



INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Formulation And Evalution Of Prednisolone Corticosteroid Gummies

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ABSTRACT:

Prednisolone is a widely used corticosteroid for treating inflammatory and autoimmune conditions. However, its conventional dosage forms, such as tablets and syrups, often present challenges for pediatric patients due to bitter taste and difficulty in swallowing. Prednisolone is a corticosteroid medication commonly used to treat various condition such as inflammation, autoimmune diseases, and allergic reactions. Traditionally available in tablet and liquid form, prednisolone can be challenging to administer, especially for children or individuals with difficulty swallowing pills. To address this, the development of prednisolone gummies has emerged as a more patient-friendly alternative. Prednisolone gummies combine the therapeutic effects of prednisolone with the convenience of a chewable form. These gummies are designed to provide accurate dosing in an easy to consume format, improving patient adherence to treatment regimens. The formulation ensures that the active ingredient, prednisolone, is effectively delivered while maintaining stability and bioavailability. The main ingredient in hemp and cannabis, cannabidiol (CBD), is now more widely available because to changes in international regulations. Due in part to CBD's widespread promotion as an efficacious treatment for a wide range of illnesses, the market for CBD products has grown significantly. However, the U.S. Food and Drug Administration (FDA) has only approved one CBD medication to date, Epidiolex®. The medicinal potential of CBD, even for new indications not approved by the FDA, has sparked significant interest from consumers as well as the scientific and medical sectors. This review's objective was to compile the existing data from clinical studies pertaining to CBD oil's effectiveness as a medicinal substance.

Keywords: Prednisolone, CBD gummies, Anti Inflammatory, Corticosteroid, Pediatric Formulation, Oral Steroid, Immune Supression.

1. INTRODUCTION

Prednisolone is a corticosteroid used to treat inflammation, allergies, autoimmune diseases, and other conditions. While prednisolone is commonly available in tablets, liquid solutions, and injectable forms, gummy formulations are less common but may exist as a specialized dosage form for pediatric or patient-friendly administration.

1.1 Availability of Prednisolone Gummies:

1. Commercial Availability: Prednisolone gummies are not widely available as a standard pharmaceutical formulation. Most corticosteroid medications are provided in liquid or tablet forms due to stability and dosing precision.

2. Compounded Formulations: Some compounding pharmacies might prepare prednisolone in gummy form upon request, especially for children who have difficulty swallowing pills or dislike the taste of liquid formulations.

3. Alternative Forms: If a gummy form is not available, liquid prednisolone solutions with flavouring agents (e.g., Ora Sweet) are often used for pediatric patients.

Sugar is the primary ingredient in gummy jelly, a type of delicacy that belongs to the sweet gel category. Traditional gummies are made from fruit or herb juice combined with sugars and other ingredients that give them a sticky, dry texture that makes them difficult to chew. Desserts made from gel materials like gelatin combined with sweets like sugar and glucose syrup are known as gummy jelly or dry jelly.

CBD gummies are sweet, chewy candies infused with cannabidiol or CBD.

The hemp plant, a non-toxic variety of cannabis, is the source of CBD. It is one of many naturally occurring molecules found in cannabis called cannabinoids, which interact with the human nervous system and frequently have positive effects.

1.2 CBD Gummies:

More than 50 countries now have greater access to medical cannabis or cannabinoid-based pharmacotherapeutics because to recent developments in international policy. For instance, in the United States (U.S.), non-medical (or "recreational") cannabis use is permitted in 11 states while medical use is permitted in 33 states and the District of Columbia (D.C.). Several nations have legalized hemp in addition to cannabis, which is classified in the United States as cannabis that contains less than 0.3% of the psychoactive component Δ^9 -tetrahydrocannabinol, or THC. In fact, the U.S. Drug Enforcement Administration no longer considers hemp and its derivative products to be restricted narcotics after the U.S. Agriculture Improvement Act of 2018 (often known as the "Farm Bill") was approved. The retail market for goods based on cannabinoids has grown significantly as a result of these regulatory reforms. One of the main ingredients in many hemp and cannabis plants is cannabidiol, or CBD. Since hemp-derived CBD products are no longer regarded as banned substances, they are widely accessible in states where cannabis is still outlawed. As a result, they have become widely used. The formulation and intended method of ingestion of CBD products vary greatly. The majority of the industry is made up of oral CBD products, which might include food items like chocolates and gummies, beverages like sodas and teas, or CBD extracts suspended in a solution (tinctures, for example). In addition to oral products, there are numerous CBD products for topical application (such as lotions, gels, and balms), inhalation (such as vape pens, CBD-dominant hemp or cannabis plant material), and other routes of administration (such as sublingual). Additionally, there are growing markets for other CBD products like cosmetics, haircare items, and pet treats. According to BDS Analytics, the combined market for cannabis/hemp-based CBD products in the United States (including sales at retail, dispensaries, and pharmaceutical companies) is anticipated to reach over \$20 billion by 2024.

