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Review Article

A Brief Review on Formulation and Evaluation of Corticosteroid Prednisolone 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 conditions 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. Global policy changes have increased access to products containing cannabidiol (CBD), a primary constituent of hemp and cannabis. The CBD product industry has experienced tremendous growth, in part, because CBD is widely touted as an effective therapeutic for myriad health conditions. However, only CBD product (Epidiolex®) has been approved by the U.S. Food and Drug Administration (FDA) to date. There is substantial interest among consumers and the medical and scientific communities regarding the therapeutic potential of CBD, including for novel indications that are not recognized by the FDA. The purpose of this review was to synthesize available evidence from clinical research regarding the efficacy of CBD oil as a therapeutic agent.

INTRODUCTION

Prednisolone is a corticosteroid used to treat inflammation, allergies, autoimmune diseases, and other conditions. While prednisolone is commonly

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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]

➤ **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.^{[1][2]}

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.^{[1][2]}

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.^[1] Gummy jelly is a kind of confectionery products in a group of candy gel whose main ingredient is sugar. Traditional gummy is a product of fruit or herb juice mixed with sweeteners and substances causing gel to make product with a dry-sticky texture and are tough to chew. Gummy jelly or dry jelly is dessert products derived from the gel substances such as gelatin mixed with sweeteners including sugar and glucose syrup.^{[1][2]} CBD gummies are sweet, chewy candies infused with cannabidiol or CBD.^[1] CBD is an extract of the hemp plant, a non-intoxicating breed of cannabis. It's one of a multitude of cannabinoids, the naturally occurring compounds in cannabis that interact with the human nervous system, often with beneficial effects.^{[1][2]}

➤ **CBD Gummies:**

Recent global policy changes have increased access to medical cannabis or cannabinoid-based pharmacotherapeutics in over 50 countries. In the United States (U.S.) for example, medical cannabis use is legal in 33 states and the District of Columbia (D.C.) and non-medical use (i.e., “recreational”) is legal in 11 states.^[6] In addition to cannabis, the legalization of hemp (defined in the U.S. as cannabis with $\leq 0.3\%$ of the psychoactive cannabis constituent Δ -9-tetrahydrocannabinol, THC) has expanded in many countries. Indeed, with the approval of the U.S. Agriculture Improvement Act of 2018 (i.e., the “Farm Bill”), hemp and its derivative products are no longer considered controlled substances by the U.S. Drug Enforcement Administration.^{[6][7]} These legislative changes have led to the emergence of a large, and growing, retail market of cannabinoid-based products. Cannabidiol (CBD) is a chief constituent of many cannabis and hemp plants. Hemp-derived CBD products have become ubiquitous because they are no longer considered controlled substances, meaning they are widely available in jurisdictions in which cannabis remains illegal. CBD products vary widely in regards to their formulation and intended route of administration. Oral CBD products make up the majority of the market, and these products may consist of CBD extracts suspended in a solution (e.g., tinctures), food products (e.g., chocolates, gummies), or beverages (e.g., sodas, teas). Beyond oral products, CBD products intended for inhalation (e.g., vape pens, CBD-dominant hemp or cannabis plant material), topical application (e.g., lotions, gels, balms), and other routes of administration (e.g., sublingual) abound; there are also burgeoning markets for other CBD products such as cosmetics, haircare products, and pet treats. The collective market for cannabis/hemp-based CBD products (including retail, dispensary, and pharmaceutical sales) is



expected to exceed \$20 billion in the U.S. by 2024 (BDS Analytics).^{[6][7]}

➤ Pharmacology of Prednisolone

Summary

Prednisolone is a glucocorticoid used to treat adrenocortical insufficiency, inflammatory conditions, and some cancers.

Brand Names: Millipred Dp 6 Day

Generic Name: Prednisolone

Background: Prednisolone is a glucocorticoid similar to cortisol used for its anti-inflammatory, immunosuppressive, anti-neoplastic, and vasoconstrictive effects.^{[13][14]}

Pharmacodynamics:

Corticosteroids bind to the glucocorticoid receptor, inhibiting pro-inflammatory signals, and promoting anti-inflammatory signals.⁴ Prednisolone has a short duration of action as the half life is 2.1-3.5 hours.¹ Corticosteroids have a wide therapeutic window as patients make require doses that are multiples of what the body naturally produces.⁴ Patients taking corticosteroids should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.^{[13][14]}

Mechanism of action:

The short term effects of corticosteroids are decreased vasodilation and permeability of capillaries, as well as decreased leukocyte migration to sites of inflammation.⁴ Corticosteroids binding to the glucocorticoid receptor mediates changes in gene expression that lead to multiple downstream effects over hours to days.^{[13][14]}

Glucocorticoids inhibit neutrophil apoptosis and demargination; they inhibit phospholipase A2, which decreases the formation of arachidonic acid derivatives; they inhibit NF-Kappa B and other inflammatory transcription factors; they promote anti-inflammatory genes like interleukin-10.⁴ Lower doses of corticosteroids provide an anti-inflammatory effect, while higher doses are immunosuppressive.⁴ High doses of glucocorticoids for an extended period bind to the mineralocorticoid receptor, raising sodium levels and decreasing potassium levels.^{[13][14]}

Absorption:

Oral prednisolone reaches a Cmax of 113-1343ng/mL with a Tmax of 1.0-2.6 hours.¹ Oral prednisolone is approximately 70% bioavailable.^{[10][11]}

Volume of distribution:

A 0.15mg/kg dose of prednisolone has a volume of distribution of 29.3L, while a 0.30mg/kg dose has a volume of distribution of 44.2L.^{[10][11]}

Protein binding:

