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FORMULATION AND EVALUATION OF ORAL MEDICATED JELLY

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ABSTRACT

The present study focuses on the formulation and evaluation of an oral medicated jelly containing glibenclamide, an antidiabetic drug used in the management of Type 2 diabetes mellitus. Oral medicated jellies are patient-friendly dosage forms particularly suitable for pediatric, geriatric, and dysphagic patients due to ease of administration and improved palatability. Glibenclamide oral jellies were prepared using varying concentrations of guar gum and pectin as gelling agents. The prepared formulations were evaluated for physical appearance, viscosity, pH, syneresis, drug content, in vitro drug release, and stability. Among the six formulations, batch F5 demonstrated optimal physicochemical properties, acceptable viscosity, absence of syneresis, uniform drug content, satisfactory drug release, and good stability under different storage conditions. The results suggest that oral medicated jelly is a promising alternative delivery system for glibenclamide, offering improved patient compliance and therapeutic effectiveness.

KEYWORDS: Oral medicated jelly, Glibenclamide, Guar gum, Pectin, Type 2 diabetes mellitus, Patient compliance.

1. INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Glibenclamide, a second-generation sulfonylurea, is widely prescribed for the treatment of Type 2 diabetes mellitus due to its

ability to stimulate insulin release from pancreatic β-cells. However, conventional oral solid dosage forms such as tablets may pose swallowing difficulties, particularly in pediatric and geriatric populations.

Oral medicated jellies have emerged as an innovative drug delivery system that combines ease of swallowing, palatability, and rapid onset of action. These formulations improve patient compliance while maintaining therapeutic efficacy. Natural polymers such as guar gum and pectin are commonly used as gelling agents due to their biocompatibility, safety, and desirable rheological properties. The present study aims to formulate and evaluate glibenclamide-loaded oral soft jellies using different concentrations of guar gum and pectin and to assess their physicochemical characteristics, drug release behavior, and stability.

Fig. 1: Oral Jelly.

2. DRUG PROFILE: (GLIBENCLAMIDE)

- **Trade name:** Diabeta
- **Other name:** Glyburide
- **Drug category:** Anti-diabetic
- **Class:** Sulfonylureas
- **Description:** Anti-diabetic agent used for treatment of Diabetes mellitus type 2
- **Chemical Formula:** $C_{23}H_{28}ClN_3O_5S$
- **IUPAC Name:** 5-Chlor-N-(2-{4[(cyclohexylcarbamoyl)sulfamoyl]Phenyl}ethyl)2-Methoxybenzamid

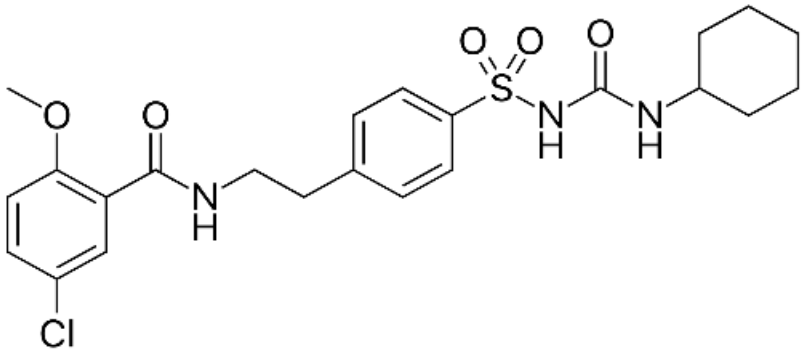

Fig: 2 Chemical Structure Of Glibenclamide.

- **Storage:** Stored at room temperature
- **Physical appearance:** White solid
- **Molecular weight:** 494.000 gram/mol
- **Melting point:** 169 to 170°C
- **Solubility:** Soluble in 330 parts of alcohol, in36 parts of $CHCl_3$
- **Adverse effects:** Nausea, heart burn, weight gain.
- **Absorption:** Tmax ranged from 1.62 hours to 2.09 hours
- **Distribution:** Volume of distribution 14.63L-32.48L
- **Metabolism:** liver hydroxylation(CYP2C9-Mediated)
- **Excretion:** kidney and biliary lodextrin
- **Half-life:** 10 hours

3. MATERIALS AND METHODS

3.1 PREPARATION OF ORAL SOFT JELLY

All the required ingredients of the formulation were weighed accurately. Dry guar gum powder and pectin were dispersed in 50 ml of distilled water maintained at 95°C. The dispersion was stirred at 95 ℃for 20 min using a magnetic stirrer (Remi magnetic stirrer Mumbai, India) to facilitate hydration of guar gum. The required amount of mannitol was added to the gelling agent solution with continuous stirring and the temperature was maintained about 80 - 85 °C Glibenclamide was added with stirring. Then stevia, citric acid, and preservatives (methylparaben) were added with stirring. Finally, required amount of sodium citrate and sodium citrate was dissolved in 10 ml of distilled water and added to the mixture. At last flavour was added. The weight of the gel was monitored continuously during manufacturing and finally it was adjusted to the 100 g with distilled water. The jelly was packed in polyethylene mould with airtight seal. The mixture was allowed to cool up to room

temperature to form jelly. The gels were prepared using three different concentrations of guar gum (0.3, 0.4 and 0.5% w/v), each with two different pectin concentrations (0.2 and 0.3% w / v).

