder flow

| Angle of repose | Powder flow |
|---|---|
| <25 | Excellent |
| 25–30 | Good |
| 30–40 | Passable |
| >40 | Very poor |

## RESULTS AND DISCUSSION

Various natural polymers have been investigated for their application as pharmaceutical adjuvants. Cordia gum is a biopolymer obtained from the plants and the present communication is an investigation of the physicochemical characteristics and film-forming properties of Cordia gum.

### Extraction of Gums from Plant Materials

Three selected plant gums were extracted from the fruits of *C. dichotoma* frost. The percent yields of the plant gum were calculated. The calculated percent yield of 7.50% for the extraction of *C. dichotoma* gum [Table 4]. The gum is initially white in color but changes to reddish brown to brownish-black on exposure to air and temperature as it goes to dry. It is sparingly soluble in water but swells in contact with water, giving a highly viscous solution.

### Phytochemical Evaluation of the Extracted Gum

These extracted gum *C. dichotoma* gum was characterized for various important phytochemical qualitative tests.

### Physical Parameters of Extracted Gums

The extracted plant-derived *C. dichotoma* gum was characterized for physical parameters such as color, odor, taste, pH, LOD, solubility, SI, viscosity, angle of repose, bulk and tap densities, Hausner's ratio, optical rotation, total, and acid soluble ash values. The obtained results of various physical parameters of these three selected extracted gums are presented in Table 6.

### Characterization of Extracted Gums by FTIR Spectroscopy Analysis

The spectrum of extracted *C. dichotoma* gum showed an identical broad band at 3696.54 $cm^{-1}$ due to –OH stretching vibrations, peak at 2981.08 $cm^{-1}$ due to C–H stretch, a small peak at 1567.52 $cm^{-1}$ due to -C=O stretching, peak at 1454.04 $cm^{-1}$ due to -C–H bend and small peaks at 1033.03 and 1011.52 $cm^{-1}$ due to secondary –OH stretching [Figure 1].

**Table 4:** Percent yield of gum extractions

| Plant gums | *Cordia dichotoma* Gum |
|---|---|
| Source plant parts | Fruits |
| % Yield | 7.50% |

**Table 5:** Phytochemical qualitative tests on extracted gums

| S. No | Tests | *C. dichotoma* gum |
|---|---|---|
| 1 | Tests for Alkaloids: | |
| | a. Dragendorff's test | - ve |
| | b. Mayer's | - ve |
| | c. Wagner's | - ve |
| | d. Hager's | - ve |
| 2 | Tests for Glycosides: | |
| | a. Keller - Killaine test | - ve |
| | b. Balget test | - ve |
| | c. Bromine water test | - ve |
| | d. Legal test | - ve |
| 3 | Tests for Carbohydrates: | |
| | a. Barfoed's test | + ve |
| | b. Benedict's test | + ve |
| | c. Molisch's test | + ve |
| | Tests for Starches: | |
| | a. Iodine test | - ve |
| 4 | Tests for Flavonoids: | |
| | a. Shinoda test | - ve |
| | b. Alkaline reagent tests | - ve |
| | c. Ferric chloride test | - ve |
| | d. Lead acetate solution test | - ve |
| 5 | Tests for Triterpenoids and Sterols: | |
| | a. Liebermann-Burchard test | - ve |
| | b. Salkowaski test | - ve |
| 7 | Tests for Saponins | |
| | a. Haemolysis test | - ve |
| | b. Foam test | - ve |
| 8 | Tests for Proteins: | |
| | a. Xanthoproteic test | - ve |
| | b. Ninhydrine test | - ve |
| | c. Millon's test | - ve |
| | d. Biuret test | - ve |
| 9 | Tests for tannins | |
| | a. Gelatin test | - ve |
| | b. Ferric chloride test | - ve |

## Film Casting Evaluations for the Extracted Gum

The prepared films containing extracted *C. dichotoma* gum of 5–30 % w/w were found to have dried appearances; whereas, films containing 30% w/w of *C. dichotoma* gum demonstrated a wet appearance [Table 7]. However, films containing *C. dichotoma* gum of 15–25% w/w (CDF3, CDF4, and CDF5) revealed satisfactory appearances and accepted suitable for further evaluation.

