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# Pharmaceutical Characterization of *Cassia tora* of Seed Mucilage in Tablet Formulations

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## ABSTRACT

*Cassia tora (Cassia obstusifolia L) is a common herbaceous annual occurring as a weed throughout India and belongs to the family of Caesalpiniaceae. Seeds of plant contain gluco-mannose hence attempt to evaluate the seeds for suitability as tablet binder is considered and the present investigation repots the isolation of mucilage of Cassia tora seed. The DSC and FTIR thermograms of drug and gum indicated no chemical interaction. Phytochemical characteristics of mucilage such as carbohydrate, protein, fat and flavanoids etc. were studied. Physiochemical characteristics of mucilage such as solubility, swelling index, loss on drying, viscosity, hydration capacity, powder porosity, microbiological properties and pH were studied. The mucilage was evaluated for its granulating and binding properties in compressed tablet using Zidovudine as model drug. Mucilage was used in four different concentrations i.e. 2.0, 4.0, 6.0 and 8.0% w/v. The granules were prepared by wet granulation process. The prepared granules were evaluated for percentage of fines, average particle size, compressibility index and flow properties. The properties were compared with Guar gum which was used as standard binder at 8.0% w/v concentration. The tablet were prepared and evaluated for content uniformity, hardness, friability, disintegration time and in vitro dissolution profile. The tablets had good physiochemical properties and the drug release was more than 85% within 4 hour. It was observed that increasing the concentration of mucilage increases hardness and decreases the disintegration time. All the formulations (F1, F2, F3, F4 and F5) were subjected to stability studies for three months at 25°C/60% RH, 30°C/65% RH and 40°C/75% RH as per ICH guidelines all four formulation showed stability with respect to release pattern and other parameters which confirm the use of mucilage as excipient.*

**Keywords**: *Cassia tora,* Mucilage, Hydrogel, Binder.

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## INTRODUCTION

Seed gums are important agrochemical used in various industries worldwide. The growing industrial utility of these gums in the field of paper, textile, petroleum recovery and pharmaceutical industries has resulted in an impetus in India for intensified research on new sources of gums and their modified products. *Cassia tora* mucilage (CTM) derived from the seeds of *Cassia tora* Linn. belonging to *Caesalpiniaceae* is a wild crop and grows in most parts of India as a weed and locally known as charota. A natural gelling agent which has industrial and food applications is made commercially from the seed [1]. Cassia grows in hot, wet, tropical climates both wild and commercially. Cassia is used as tonic, carminative and stimulant. Cassia contains 1-2 % volatile cassia oil which is mainly responsible for the spicy aroma and taste. The primary chemical constituents of Cassia include cinnamaldehyde, gum, tannins, mannitol, coumarins and essential oils (aldehydes, eugenol, and pinene); it also contains sugars, resins and mucilage among other constituents [2-3]. Although some work had already been carried out on gums as excipients [4-6] it seems that no work has been done on the suitability of *Cassia tora* mucilage as a binding agent in tablet preparation as compared to the relatively common natural agents as Acacia, guar gum and xanthan gum using disintegration time, rheology and *in vitro* analysis as assessment parameters. Hence the present work was attempted to evaluate binding properties of seed mucilage of *Cassia tora*.

## MATERIALS AND METHODS

*Cassia tora* seeds were procured from the forest of KORIA, Chhattisgarh, India. Zidovudin was obtained as gift sample from Active Pharmaceutical Ingredient. All other ingredients were of analytical grade and purchased from Loba chemicals, Mumbai.

## METHODS

### Isolation of mucilage from *Cassia tora* seeds

*C. tora* seeds Kernel's powder (20g) were soaked in cold distilled water (200 ml) and slurry was prepared. Then slurry was mixed with 800ml of boil distilled water. The solution was boiled for 20 minutes under stirring condition in water bath. The resulting thin clean solution was kept overnight for settling protein and fibers. The solution is centrifuge at 5000 rpm for 20 minutes. The supernant was separated and poured in to twice the volume of absolute ethanol by continues stirring to precipitate the polysaccharides. The precipitate was washed with absolute ethanol, diethyl ether and petroleum ether and then dried at 40-45ºC and passed through sieve #120 and stored in desiccators until used for further studies [7-9].

