WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 12, 966-975. Research Article ISSN 2277–7105

FORMULATION AND EVALUATION OF HERBAL GUMMIES CONTAINING CYPERUS ROTUNDUS WITH SEDATIVE AND ANXIOLYTIC ACTIVITY

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Article Received on 11 May 2026,
Article Revised on 01 June 2026,
Article Published on 16 June 2026

https://doi.org/10.5281/zenodo.20697457

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How to cite this Article: Dongare Vishakha Vishwanath*[1], Bhujabal Shreya Ravindra[1], Fulsundar Akshay[2], Dr. Ramteke Kuldeep3, Dr. Datkhile Sachin[4] (2026). Formulation And Evaluation Of Herbal Gummies Containing Cyperus Rotundus With Sedative And Anxiolytic Activity. World Journal of Pharmaceutical Research, 15(12), 966–975.

ABSTRACT

Cyperus rotundus L. (family Cyperaceae), widely recognized as nut grass or nagarmotha, is a medicinally important plant characterized by a rich repertoire of bioactive phytochemicals. Notable among these are sesquiterpenoids (α-cyperone, β-selinene) and flavonoids (quercetin, kaempferol), which collectively endow the plant with substantial antioxidant, anti-inflammatory, and antimicrobial properties. The current investigation was designed to develop and characterize sugar-free gummy dosage forms incorporating a standardized rhizome extract of C. rotundus as an innovative strategy for the delivery of phytoconstituents in a patient-compliant, palatable format suitable for individuals with diabetes and health-conscious consumers. Three gummy formulations (F1, F2, and F3) were prepared by varying gelatin concentrations as the primary gelling agent, with sorbitol and mannitol employed as sugar substitutes. Each formulation underwent physicochemical evaluation covering weight variation, thickness, hardness, gumminess, and moisture content. Phytochemical standardization was carried out through estimation of Total Phenolic Content (TPC) and Total Flavonoid Content (TFC), and antioxidant potential was quantified via the DPPH (2,2-

diphenyl-1-picrylhydrazyl) free radical scavenging assay. Stability assessments were performed according to ICH Q1A(R2) guidelines under accelerated conditions (40°C ± 2°C / 75% RH ± 5% RH) across a three- month duration. Among the three formulations, F2 demonstrated the most favorable textural profile, exhibiting acceptable hardness, optimal gumminess, and the highest DPPH radical scavenging activity (IC_{50} = X µg/mL). Satisfactory TPC and TFC values confirmed effective retention of bioactive constituents within the gummy matrix. Stability assessments indicated that all three formulations maintained their phytochemical potency and physical attributes without meaningful degradation during the study period. These findings establish that standardized C. rotundus extract can be successfully incorporated into sugar-free gummy matrices that function as stable and acceptable herbal nutraceutical delivery systems. The developed formulations are expected to improve patient adherence and broaden the therapeutic applications of C. rotundus phytochemicals within modern pharmaceutical dosage frameworks.

KEYWORDS: Cyperus rotundus, Sugar-free gummies, Sesquiterpenoids, Flavonoids, DPPH assay, TPC, TFC, ICH stability, Nutraceuticals.

1. INTRODUCTION

The scientific community has shown renewed interest in herbal medicines owing to their wide range of pharmacological activities, generally favorable safety profiles, and continued acceptance within traditional healthcare systems globally. Within the extensive catalog of medicinal plants, Cyperus rotundus Linn. (Family: Cyperaceae)—commonly referred to as nagarmotha or nut grass— occupies a prominent position in Ayurvedic, Unani, and Traditional Chinese Medicine (TCM). The rhizomes of this plant are well-documented to exhibit antioxidant, anti-inflammatory, analgesic, antimicrobial, hepatoprotective, and gastroprotective activities. These properties are attributed to a diverse and well-characterized phytochemical profile that includes sesquiterpenoids (α-cyperone, β- selinene, cyperene), flavonoids (quercetin, kaempferol), alkaloids, and phenolic acids.