**Table 6:** Physical parameters of extracted gums

| Physical parameters | *Cordia dichotoma* gum |
|---|---|
| Color | Firstly white, with time buff to brown |
| Odor | Characteristic |
| Taste | Mucilaginous |
| pH | 6.2 |
| LOD | 9.62 |
| Melting point | 242–274°C |
| Solubility In water | Soluble |
| Solubility In organic solvent | Insoluble |
| Swelling index | NMT 5.7 |
| Viscosity | 373.6 cps |
| Angle of repose | 12° |
| Bulk density | 0.5852 g/mL |
| Tap density | 0.8753 g/mL |
| Hausner's ratio | 1.49 |
| Optical rotation (hydrolyzed solution of 1% w/v) | + 1.49 |
| Total ash value | 8.3 w/v |
| Acid soluble ash values | 1.2% w/v |

## Selection of the Optimized Films

The optimized films (drug-free) made of *C. dichotoma* gum were selected for further evaluations. The drug-free films, which showed satisfactory film appearances, were selected as optimized films and were tested fatherly CDF3 (containing extracted *C. dichotoma* gum of 15% w/w) were selected as optimized films for further evaluations.

## Evaluation of Mechanical Properties of Drug Free Films

The optimized films (drug-free) containing extracted *C. dichotoma* gum were evaluated for their mechanical properties such as weight, mean thickness, folding endurance, water uptake, tensile strength, piercing load, and surface pH.

**Table 7:** Film casting ability of *Cordia dichotoma* gum

| Ingredients | Formulations | | | | | |
|---|---|---|---|---|---|---|
| | CDF1 | CDF2 | CDF3 | CDF4 | CDF5 | CDF6 |
| *Cordia dichotoma* gum (% w/w) | 05 | 10 | 15 | 20 | 25 | 30 |
| Glycerine (%w/v) | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 |
| Methyl paraben (%w/v) | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Appearance | Dried | Dried | Satisfactory* | Satisfactory* | Satisfactory* | Wet |

Satisfactory* means films which were suitable for further evaluation

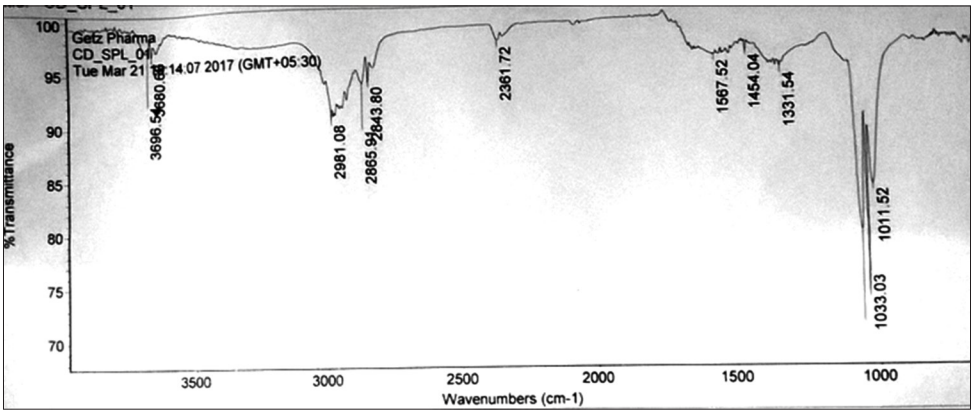


**Figure 1:** FTIR spectrum of extracted *Cordia dichotoma* gum

The weight of CDF3 film was measured as 211.14 ± 0.11 mg/cm$^2$. The mean thicknesses of these optimized film was measured as 0.412 ± 0.210 mm for CDF3. Folding endurance of CDF3 film was determined as 258 ± 0.410. The water uptake by CDF3 film was measured 7.54 ± 0.41%. The tensile strength of the film was calculated and found as 7.58 ± 0.42. The CDF3 films possessed higher tensile strength. CDF3 film was computed as 0.276 ± 0.034 kg. The surface pHs of the film CDF3 were measured and almost neutral pHs were measured as 6.90 ± 0.04. The almost neutral pH of the drug-free film containing extracted plant gum entails slighter chances of gastrointestinal irritation, when these will be applied as pharmaceutical excipients in the formulations for oral administration. The results of mechanical properties of drug-free films containing extracted gums are presented in Table 8.