3.2 EVALUVATION AND PARAMETER

General appearance: Texture and clarity of the soft gel was evaluated in terms of stickiness and grittiness by mildly rubbing the gel between two fingers. Consistency and odour were also evaluated by physical observation.

Rheological measurement: Viscosity of the all the batches of soft gels were measured using Brookfield DV-II+ Pro viscometer. The Glibenclamide containing soft jelly was squeezed out from the polyethylene plastic bag by making a cut of uniform size on the bag and viscosity was measured using spindle number LV4 at the rotation of 50 rpm at room temperature. The viscosity measurements were made in triplicate using fresh sample each time.

pH of the soft jelly: The pH of the final gel has a great influence not only on stability, but also on the taste. The pH of glibenclamide containing soft jelly was measured using Electroquip Digital pH meter at room temperature.

Syneresis: Syneresis is one of the major problems associated with low acylated gellan gum gels. Syneresis means contraction of gel upon standing and separation of water from the gel. Syneresis is more pronounced in the gels where lowerconcentration of gelling agent is used. Gels were kept under scrutiny for signs of syneresis. The gels showing signs of syneresis were rejected and not considered for further studies.

Drug content: Take 10 jellies from jelly mould in a beaker and there average weight was determined. They were breaked into gel consistency. Then gel equivalent 5.0 mg of glibenclamide was taken in 100 mL volumetric flask and dissolved in 70 ml of methanol with vigorous shaking for 5-10 min. Finally the volume was made up to the mark with methanol. Finally it was analyzed in HPLC after proper dilution and filtration.

In vitro drug release: In vitro drug release studies was carried out using USP dissolution apparatus 2 using paddle at a speed of 50 rpm using 900 ml of 0.1N HCl as dissolution media containing 0.1% sodium lauryl sulphate at 37±2°C. The ready to use soft jelly (2.5 gm) containing 5.0 mg of glibenclamide was used in the dissolution test. 5 ml of sample was withdrawn at the interval of every 5 min and the drug solution was replaced with the same

volume of 0.1N HCl (pH 1.2) maintained at 37±2°C. 1 ml of the filtered sample was diluted up to 50 ml with methanol and absorbance was measured at 255 nm using HPLC.

Stability studies of soft gel: A physically stable oral gel retains its viscosity, color, clarity, taste, and odour throughout its shelf-life. Gels were checked for syneresis during storage. A freshly made sample should serve as a reference standard for subjective evaluations. The samples were kept at different temperatures (0-8 °C and at room temperature) for 3 months. The samples of soft gel were observed for pH, viscosity and appearance at the interval of one month. All the measurements were performed after allowing the sample to be equilibrated at 25 °C for 2 h.

4. RESULTS AND DISCUSSION

4.1 GENERAL APPEARANCE

Table 1: Physical Appearance Of Formulated Jelly.

BATCH CODE	CLARITY	CONSISTENCY	TEXTURE	ODOUR
F1	Transparent	Fruity Liquid	Non sticky & Non Gritty	Pleasant & Fruity
F2	Transparent	Fruity Liquid	Non sticky & Non Gritty	Pleasant & Fruity
F3	Transparent	Fruity Liquid	Non sticky & Non Gritty	Pleasant & Fruity
F4	Transparent	Acceptable	Non sticky & Non Gritty	Pleasant & Fruity
F5	Transparent	Acceptable	Non sticky & Non Gritty	Pleasant & Fruity
F6	Transparent	Acceptable	Sticky & Non Gritty	Pleasant & Fruity

4.2 EVALUATION OF JELLY

Table 2: Evaluation Of Jelly.