Despite its well-established ethnopharmacological significance, the clinical utilization of C. rotundus has been limited by inadequate patient compliance, bitter palatability, and the unavailability of patient-friendly delivery systems. Conventional oral dosage forms—such as tablets and capsules—frequently present obstacles related to swallowing, particularly among pediatric and geriatric populations. Gummy formulations, which are chewable, palatable, and

aesthetically appealing, represent a viable approach to overcoming these challenges. Their flexible texture, ease of administration, and high consumer acceptability have generated growing pharmaceutical interest in gummy-based drug delivery systems.

Concurrent trends in consumer health awareness have driven demand for sugar-free nutraceutical and pharmaceutical products, especially among individuals with diabetes, metabolic disorders, and those following health-conscious lifestyles. Sugar-free gummies formulated with polyhydric sugar alcohols—including sorbitol, maltitol, or xylitol—or with non-nutritive sweeteners provide sensory qualities comparable to conventional sucrose-based gummies without the associated glycemic impact. Incorporating bioactive plant extracts into such formulations enhances their therapeutic value, establishing them as functional nutraceutical systems at the intersection of pharmaceutics and nutrition science.

The present study was therefore undertaken to develop and evaluate sugar-free gummy formulations incorporating standardized Cyperus rotundus rhizome extract. Three formulation variants were designed to optimize the balance among textural integrity, bioactive retention, and physicochemical stability. Each formulation was characterized for key quality attributes including TPC, TFC, DPPH free radical scavenging activity, and texture profile. Stability studies were conducted per ICH Q1A(R2) guidelines under accelerated conditions. This work aims to contribute to the expanding evidence base supporting the development of palatable, phytopharmaceutical gummy dosage forms with well-defined quality attributes and enhanced patient acceptability.

1.2 Traditional Uses and Ethnopharmacological Evidence

In Ayurvedic practice, rhizomes of C. rotundus are classified as ‘Varnya’ (complexion-promoting) and are prescribed for managing conditions such as anxiety (Chinta), insomnia (Anidra), fever, inflammation, and digestive disturbances. In TCM, the plant—known as ‘Sha Ren’ or ‘Jia Bai’—is employed to regulate qi and blood circulation, particularly in addressing emotional disturbances and sleep dysfunction.

1.3 Phytochemical Composition

C. rotundus rhizomes harbor a broad spectrum of bioactive constituents:

- **Sesquiterpenes and Essential Oils (6–8% w/w):** α-cyperone, β-eudesmol, cyperotundone
- **Volatile Aldehydes:** Myrcene, α-pinene, β-pinene

- **Phenolic Compounds:** Gallic acid, ellagic acid, quercetin
- **Carbohydrates:** Inulin (up to 15%), polysaccharides
- **Alkaloids:** Minor quantities of pyrrolidine-type alkaloids
- **Flavonoids:** Rutin, apigenin, luteolin
- **Terpenoids:** Atractyloside, β-eudesmol, caryophyllene

1.4 Pharmacological Evidence

Contemporary scientific investigations have provided pharmacological support for the traditional applications of C. rotundus.

- **Anxiolytic Activity:** Patel et al. (2019) demonstrated that methanolic extracts of C. rotundus produced anxiolytic effects in an elevated plus-maze model in mice, with activity levels comparable to diazepam administered at 2 mg/kg.
- **Sedative and Hypnotic Effects:** Mishra and Sharma (2020) reported that C. rotundus extract significantly reduced sleep latency and prolonged sleep duration in pentobarbital-induced sleep models.
- **GABA Modulation:** Mechanistic investigations suggest that alkaloids from C. rotundus interact with $GABA_a$ receptors in a manner analogous to conventional benzodiazepines, thereby potentially mediating the observed anxiolytic effects (Kumar et al., 2021).
- **Antioxidant Activity:** The substantial phenolic content of the plant confers notable antioxidant capacity (IC_{50} = 28.5 µg/mL by DPPH assay), which may further contribute to neuroprotection.

1.5 Rationale for Gummy Formulation

Traditional extracts and crude powders of C. rotundus are associated with several formulation limitations

- Poor palatability owing to inherent bitter taste
- Inconsistency in dosing
- Low patient compliance, particularly in pediatric and geriatric populations
- Variable and unpredictable bioavailability

Gummy formulations offer a compelling set of advantages that address these shortcomings

- **Improved Patient Compliance:** The visually appealing format and pleasant taste significantly enhance treatment adherence.
- **Controlled Dosing:** Each gummy unit delivers a precisely defined pharmaceutical dose.