## SEM Observation Study

The optimized film (drug free) containing extracted *C. dichotoma* gum was characterized morphological observation. CDF4 films are presented in Figure 2. The topographical morphology of CDF3 film containing *C. dichotoma* gum indicated smoother surface. Some polymeric derbies were seen on the film, which might be due to the migration of water during drying (Nayak *et al*., 2012). CDF3 film (containing extracted *C. dichotoma* gum) were characterized and presented in Figure 3. The cross-sectional morphology of *C. dichotoma* gum exhibited smother layer.

## Stability Studies of Drug Free Films

Stability testing was performed to reveal the stability of the optimized film (drug-free) containing extracted *C. dichotoma* gum (CDF3). The test was conducted for 30 days at different temperatures: 40, 45, and 60°C. At specific intervals of time (Day 5, 10, 15, 20, 25, and 30), appearance and texture profiles of these drug-free films were analyzed. The result of the stability study demonstrated the absence of any significant changes in the appearances and textures. Therefore, the tested drug-free film was found stable enough.

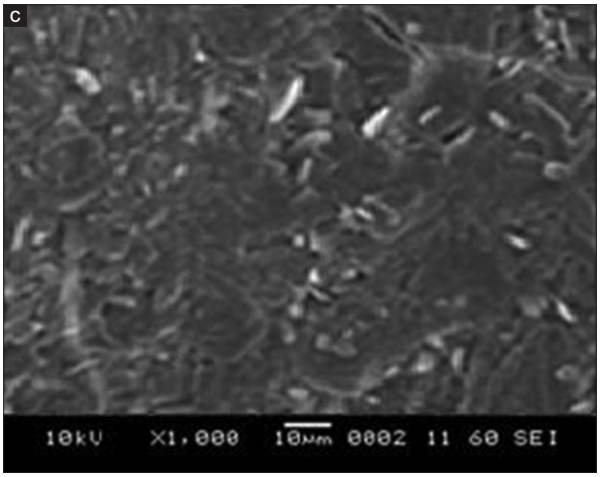


**Figure 2:** Topographical morphology CDF4 film (containing extracted *Cordia dichotoma* gum) [C] by Scanning Electron Microscope

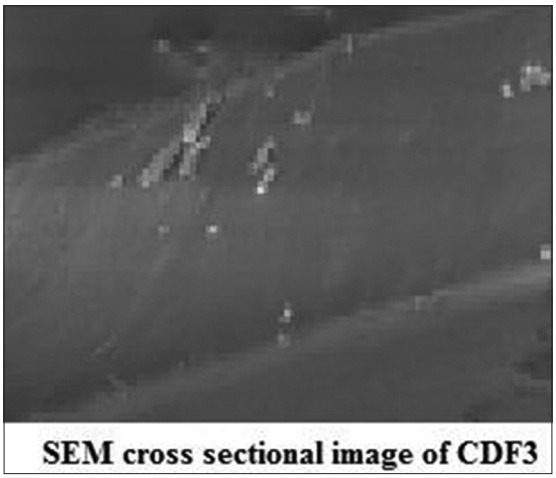


**Figure 3:** The cross-sectional morphology of CDF3 film (containing extracted *Cordia dichotoma* gum) by Scanning Electron Microscope

**Table 8:** Mechanical properties of drug free films containing extracted gums

| Films | Weight (mg/cm$^2$) | Mean thickness (mm) | Folding endurance (No. of folds) | Water uptake (%) | Tensile strength (kg/cm$^2$) | Piercing load (kg) | Surface pH |
|---|---|---|---|---|---|---|---|
| *Cordia dichotoma* gum film | | | | | | | |
| CDF3 | 211.14±0.11 | 0.412±0.210 | 258±0.410 | 7.54±0.41 | 7.58±0.42 | 0.267±0.034 | 6.90±0.04 |

Mean±SE.; *n*=3

## Identification of Model Drug for the Formulation of Solid Dosage Forms

Diclofenac sodium (a NSAID) is selected as model drug for the formulation of solid dosage forms. The physical nature, color, melting point, and solubility of diclofenac sodium were determined and assessed [Table 9]. Diclofenac sodium powder was found crystalline and of highly hygroscopic in nature. The color of it was white to slightly yellowish. The melting point of diclofenac sodium was measured as 280 ± 0.5°C. Diclofenac sodium was found soluble in ethanol and methanol. However, it was found sparingly soluble in water.