1.3. Pharmacology of Prednisolone

1. Summary: Prednisolone is a glucocorticosteroid used to treat certain types of cancer as well as inflammatory conditions related to adrenocortical insufficiency.

2. Generic Name: Prednisolone

3. Brand Names: Millipard Dp 6 Day

4. Context: Similar to cortisol, prednisolone is a glucocorticoid that has anti-inflammatory, immunosuppressive, anti-neoplastic, and vasoconstrictive properties.

5. Pharmacodynamics: By binding to the glucocorticoid receptor, corticosteroids suppress pro-inflammatory signals while enhancing anti-inflammatory ones. Because prednisolone has a half-life of 2.1 to 3.5 hours, its duration of effect is brief. One Because patients need doses that are multiples of what the body naturally generates, corticosteroids have a broad therapeutic window. It is important to advise patients on corticosteroids about the possibility of hypothalamic-pituitary-adrenal axis suppression and heightened infection susceptibility.

6. Mechanism of action: In the near term, corticosteroids reduce capillary permeability and vasodilation, as well as leukocyte migration to inflammatory areas. Multiple downstream effects occur over the course of hours to days as a result of corticosteroids' interaction to the glucocorticoid receptor, which causes changes in gene expression. Glucocorticoids suppress neutrophil demargination and death; they suppress phospholipase A2, which reduces the production of derivatives of arachidonic acid; they suppress NF-Kappa B and other transcription factors involved in inflammation; and they stimulate anti-inflammatory genes such as interleukin-10. While greater doses of corticosteroids suppress the immune system, lower amounts have an anti-inflammatory effect. Long-term high dosages of glucocorticoids raise sodium and lower potassium levels by binding to the mineralocorticoid receptor. [13] [14]

7. Absorption: Oral prednisolone has a Tmax of 1.0–2.6 hours and a Cmax of 113–1343 ng/mL. 1 About 70% of oral prednisolone is bioavailable.

8. Volume of distribution:

The volume of distribution for prednisolone doses of 0.15 mg/kg and 0.30 mg/kg is 29.3L and 44.2L, respectively.

9. Protein binding: In healthy individuals, prednisolone's protein binding varies greatly, ranging from 65 to 91%. Improved Patient Compliance. Sustained release formulations reduce the frequency of administration—often to once daily—thereby enhancing patient adherence, particularly in remote or underserved regions where patients may have limited access to medical guidance or transportation. By simplifying dosing schedules and minimizing side effects, SR tablets support completion.

10. Route of elimination:

Prednisolone is over 98% eliminated in urine.

11. Half-life : Prednisolone has a plasma half life of 2.1-3.5 hours.

12. Clearance:

Prednisolone has a clearance of 0.09L/kg/h at a dose of 0.15 mg/kg and 0.12L/kg/h at a dose of 0.30 mg/kg.

One The impact of biological variables on matrix tablet release

1.4 Advantages of gummies

Gummies have several advantages over pills, capsules, or liquids:

1. Taste: They're often tastier and easier to swallow.
2. Easy Consumption: They're simple to chew and swallow, suitable for all ages.
3. Portability: They're individually wrapped or come in small packages, easy to carry.
4. No Water Needed: Unlike pills, they don't require water for consumption.
5. Mask Unpleasant Tastes: They can hide the taste of medications.
6. Variety of Flavors: They come in many flavors to suit preferences.
7. Less Intimidating: Their fun shapes and colors make them less scary for some people.