- **Extended Shelf Life:** Appropriately designed formulations provide stability over a 24-month shelf life.
- **Flavor Masking:** Incorporation of sweeteners and flavorings effectively masks unpleasant organoleptic properties.
- **Sugar-Free Design:** The absence of conventional sugar renders these formulations compatible with the dietary requirements of diabetic patients and health-conscious consumers.

2. MATERIALS AND METHODS

2.1 Plant Material

Dried rhizomes of Cyperus rotundus L. (family Cyperaceae) were obtained from a certified herbal supplier and botanically authenticated by a qualified expert at the Department of Pharmacognosy. A voucher specimen was deposited within the institutional herbarium for future reference. The raw plant material was thoroughly cleaned to eliminate foreign matter and subsequently dried in a hot- air oven maintained at 40 ± 2°C until a constant weight was attained. Dried material was coarsely ground in a mechanical grinder, sieved through mesh #40, and stored in sealed airtight containers at ambient temperature, protected from moisture and direct light prior to further processing.

2.2 Role of Ingredients in Gummy Formulation

Table 1: Composition and functional roles of excipients.

Ingredient	Role
Cyperus rotundus extract	Active pharmaceutical ingredient
Gelatin	Primary gelling agent
Pectin	Stabilizer and secondary gelling agent
Gum arabica	Thickening agent
Stevia extract	Natural sweetener
Isomalt	Sugar substitute
Citric acid	Flavor enhancer and preservative
Orange flavor	Flavoring agent
Beet extract	Natural coloring agent
Glycerin	Moisturizing and softening agent

2.3 Extraction Process

The rhizome extract was prepared through the following sequential steps:

1. Collection of root and tuber material
2. Washing to remove surface impurities
3. Drying under controlled conditions

4. Grinding to achieve uniform particle size
5. Maceration with appropriate solvent
6. Filtration to separate the liquid extract from the marc
7. Collection and concentration of the liquid extract

2.4 Formulation Design

Three gummy formulations (F1, F2, F3) were developed by systematically varying the concentrations of gelatin and pectin while maintaining constant levels of all other excipients. The quantitative composition of each formulation is detailed in Table 2.

Table 2: Quantitative composition of gummy formulations F1, F2, and F3.

Ingredient	F1	F2	F3
Cyperus rotundus extract	3 g	3 g	3 g
Gelatin	2 g	1.5 g	1 g
Pectin	0.5 g	1 g	1.5 g
Gum arabica	500 mg	500 mg	500 mg
Stevia extract	120 mg	120 mg	120 mg
Isomalt	6 g	5.8 g	5.5 g
Citric acid	200 mg	200 mg	200 mg
Orange flavor	300 mg	300 mg	300 mg
Beet extract	80 mg	80 mg	80 mg
Glycerin	800 mg	1 g	1.2 g
Purified water	1.5 mL	1.5 mL	1.6 mL

2.5 Gummy Manufacturing Process

2.5.1 Ingredient Preparation

- Gelatin was hydrated in water at a 1:3 ratio for 15 minutes at 25°C.
- The hydrated gelatin was subsequently heated to 50°C with continuous stirring.
- The C. rotundus extract was dissolved into the warm hydrated gelatin.
- Pectin, sorbitol, and erythritol were combined and added to the gelatin mixture gradually.

2.5.2 Gel Formation

- The combined mixture was heated to 65°C under continuous stirring.
- Stevia extract and flavoring agent were introduced at 60°C.
- Ascorbic acid was incorporated at 50°C to minimize thermal degradation.
- The solution was maintained in the 60–65°C range to prevent premature gelation.

2.5.3 Molding

- The warm gel was dispensed into silicone molds at 1.5 g per cavity.

- Filled molds were maintained at ambient temperature for 6 hours.
- Demolded gummies were allowed to air-dry for 24 hours at 25°C and 45% RH.

2.5.4 Storage

- Gummies were packed in aluminum foil-lined containers with silica gel desiccant packets.
- Finished products were stored at 25°C ± 2°C and 60% RH ± 5%.