**Table 9:** Physical description of diclofenac sodium

| Parameters | Descriptions |
|---|---|
| Nature | Crystalline powder; slightly hygroscopic |
| Color | White to slightly yellowish |
| Melting point | 280±0.5ºC. |
| Solubility | Soluble in ethanol and methanol, sparingly soluble in water |

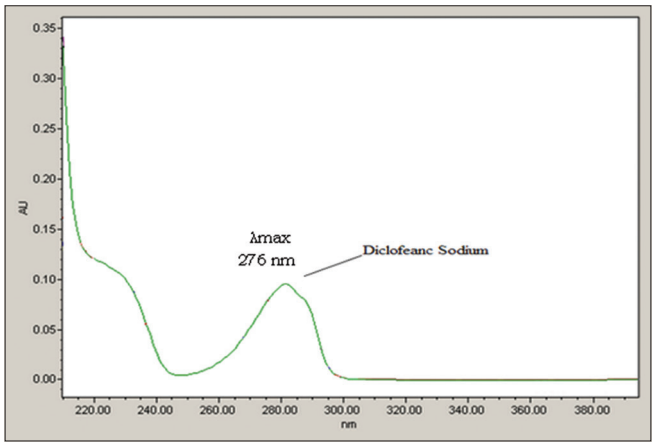


**Figure 4:** Identification of diclofenac sodium by UV absorption

Diclofenac sodium was scanned for UV absorption with phosphate buffer pH 7.4 using a UV-VIS spectrophotometer and λmax value was determined. The λmax value of diclofenac sodium in phosphate buffer pH 7.4 was found 276 nm [Figure 4].

Diclofenac sodium was also identified by FTIR spectroscopy analysis. The FTIR spectrum of diclofenac sodium is presented in Figure 5. The FTIR spectrum of diclofenac sodium showed that the principal peaks at 1221.56 and 1318.68 $cm^{-1}$ resulted from C-N stretching; whereas at 1517.56 $cm^{-1}$ and 1603.34 $cm^{-1}$ resulted from C=C stretching and C=O stretching of carboxyl group, respectively. The results of FTIR spectroscopy analyses were matched with the results of some previous studies (Nayak and Pal, 2011; Nayak *et al*., 2013; Sinha *et al*., 2015) and suggested that the tested sample can be diclofenac sodium.

## Calibration Curve of Diclofenac Sodium

Solutions of diclofenac sodium ranging from 2 to 10 µg/mL were prepared in phosphate buffer, pH 7.4. Absorbance was measured for each solution at λmax of 276 nm, using UV-VIS spectrophotometer (Shimadzu, Japan). Correlation coefficient was found to be 0.9973 in phosphate buffer, pH 7.4. The equation obtained is: Y =