BATCH CODE	VISCOSITY	pH	SYNERESIS	DRUG CONTENT
F1	1868±30	6.63	+++	98.23
F2	2578±52	6.78	+++	98.26
F3	4352±32	6.74	++	98.22
F4	5790±35	6.94	+	98.23
F5	6548±20	6.98	-	98.58
F6	8161±20	6.10	-	98.22

4.3 IN VITRO DISSOLUTION STUDIES

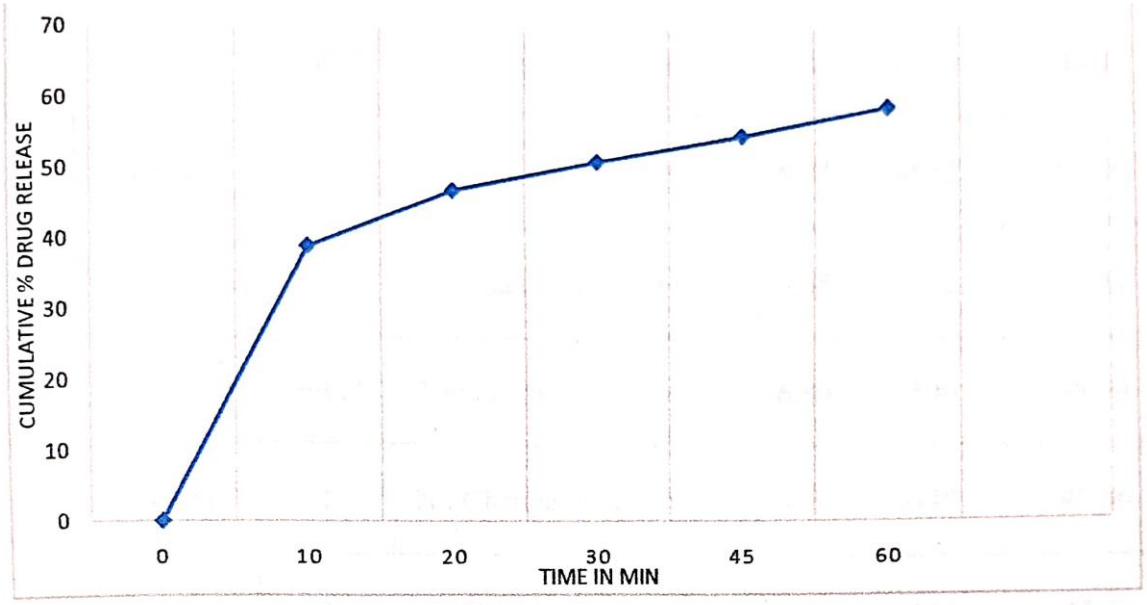

Fig. 3: Release Of Glibenclamide Containing Jelly Batch F5 In 0.1N HCI.

4.4 STABILITY STUDIES

Table 3: Stability Study Of Oral Soft Jelly Batch F5.

S.NO	STORAGE CONDITION	MONTHS	GENERAL APPEARANCE	SYNERESIS	PH	VISCOSITY	DRUG CONTENT
1.	2 - 8°C	Initial	Not gritty	+	6.80	6540	98.44
		1	No change	+	6.74	6572	98.00
		3	No change	++	6.68	6592	97.12
2.	25±5°C	Initial	Not gritty	+	6.80	6540	98.44
		1	No change	+	6.70	6549	97.86
		3	No change	+	6.45	6511	97.50

DISCUSSION

The prepared glibenclamide oral medicated jellies were found to be transparent with pleasant fruity odor, indicating good aesthetic appeal. Texture evaluation revealed that most formulations were non-sticky and non-gritty, although higher concentrations of guar gum resulted in slight stickiness, as observed in batch F6. Viscosity increased proportionally with increasing concentrations of gelling agents, confirming their role in gel structure formation.

The pH of all formulations ranged between 6.10 and 6.98, which is suitable for oral administration and contributes to formulation stability and patient acceptability. Syneresis was observed in formulations with lower concentrations of guar gum, highlighting the importance of optimal polymer concentration to prevent water separation. Drug content

analysis demonstrated uniform distribution of glibenclamide across all batches, with values close to 100%, indicating good content uniformity.

In vitro dissolution studies revealed satisfactory drug release profiles, with batch F5 exhibiting optimal release characteristics. Stability studies conducted over three months under refrigerated and room temperature conditions showed no significant changes in physical appearance, pH, viscosity, or drug content, confirming the formulation's stability. Overall, batch F5 was identified as the optimized formulation due to its balanced rheological properties, absence of syneresis, acceptable drug release, and stability.

5. CONCLUSION

The study successfully formulated and evaluated an oral medicated jelly containing glibenclamide using guar gum and pectin as gelling agents. Among the formulations tested, batch F5 demonstrated superior physicochemical properties, optimal drug release, and good stability. Oral medicated jelly proved to be a suitable alternative dosage form for glibenclamide, offering enhanced patient compliance, ease of administration, and therapeutic effectiveness. This dosage form holds promise for improving diabetes management, particularly in populations with swallowing difficulties.

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