### Drug-excipient compatibility studies

This study perform to check whether there is any compatibility related problems are associated with drug and excipients used for the formulation of tablet. The drug and excipients must be compatible with one another to produce a product that is stable, efficacious, attractive and easy to administer and safe. If the excipients are new and not been used in formulations containing the active substance, the compatibility studies are of paramount importance. Thermal analysis and FTIR can be used to investigate and predict any physicochemical interactions between components in a formulation and can therefore be applied to the selection of suitable chemically compatible excipients.

**FTIR Spectroscopy**
The IR spectral analysis of a drug and other excipients were taken using Press pellet technique (using KBr). The IR spectra's were determined by using 1601 PC Shimadzu FTIR Spectrophotometer [10-13].

**Differential Scanning Calorimeter Studies (DSC)**
DSC was performed on a Shimadzu DSC-60 (Shimadzu Limited Japan). A 1:1 ratio of drug and excipient was weighed into aluminum crucible and sample was analyzed by heating at a scanning rate of $10^0$C/min over a temperature range $20^0$-$300^0$C under a nitrogen flow of 40ml/min. Reproducibility was checked by running the sample in triplicate[14].

**Preliminary Phytochemical Screening of Isolated Mucilage**
The phytochemical properties such as presence of carbohydrate, protein, flavanoids, sterols, alkaloids, tannins, saponins, fats and terpenoids were determined [15].

**Physicochemical properties of dried mucilage**
The physicochemical properties such as solubility, pH, specific gravity and viscosity of dried CTM were determined at 20ºC. The loss on drying, total ash content, acid insoluble ash and water soluble ash were determined according to Ayurvedic Pharmacopoeia of India (A.P.I) [16].

**Microbiological properties**
**Microbial Load**
**Preparation of Inoculums**
1g powder of CTM was suspended in 10 ml of sterile water (inoculum). 1ml of inoculum was transferred to 99ml dilution blank (sterile water) which was diluted inoculum.

**Plate Count Technique**
Inoculum (1 ml) and diluted inoculum (1 ml) were transferred to separate petridishes 9 to 10 cm in diameter. After addition of both the inoculum to the plate, 20 ml of agar medium (40-45°C) was poured in to a each plate. Both the plates were gently rotated for through distribution of inoculum throughout the medium and solidified [17].

**Preparation and evaluation of granules**
Zidovudin was used as model drug to formulate the granules. Hydroxypropylcellulose was used as matrix former, were lactose and aerosil was used as diluents and lubricant respectively. Binder solution was prepared by dissolving CTM in water at 2.0%, 4.0%, 6.0% and 8.0% w/v concentrations. The batch size was 100gm. The drug, lactose, aerosil, and HPMC were mixed thoroughly and sufficient volume of 20 ml of 2.0%, 4.0%, 6.0% and 8.0% w/v of CTM was added slowly to powder blend and kneading was performed for near about 10 min until the formation of wet mass with enough cohesiveness [Table1]. The wet mass forced through the sieve # 16 and dried at 40-45ºC in hot air oven for 2hr. the dried granules were received through sieve # 20. The prepared granules were then evaluated for percentage of fines, particles size and flow properties by measurement of angle of repose [18-20]. The bulk and tapped densities of the granules were then assessed in accordance with the USP XXV tapped volume meter apparatus compressibility index of the granules was determined by Carr's compressibility index [21-24].

**Table 1. Composition of Tablet Formulation**

| Ingredient | Seed mucilage of *Cassia tora* as binder | | | | Guar gum |
|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 |
| Zidovudin | 50 mg | 50 mg | 50 mg | 50 mg | 50 mg |
| CTM (%w/v) | 2.0% | 4.0% | 6.0% | 8.0% | 8.0% |
| HPMC | Q.S | Q.S | Q.S | Q.S | Q.S |
| Lactose | Q.S | Q.S | Q.S | Q.S | Q.S |
| Aerosil | 4 mg | 4 mg | 4 mg | 4 mg | 4 mg |
| Total weight | 200 mg | 200 mg | 200 mg | 200 mg | 200 mg |

**Preparation and evaluation of tablet**

The lubricated granules were compressed into tablet using 8 mm standard concave punch with 10 station single rotary Clit (Jemkay) machine and keeping average weight 200 mg. The prepared tablets were evaluated for content uniformity, hardness, disintegration time and *in vitro* dissolution profile using method specified in Indian pharmacopeia [18].