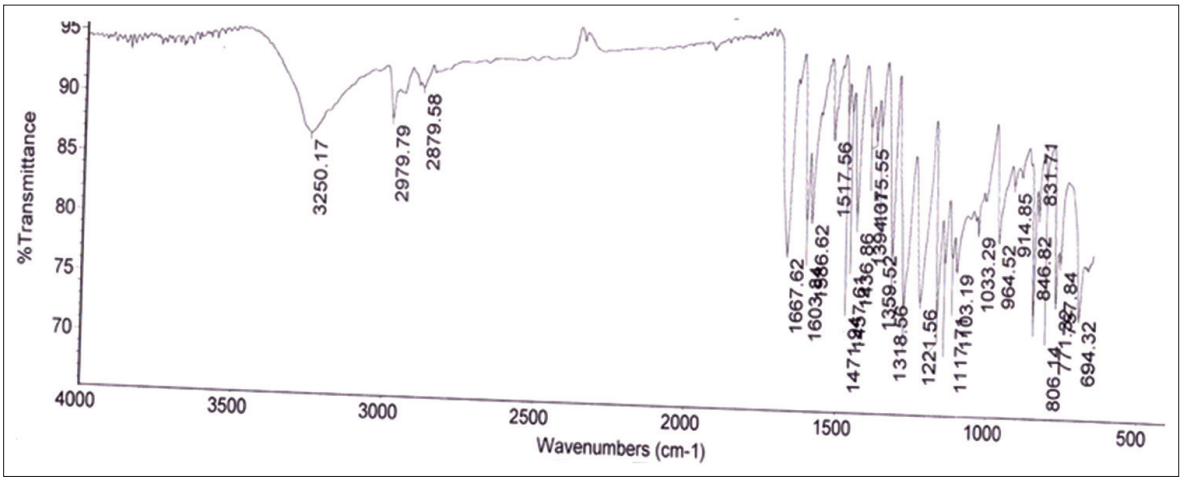


**Figure 5:** FTIR spectrum of diclofenac sodium

0.0023 + 0.0021 X**.** The Standard calibration curve of diclofenac sodium is presented in Figure 6.

## Preparation and Evaluation of Drug (Diclofenac Sodium) Loaded Films Containing Extracted Gums

### *Drug-loaded films containing extracted C. dichotoma gum*

The drug-loaded films containing extracted *C. dichotoma* gum prepared using glycerin of 0.05 and 0.10% w/v were found to have dried appearances; whereas, the drug-loaded films prepared using glycerin of 0.20 and 0.25 % w/v demonstrated a wet appearance [Table 10]. However, the drug-loaded films containing *C.dichotoma* gum prepared using 0.15 % w/v glycerin. (CDF3) revealed satisfactory appearances and accepted suitable for further evaluation.

### *Evaluation of mechanical properties of drug loaded films*

The optimized drug-loaded film containing extracted *C. dichotoma* gum was evaluated for the mechanical properties like weight, mean thickness, folding endurance, water uptake, tensile strength, piercing load, surface pH, and drug content uniformity. These drug loaded film of area 211.14 ± 0.11 mg/cm2 for CDF3. The mean thicknesses of CDF3 films (drug-loaded) were measured as 0.412 ± 0.210 mm. Folding endurance of CDF3 drug-loaded films was measured as 258 ± 0.410. The water uptake by CDF3 films loaded with diclofenac sodium was measured 7.54 ± 0.41%. The tensile strength was calculated as 7.58 ± 0.42 for CDF3 film. The piercing load of CDF3 film loaded with diclofenac sodium was computed as 0.276 ± 0.034 kg. The surface pHs of CDF3 film were measured as 6.90 ± 0.04. The surface pHs of the film were measured and almost neutral pH was observed. The almost neutral pH of the drug-free films containing extracted plant gum entails slighter chances of gastrointestinal irritation when these will be applied as pharmaceutical excipients in the formulations for oral administration. The results of mechanical properties of film containing extracted *C. dichotoma* gum are presented in Table 11.

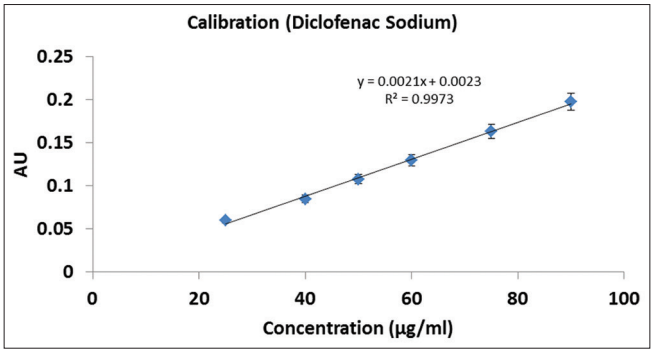


**Figure 6:** Standard curve of diclofenac sodium in phosphate buffer, pH 7.4

**Table 10:** Composition of drug-loaded films containing extracted *Cordia dichotoma* gum

| Composition of film /film code | CDF1 | CDF2 | CDF3 | CDF4 | CDF5 |
|---|---|---|---|---|---|
| Gum (10% w/w) | 5 ml | 5 ml | 5 ml | 5 ml | 5 ml |
| Glycerine (% w/v) | 0.05 | 0.10 | 0.15 | 0.20 | 0.25 |
| Methyl paraben (% w/v) | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Diclofenac sodium (% w/v) | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Appearance | Dried | Dried | Satisfactory* | Wet | Wet |