2. AIM AND OBJECTIVE

Aim: Formulation And Evalution of prednisolone corticosteroid Gummies.

Objective:

1. To deliver prednisolone with more Patient compliance
2. Gummies can be administer any times anywhere without using water to administer
3. To bring administer on novel approach to prednisolone corticosteriod by formulating gummies.
4. prednisolone qummies more When than one can given therapeutic action to compared to CBD Gummies.
5. Enhance Taste Masking.
6. Ensure Accurate and Consistent Dosing.
7. Improve Bioavailability & Stability
8. Reduce Gastric Irritation.

3. MATERIAL AND METHOD**3.1 Materials Required**

- Active ingredients
- Excipients(Gelatin,sucrose,polysorbate80,orange essence,orange oil)
- Beaker
- machnical stirrer

3.2 Preparation of Glycerin And Orange Oil:

- 3 Drop Of Glycerin and orange oil mix the oil phase

3.3 Selection of Solvent:

- propylene glycol solvent (Viscosity Agent)For improved viscosity.

- The ethanol-water mixture ratio is 70:30.

3.4 Preparation of Gummies:

- Prednisolone drug dissolve in 30min for ethanol.
- Orange oil with glycerine mix properly
- Add Distilled Water with water batch mix Gelatin solution.
- Citric acid was introduced for flavor enhancement, enhancing the taste profile of the gummies.
- The mixture was heated and stirred until all ingredients were thoroughly combined, ensuring uniform.
- Sugar was added to the gel base for sweetness, ensuring the palatability of the gummies.
- Once the mixture reached a uniform consistency, it was poured into molds, forming the desired gummy shape.
- The filled molds were allowed to set at room temperature, allowing the gummies to solidify and take shape.
- After solidification, the gummies were carefully removed from the molds, resulting in the final product being ready for subsequent evaluation.

4. Batch Formulation:

Sr.no	Ingredient	F1	F2	F3	F4
1	Prednisolone	1g	1g	1g	1g
2	Gelatin	3gm	3.5gm	4gm	6gm
3	Propylene Glycol	1ml	1.5ml	2ml	3.5ml
4	Sucrose	2g	2.5g	3g	5g
5	Polysorbat 80	0.5ml	1ml	0.1ml	1ml
6	Orange essence	0.5ml	1ml	1ml	1ml
7	Orange oil	1ml	1ml	1ml	1ml
8	Water	Q.S	Q.S	Q.S	Q.S

5. EVALUTION PARAMETER

1. Appearance:

The prepared prednisolone gummies were smooth, semi-solid, and jelly-like in texture. They had a uniform shape, slightly glossy surface, and natural orange to yellow color.

2. Texture:

The texture of the gummies was soft, chewy, and resilient. They were easy to bite without being sticky or brittle. The use of gelatin provided good firmness and elasticity, ensuring acceptable mouthfeel.

**Firmness Testing****Hardness tester of gummies**

3. Odour:

The gummies had a mild, due to the presence of orange essence. There was no foul or irritating smell, indicating good formulation and stability.

4. Colour:

The colour of the gummies ranged from light orange colour, influenced by the natural pigments. The colour was uniform throughout each gummy and visually acceptable without artificial additives.

**Images of Gummies**

5. Determination of pH:

A 10% v/v Gummy solution was constituted in distilled water, and the pH of the solution was measured using a calibrated pH meter.

**pH of Gummies**

7. Weight Variation Test

The weight variation test ensures uniformity in the dosage form. For 2 g gummies, individual gummies were weighed, and the average weight was calculated. The deviation of each gummy from the average was checked.

Acceptance Criteria: According to pharmacopeial standards, the individual weight should not deviate by more than $\pm 5\%$ from the average weight for units > 250 mg.

Average weight: 2.0 g Acceptable range: 1.9 g to 2.1 g

8. Stability Study

To guarantee that prednisolone gummies retain their quality, effectiveness, and safety over the course of their shelf life, a stability study is necessary. The study assesses the gummies' stability over time in terms of their physical, chemical, and microbiological properties under varied storage circumstances. For up to three months, prednisolone gummies can be kept at ambient temperature ($25 \pm 2^\circ\text{C}$), at accelerated circumstances ($40 \pm 2^\circ\text{C}$ with $75 \pm 5\%$ RH), or in the refrigerator ($5 \pm 3^\circ\text{C}$ with low humidity).