**Accelerated stability studies**

Formulation were stored at various temperature *viz.*25°C/60% RH, 30°C/65% RH and 40°C/75% RH as per ICH guidelines and various physicochemical parameter (appearance, percentage drug content and *in vitro* release profile) were monitored periodically for 3 months [24].

## RESULT AND DISCUSSION

**Drug-excipient compatibility studies**

The dried and coarsely powdered seeds of *C. tora* yielded high percentage (10.8% w/v) of mucilage using ethanol as mucilage precipitating solvent. The thermograms of drug and CTM shows that there is no change in melting point which confirms that there is neither change in crystallinty of the drug nor any interaction Figure 1., further drug polymer interaction was checked by comparing the IR spectra of the physical mixture of drug with the CTM used with the IR spectrum of pure drug. Frequencies of functional groups of pure drug remained intact in physical mixture containing CTM Figure 2; so it was concluded that there was no major interaction occurred between the drug and CTM used in the study.

**Figure1. DSC of pure drug Zidovudine**

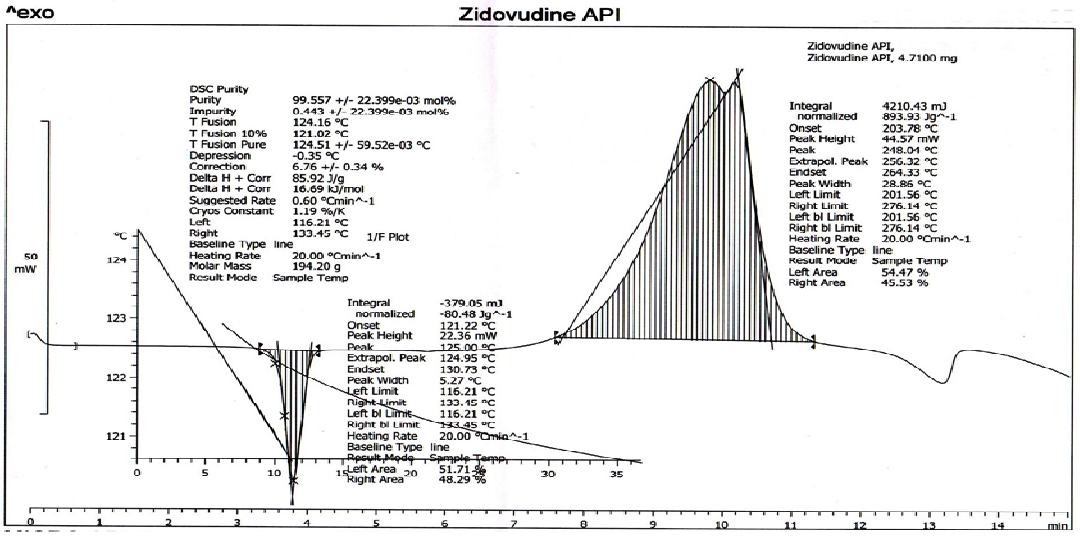
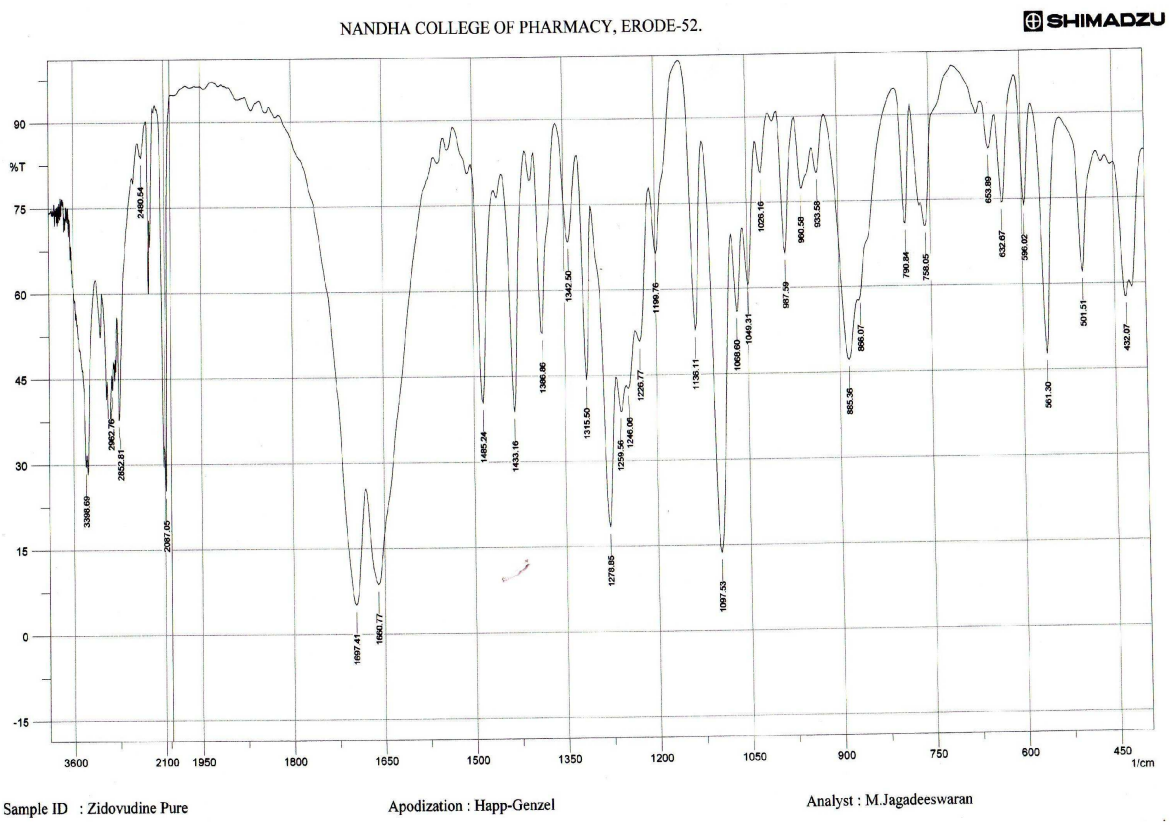