Satisfactory* means films which were suitable for further evaluation

## Preparation and Evaluation of Pellets and Gum-coated Pellets Containing Diclofenac Sodium

### *Preparation of pellets*

By layering the drug (diclofenac sodium) on non-pareil seeds (NPS) of 1.3 mm average size, the drug-coated NPS were prepared.

## SEM Observation Study

The morphology of diclofenac sodium-coated pellets *C. dichotoma* gum-coated pellets were characterized by SEM analyses. The SEM photographs of diclofenac sodium-coated pellets are presented in Figure 7. The diclofenac sodium-coated pellets were of spherical shaped as seen in the SEM photograph [Figure 7a]. The surface topographical morphology of the diclofenac sodium-coated pellets showed an almost smooth surface [Figure 7b].

### *In Vitro* Drug Releases from Drug (Diclofenac Sodium) Loaded Films Containing Extracted Gums

*In vitro* drug releases from drug (diclofenac sodium) loaded pallets containing extracted *C. dichotoma* gum in the phosphate buffer saline, pH 6.8 was evaluated. The diclofenac sodium-loaded pallets exhibited sustained drug releasing over a period of 11 h of dissolution in phosphate buffer saline, pH 6.8 shown in Figure 8. The drug releasing from diclofenac sodium-loaded pallets containing extracted *C. dichotoma* gum was found sustained. This phenomenon might be due to the higher viscosity of the extracted *C. dichotoma* gum.

*In vitro* drug-releasing data were evaluated kinetically by testing fitting with various mathematical models zero-order model, first-order model, Higuchi model, and Korsmeyer-Peppas model. The results of curve-fitting into above mentioned mathematical models are presented in Table 12 for diclofenac sodium-loaded pallets containing extracted *C. dichotoma* gum.

When respective correlation coefficients ($R^2$) were compared, it was found to follow Korsmeyer–Peppas model dominantly with a correlation coefficient closer to 1 for the drug-loaded pallets made of the extracted gum. The determined values of release exponent (n) of these prepared films containing diclofenac sodium were calculated as below 0.5 which indicate that the drug releasing followed the Fickian (non-steady) diffusion mechanism (when $n \leq 0.5$). Fickian diffusion refers to the solute transport process in which the polymer relaxation time is much greater than the characteristic solvent diffusion time.