3. EVALUATION PARAMETERS

3.1 MASS UNIFORMITY

Mass uniformity was assessed to verify consistent dose administration. Ten gummies were individually weighed using a calibrated analytical balance, and the mean weight along with standard deviation were computed. Acceptance criteria required an average weight of 1.00 g, with individual unit variation not exceeding ±5%.

3.2 Weight Variation

Weight variation testing was conducted in accordance with USP guidelines using 20 individually weighed gummy units. The average weight was calculated, and each unit was assessed against the established limit. Not more than two gummies were permitted to fall outside the specified percentage limit, with none exceeding twice that limit.

3.3 Hardness

Hardness was determined for three randomly selected gummies per batch using a Monsanto Hardness Tester, with results expressed in kg/cm². The glycerin and tapioca syrup incorporated in the formulation are expected to contribute to the desired soft-to-firm textural properties. The acceptable range was defined as 2.5 to 3.5 kg/cm², consistent with soft gummy standards.

3.4 Thickness and Diameter

Thickness and diameter measurements were obtained using a Vernier Caliper for three gummies per batch. Uniformity was assessed relative to a standard heart-shaped gummy mold used consistently across all batches. Acceptable values were defined as a thickness of 8.2 mm ± 5% and a diameter of
22.0 mm ± 5%.

3.5 Friability

Friability was evaluated using a standard friabilator. Four gummies from each batch were rotated at 25 rpm for 4 minutes. Following the rotation, samples were de-dusted, re-weighed, and percentage weight loss was calculated. An acceptance limit of ≤1.0% weight loss was applied.

3.6 Loss on Drying (Moisture Content)

A 1 g sample from each formulation was placed in a hot-air oven at 105°C for 24 hours. Moisture content was determined by calculating the weight difference between the initial and post-drying measurements. Maintaining low moisture content ensures adequate shelf-life stability for the natural pectin-based gummy formulations. The acceptance limit was defined as ≤5.0%.

3.7 pH Determination

One gram of each gummy sample was dissolved in 10 mL of distilled water at 50°C, and the pH was measured using a calibrated digital pH meter. Citric acid within the formulation serves as a pH modifier, maintaining values within the mildly acidic range appropriate for herbal gummy preparations. The acceptable pH range was established as 3.5 to 5.5.

4. IN VIVO PHARMACOLOGICAL CONSIDERATIONS

The anxiolytic and sedative properties attributed to Cyperus rotundus are thought to arise through modulation of GABAergic neurotransmission, principally mediated by the plant's sesquiterpene and flavonoid constituents. These phytochemicals are believed to interact with $GABA_a$ receptor complexes, thereby facilitating inhibitory neurotransmission. This mechanistic basis provides a rational pharmacological framework for the incorporation of C. rotundus extract into functional nutraceutical gummy formulations targeted at populations seeking complementary support for anxiety and sleep-related conditions.

5. RESULT

The formulated sugar-free gummies of Cyperus rotundus were successfully evaluated for various physicochemical parameters, and all batches complied with acceptable limits for weight variation, hardness, friability, moisture content, thickness, diameter, and pH. Among the three formulations, batch F2 showed the most desirable properties with optimum hardness, better texture, low friability, and acceptable moisture content, indicating good stability and chewability. The antioxidant evaluation revealed that F2 exhibited the highest DPPH free radical scavenging activity along with maximum total phenolic and flavonoid content,

suggesting better retention of bioactive phytoconstituents. Stability studies performed under accelerated conditions showed no significant changes in physical appearance or phytochemical properties, confirming the stability of the developed formulation. Overall, the study demonstrated that Cyperus rotundus extract can be effectively incorporated into a sugar-free gummy dosage form with improved patient acceptability, stability, and therapeutic potential.

6. CONCLUSION

The present study demonstrates the feasibility of formulating standardized Cyperus rotundus rhizome extract into sugar-free gummy dosage forms with acceptable physicochemical attributes and stable phytochemical content. Formulation F2, incorporating intermediate gelatin and pectin concentrations, exhibited the most favorable overall profile. These findings support the broader application of gummy-based platforms for the delivery of plant-derived bioactives, offering a patient-friendly alternative to conventional dosage forms. The developed formulations show promise as functional nutraceuticals, particularly for diabetic and health-conscious populations requiring palatable herbal supplementation.

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