**Figure 2. FTIR spectrum of physical mixture of Zidovudine with CTM.**




**Preliminary Phytochemical Screening of Isolated Mucilage**

The Phytochemical screening of natural mucilage confirmed polysaccharides in nature [Table 2]. The physicochemical and microbiological properties of CTM were determined. The CTM completely soluble in warm water, swelling index, viscosity obtained 33% and 20-100cps. The pH of the mucilage was found to be 5.6-6.5 were very near to neutral it may be less irritating on gastrointestinal tract and hence gum is suitable for uncoated tablet [Table 3].

**Table 2. Data Showing, Preliminary Phytochemical Screening of Isolated Mucilage**

| **Active constituent** | "CTM" **Mucilage** |
|---|---|
| Carbohydrate | + |
| Protein | - |
| Flavanoids | - |
| Tannins | - |
| Saponins | - |
| Sterols | - |
| Alkaloids | - |
| Terpenoids | - |
| Protien | + |
| Starch | - |
| Fat | + |

***+ Present, - Absent.***

**Table 3. Physicochemical properties of CTM mucilage**

| Parameter | Result* |
|---|---|
| Appearance | Yellow white powder |
| Solubility | Soluble in cold water and hot water forming viscous colloidal solution |
| Swelling index (%) | 33.0 ± 0.15 |
| pH | 5.5 - 6.5 |
| Hot viscosity (1.0%w/v solution) | 20 -100 cps |
| Specific gravity (g/ml of 1.0%w/v solution) | 0.9975 |
| Loss on drying (%) | 8.2 ± 0.02 |
| Total ash (%) | 1.00± 0.13 |
| Acid insoluble ash (%) | 3.00± 0.05 |
| Water soluble ash (%) | 4.532± 0.08 |
| Moisture content | 12.00% |

***All values are mean ± S.D. for n=3**

**Microbiological properties**

The isolated and purified natural gum were evaluated for microbial load CTM shows 120 CFU per gram of gum which shows mucilage were under microbial limit [Table 4].