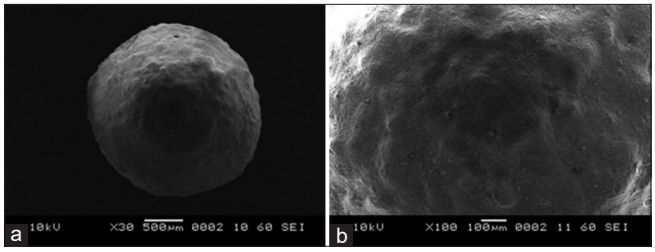


**Figure 7:** SEM photographs of diclofenac sodium-coated pellets at different magnifications: (a) ×30 and (b) ×100

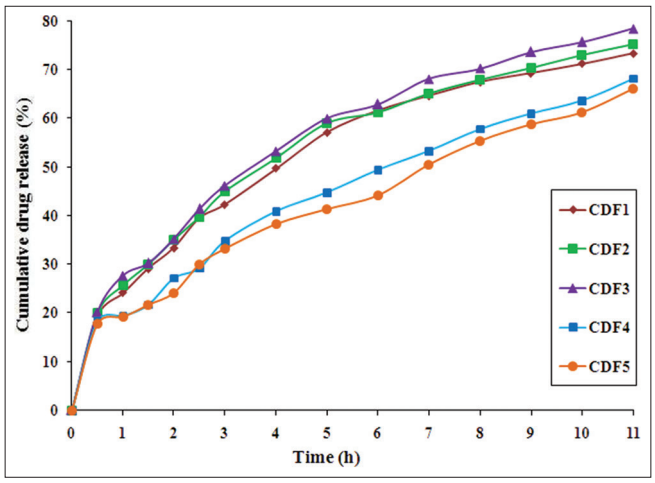


**Figure 8:** *In vitro* drug release from diclofenac sodium-loaded films containing extracted *Cordia dichotoma* gum

**Table 11:** Mechanical properties of drug-loaded films containing extracted gums

| Weight (mg/cm²) | Mean thickness (mm) | Folding endurance (No. of folds) | Water uptake (%) | Tensile strength (kg/cm²) | Piercing load (kg) | Surface pH | Content uniformity (mg/cm²) |
|---|---|---|---|---|---|---|---|
| 211.14±0.11 | 0.412±0.210 | 258±0.410 | 7.54±0.41 | 7.58±0.42 | 0.267±0.034 | 6.90±0.04 | 4.93±0.74 |

Mean±SE, *n*=3

**Table 12:** Curve-fitting results of *in vitro* drug release from diclofenac sodium-loaded films containing extracted Cordia dichotoma gum

| Code | Correlation coefficient ($R^2$) | | | | Release exponent (n) |
|---|---|---|---|---|---|
| | Zero-order model | First-order model | Higuchi model | Korsmeyer-Peppas model | |
| CDF1 | 0.9288 | 0.8395 | 0.9744 | 0.9903 | 0.46 |
| CDF2 | 0.9306 | 0.8375 | 0.9692 | 0.9918 | 0.45 |
| CDF3 | 0.9373 | 0.8434 | 0.9761 | 0.9921 | 0.46 |
| CDF4 | 0.9794 | 0.9124 | 0.9701 | 0.9978 | 0.47 |
| CDF5 | 0.9775 | 0.9295 | 0.9759 | 0.9855 | 0.47 |

## CONCLUSION

In this study, an effective film-forming capacity of gum extracted from fruits of *C. dichotoma* frost on solid dosage form using Diclofenac sodium as a model drug was evaluated. Hence conclude that gum of *C. dichotoma* frost may be potent excipient from natural origin over the existing one.