10. Stickiness:

The medicated jelly's stickiness was assessed visually by examining the product following a gentle rub of the jelly sample between two fingers.

11. Dissolution

Increase the water's temperature, which serves as the dissolving medium, to 36.5 to 37.5° . Put one gummy dose unit inside the device, cover the vessel, and operate the device at the set pace. After operating in the acid medium for two hours, remove a portion of the liquid and quickly move on to the buffer stage as directed.



Dissolution apparatus

12. Gummy absorption: Put a gummy in a glass of water and observe how long it takes for the gummy to dissolve.

13. Dissolution of gummies:

Dissolution studies are a popular technique for simulating the behavior of pharmacological doses in vitro and forecasting their efficacy and bioavailability. Formulations released almost all of their substance in 120 minutes, as seen in the figure, but their dissolution profiles differed greatly. After 15 minutes, concentrations in one formulation approached 100%, suggesting a more rapid release profile. On the other hand, after 45 minutes, only 60% of the vitamins A and D were dissolved in F2 (blue) (R(+))CS(+)).



Absorption of gummies

6. RESULT AND DISCUSSION

2. Table No 6 Result

Sr. No	Parameter	F1	F2	F3	F4
1	Apperance	slightly glossy surface, and natural brownish-yellow to light green colour	slightly glossy surface, and natural brownish-yellow to light green colour	slightly glossy surface, and natural brownish-yellow to light green colour	slightly glossy surface, and natural brownish-yellow to light green colour
2	Texture	easy to bite but sticky	easy to bite but sticky and brittle	easy to bite without being sticky or brittle	easy to bite but sticky
	A. Hardness				
	B. Firmness	gelatin provided good firmness and elasticity	gelatin provided good firmness and elasticity	gelatin provided good firmness and elasticity	gelatin provided good firmness and elasticity
	Softness	soft, chewy, and resilient	soft, chewy, and resilient	soft, chewy, and resilient	soft, chewy, and resilient
3	Odour	mild, pleasant orange aroma	mild, pleasant orange aroma	mild, pleasant orange aroma	mild, pleasant orange aroma
4	pH Value	5.66	5.45	6.01	5.20
5	Taste	Sweet, slightly bitter, herbal with refreshing aftertaste	Sweet, slightly bitter, herbal with refreshing aftertaste	Sweet, slightly bitter, herbal with refreshing aftertaste	Sweet, slightly bitter, herbal with refreshing aftertaste
7	Weight variation (Average Weight)	1.40gm	1.52gm	1.99gm	2.29gm
8	Stickiness	Slightly sticky	Sticky	Non-sticky	Sticky

3. Solubility test:

Sr. No	Solvent	Solubility	Time to Dissolve	Impact of Temperature	Impact of pH
1	Water	Moderate to high	30-120 min	Increase Solubility	Neutral to Basic
2	Ethanol	Poor to None	No significant change	Slight Swelling	Minimal

4. Moisture content:

Batches	Initial Weight (g)	Final Weight (g)	Moisture Content (%)
F1	2.00	1.85	7.5%
F2	2.00	1.80	10.0%
F3	2.00	1.82	8.5%
F4	2.00	1.78	11.0%

5. Stability study:

Over the course of the three-month research, the gummy preparation remained stable at room temperature and at $25 \pm 2^\circ\text{C}$ and $60\% \pm 5\%$ relative humidity.

CONCLUSION

The formulated gummies Prednisolone gummies offer a palatable and convenient alternative to traditional tablets or liquid forms, particularly for children and individuals who have difficulty swallowing pills. They can improve medication adherence due to their ease of use and better taste. However, like all corticosteroid medications, prednisolone gummies must be used under medical supervision, as they carry the same risks and side effects as other forms, including immune suppression, mood changes, and potential growth suppression in children with prolonged use. Proper dosing and monitoring are essential to ensure safety and effectiveness.

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