**Table 4. Technological Characterization of Microbial load**

| Natural gum | No. CFU/ ml | Microbial load (No. of CFU / gm of gum) |
|---|---|---|
| "CTM" | 12 | 120 |

**Table 5. Technological characterization of granules using CTM as binder.**

| Properties | Seed mucilage of CTM as binder* | | | | Guar gum* |
|---|---|---|---|---|---|
| Concentration | 2.0% | 4.0% | 6.0% | 8.0% | 8.0% |
| Percentage of fines (%) | 24.50 | 23.40 | 21.10 | 19.40 | 18.06 |
| Angle of repose | 32.56° | 30.40° | 26.64° | 22.42° | 25.84° |
| Mean particle size (mm) | 0.34 | 0.31 | 0.33 | 0.32 | 0.34 |
| Percentage friability (%) | 0.75 | 0.62 | 0.54 | 0.46 | 0.35 |
| Disintegration time in min. | 16 | 21 | 24 | 28 | 29 |
| Loose Bulk density ($g/cm^2$) ±SD | 0.600±0.05 | 0.573±0.03 | 0.560±0.06 | 0.543±0.01 | 0.532±0.04 |
| Tapped bulk density ($g/cm^2$) ±SD | 0.652±0.04 | 0.607±0.01 | 0.588±0.02 | 0.582±0.01 | 0.580±0.02 |
| Compressibility index (%) | 7.97±0.78 | 7.92±0.24 | 7.62±0.05 | 7.61±0.04 | 7.08±0.07 |
| Content uniformity (%) ± SEM | 99.6±0.44 | 100.2±0.54 | 100.1±0.52 | 101.4±0.51 | 101.0±0.70 |
| Hardness ($kg/cm^2$) ± SEM | 4.90±0.44 | 5.80±0.04 | 6.20±0.08 | 6.40±0.07 | 6.8±0.10 |

***All values are mean ± S.D. for n=3**

**Physicochemical properties of dried mucilage**

The prepared granules were evaluated for percentage of fines, flow properties etc., the result are shown in [Table 5]. It was observed that percentages of fines were reduced as the concentration of CTM was increased. The percentage of fines was little higher in granules prepared using 2.0%

of mucilage as binder. The flow properties of granules were determined by angle repose which was found to be 36º to 22º. Hence all the granules exhibited good flow properties. Bulk densities of the prepared granules were found to decrease slightly by increasing the concentration of CTM. This result may be due to the formation of larger agglomerates and decrease in fines in the granules as increasing CTM concentration. The result of compressibility index indicates decrease in flow ability with increasing CTM concentration. However, all formulation showed good flow properties. In general compressibility index values up to 15% result in good to excellent flow properties. All these result indicates that the granules possessed satisfactory flow properties and compressibility.

***In vitro* Evaluation of tablet**

To understand the release profiles of the drug from the tablets, Four batch of tablet were prepared using CTM at four different concentration (2.0, 4.0, 6.0, 8.0%w/v) guar gum mucilage (8.0%w/v) was used as standard binder for comparison. The prepared tablets were evaluated for content uniformity, hardness, friability, disintegration time and dissolution profile. All the batches of tablet exhibited good uniformity in content. Hardness of tablet increased with increase in concentration of mucilage. The tablet prepared with 8.0%w/v CTM showed the hardness nearly equal to the tablet prepared by using 8.0% w/v of guar gum mucilage. The percentage friability values were slightly decreased as increase in concentration of mucilage. Through increase in hardness of tablet, increase in concentration interestingly showed decreased in disintegration time of tablet. *In vitro* dissolution study showed that drug release from the tablets prepared by using mucilage at four different concentrations was more than 85% in 4hr.

**Accelerated stability studies**

The stability study of optimized batch was carried out at 25°C/60% RH, 30°C/65% RH and 40°C/75% RH as per ICH guidelines. The tablets of all formulation were found to be stable at such condition and other parameters were found to be unaffected and were under pharmacopoeial limits.

## SUMMARY

From the above study, we can conclude that *C. tora* mucilage can be used as a binder in formulation of uncoated tablets. Increase in concentration of mucilage increases the hardness and decrease the disintegration time. Moreover it may prove economical as binding property of 8.0% w/v *C. tora* mucilage is almost equivalent to 8.0% w/v Guar gum mucilage.

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