Prednisolone's protein binding is highly variable, ranging from 65-91% in healthy patients.¹ Improved Patient Compliance^{[10][11]} 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][11]}

Route of elimination:

Prednisolone is over 98% eliminated in urine.¹^{[10][11]}



Half-life : Prednisolone has a plasma half life of 2.1-3.5 hours. ^{[10][11]}

A 0.15mg/kg dose of prednisolone has a clearance of 0.09L/kg/h, while a 0.30mg/kg dose has a clearance of 0.12L/kg/h. Biological factors influencing release from matrix tablet: ^{[10][11]}

Clearance:

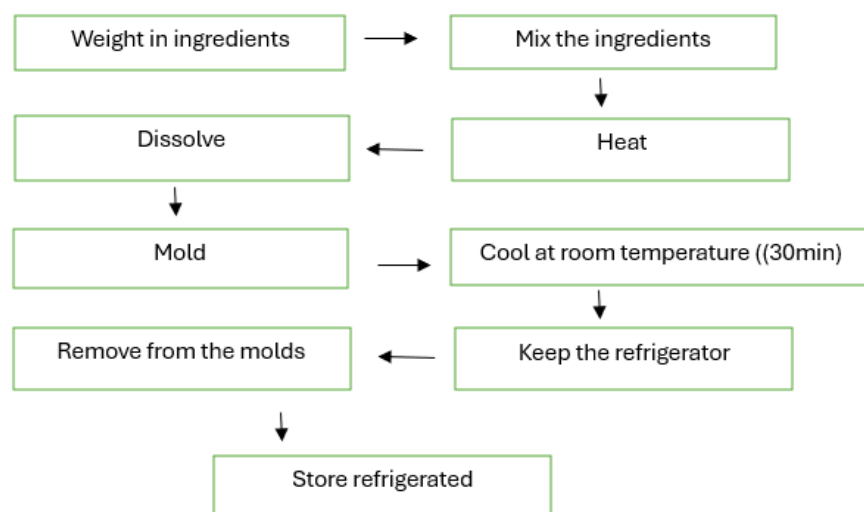


Figure:1 ^[22]

➤ Standard Gummy Formulation

A gummy is a rubbery-textured gelatin dessert created with flavour, acid, bulk sweeteners, and colours. In addition to stabilizing the product, the distinctive texture of gummies sets them apart the gelatin .Collagen is the source of gelatin, a gelling agent. Generally speaking, a gummy has 6 to 8 per cent gelatin, although you can use more or less depending on the texture you want. The ingredients in Gummies are rather simple: sweeteners, stabilizers, flavours, and colours. Nonetheless, several modifications result in a diverse array of profiles and textures Gelatin comes in two varieties: Type A and Type B. Type A gelatin is utilized in the formulations shown in The term "type" describes the method used to extract gelatin. ^[22] Type B is an alkali extraction, whereas Type A is an acid extraction. The most common source of Type A gelatin is pork skin, while the most common source of Type B gelatin is bones. The isoelectric point of the two gelatin varieties differs primarily; Type B's is 4.7 to 5.4

and Type A's is 7.0 to 9.0. There is a large variety of bloom or gel strengths for gelatins. ^[22] More costly gummies typically have firmer gelatin due to a higher bloom number. Gelatin typically has a bloom of 125 to 250, although there are instances of lower and greater blooms. Changing the bloom strength, from a greater to a lesser bloom, is a simple method to cut sugar while maintaining product quality, cost, and texture optimization. If variations in gelatin blooms are of significance, the serves as an excellent resource for facilitating a seamless transition in formulation. It's crucial to remember that gelatins with a lower bloom strength tend to result in gummies with a more chewy, elastic texture Variations in gelatin composition are not the only thing that might cause gummies to have different textures. The amount of corn syrup in a recipe, as well as the corn syrup's dextrose equivalent (de) and associated carbohydrate profile, are additional variables that impact texture. ^[22] Often, the main component of gummies is corn syrup. Corn syrup serves as an anti-crystallizer and provides the gummy body.

These anti-crystallizing qualities extend the shelf life of the product in addition to preventing crystallization. [22] Variations in gelatin composition are not the only thing that might cause gummies to have different textures. These anti-crystallizing qualities extend the shelf life of the product in addition to preventing crystallization. Higher de-syrups provide sweetness, reduce viscosity, and extend shelf life, whereas lower de-syrups typically give a gummi body and strength. [22] The quantity of reducing sugars (dextrose/glucose) in the product is known as its "dextrose equivalent," and when corn syrup is thinner, the cooked sugar slurry becomes less sticky and simpler to deposit. In addition to being sweeter than lower de, higher de also somewhat increases the final product's stability. These alterations are accompanied by a shift in texture. A product with a higher de corn syrup content will be less chewy and softer than one with a lower de corn syrup content. [22]



Figure: 2

➤ **Anti-inflammatory action of corticosteroids:**

The anti-inflammatory action of corticosteroids is complex. At a cellular level, they cause redistribution of granulocytes, resulting in increased circulating granulocytes and reduced tissue pools. They also cause lymphopenia. [23] The significance of these phenomena in relation to the

anti-inflammatory activity of steroids is unknown. The most obvious pharmacological effects of corticosteroids are seen on blood vessels. They cause adrenergically mediated vasoconstriction and non-competitive antagonism of vasodilation due to prostaglanin E and bradykinin. Prostaglandin formation is inhibited by corticosteroids but whether this is due to an effect on enzymic synthesis or release is uncertain. Corticosteroids stabilize the lysosomal membrane preventing release of lysosomal enzymes in vitro but the significance of this in vivo is debatable. [23].

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