## REFERENCES


1. Rowe RC, Shelkey PJ, Walker PJ. Handbook of Pharmaceutical Excipients. 4th ed. U.K, U.S.A: Pharmaceutical Press, American Pharmaceutical Association; 2003. p. 178-84.
2. Date AA, Nagarsenker MS. Parenteral microemulsions: An overview. Int J Pharm 2008;355:19-30.
3. Sun C, Grant DJ. Effects of initial particle size on the tableting properties of l-lysine monohydrochloride dihydrate powder. Int J Pharm 2001;215:221-8.
4. Shogren R. Water vapor permeability of biodegradable polymers. J Environ Polym Degrad 1997;5:91-5.
5. Sprockel OL, Sen M, Shivanand P, Prapaitrakul W. A melt-extrusion process for manufacturing matrix drug delivery systems. Int J Pharm 1997;155:191-9.
6. Deveswaran R, Bharath S, Furtado S, Basavaraj BV, Abraham S, Madhavan V. Studies on the disintegrant properties of mucilage and seed powder of *Plantago ovata*. Int J Chem Tech Res 2009;1:621-6.
7. Pawar HA, Jadhav P. Isolation, characterization and investigation of *Cordia dichotoma* fruit polysaccharide as a herbal excipient. Int J Biol Macromol 2015; 72:1228-36.
8. Nayak AK, Pal D, Malakar J. Development, optimization and evaluation of emulsion-gelled floating beads using natural polysaccharide-blend for controlled drug release. Polym Eng Sci 2013;53:338-50.
9. Nayak AK, Das B, Maji R. Calcium alginate/gum Arabic beads containing glibenclamide: Development and *in vitro* characterization. Int J Biol Macromol 2012;51:1070-8.
10. Nayak AK, Pal D. Development of pH-sensitive tamarind seed polysaccharide-alginate composite beads for controlled diclofenac sodium delivery using response surface methodology. Int J Biol Macromol 2011; 49:784-93.
11. Kokate CK, Purohit AP, Gokhale SB. Text Book of Pharmacognosy. 38th ed. Pune, India: Nirali Prakashan; 2000. p. 7135-445.
12. Khandelwal KR. Pharmacognosy, Techniques, and Experiments. 9th ed. Pune, India: Nirali Prakashan; 2002. p. 149-56.
13. Bruneton J. Pharmacognosy Phytochemistry Medicinal Plants. 2nd ed. Lavoisier Publishing; 1999. p. 90.
14. Jarald EE, Jarald SE. Text book of Pharmacognosy and Phytochemistry. 1st ed. New Delhi: CBS Publication; 2007. p. 177-8.
15. Lachman L, Liberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Mumbai: Varghese Publishing House; 1981. p. 359.
16. Nadkarni KM. Indian Materia Medica. 3rd ed. Mumbai: Bombay Popular Publication; 2002. p. 736-8.
17. Sundaram J, Durance TD. Water sorption and physical properties of locust bean gum-pectin-starch composite gel dried using different drying methods. Food Hydrocoll 2008;22:1352-61.
18. Harnby N, Hawkins AE, Vandame D. The use of bulk density determination as a means of typifying the flow characteristics of loosely compacted powders under conditions of variable relative humidity. Chem Eng Sci 1987;42:879-88.
19. Indian Pharmacopoeia. The controller of publication, Delhi. 2014;1:224.
20. Indian Pharmacopoeia, The controller of publication, Delhi. 2014;1:226.
21. Bagnold RA. The shearing and dilatation of dry sand and the 'singing' mechanism. Proc Royal Soc Lond A Math Phys Sci 1966;295:219-32.
22. Indian Pharmacopoeia, The controller of publication, Delhi. 2014;1:227.
23. Khandelwal KR. Practical Pharmacognosy. 10th ed. Pune: Nirali Prakashan; 2003. p. 162-72.
24. Indian Pharmacopoeia, The controller of publication, Delhi. 2014;1:62.
25. Pujari SG. Study of Some Natural Gums. Mumbai, India: UDCT; 1981.
26. Indian Pharmacopoeia, The controller of publication, Delhi. 2014;1:174.
27. Indian Pharmacopoeia, The controller of publication, Delhi. 2014;1:169.
28. Indian Pharmacopoeia, The controller of publication, Delhi. 2014;1:203.
29. Khandelwal KR. Practical Pharmacognosy. 20th ed. Pune: Nirali Prakashan; 2010. p. 23.11.
30. Khandelwal KR. Practical Pharmacognosy. 20th ed. Pune: Nirali Prakashan; 2010. p. 23.8-23.10.
31. Jindal M, Kumar V, Rana V, Tiwary AK. Exploring potential new gum source *Aegle marmelos* for food and pharmaceuticals: Physical, chemical and functional performance. Ind Crops Prod 2013;45:312-18.
32. Lachman L, Liberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Mumbai: Varghese Publishing House; 1981. p. 368.
33. Lachman L, Liberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Mumbai: Varghese Publishing House; 1981. p. 387.
34. Jindal M, Kumar V, Rana V, Tiwary AK. Exploring potential new gum source *Aegle marmelos* for food and pharmaceuticals: Physical, chemical and functional performance. Ind Crops Prod 2013;45:312-8.
35. Mundada A, Satturwar P, Fulzele S, Joshi S, Dorle A. Characterization and evaluation of novel film

forming polymer for drug delivery. Iran J Pharm Res 2011;10:35-42.
36. Zhang Z, Fang S. Novel network polymer electrolytes based on polysiloxane with internal plasticizer. Electrochim Acta 2000;45:2131-8.
37. Kalu VD, Odeniyi MA, Jaiyeoba KT. Matrix properties of a new plant gum in controlled drug delivery. Arch Pharm Res 2007;30:884-9.
38. Sinha P, Ubaidulla U, Nayak AK. Okra (*Hibiscus esculentus*) gum-alginate blend mucoadhesive beads for controlled glibenclamide release. Int J Biol Macromol 2015;72:1069-75.