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## Review Article on Prednisone Tablet

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### ABSTRACT

Rheumatoid arthritis (RA) is a chronic, systemic autoimmune disorder characterized by persistent synovial inflammation, joint destruction, and functional disability. Pharmacologic management aims to control inflammation, prevent joint damage, and maintain quality of life. Among therapeutic agents, Prednisone, a synthetic glucocorticoid, plays a key role in both initial and adjunctive treatment strategies. Prednisone exerts potent anti-inflammatory and immunosuppressive effects by inhibiting pro-inflammatory gene expression through glucocorticoid receptor-mediated pathways. Despite its efficacy in rapidly reducing disease activity and bridging therapy until disease-modifying antirheumatic drugs (DMARDs) take effect, long-term prednisone use is limited by adverse effects such as osteoporosis, hyperglycemia, and adrenal suppression.

**KEY WORDS:** Rheumatoid arthritis, Prednisone tablet, Preformulation studies, formulation, Evaluation, Documentation

### INTRODUCTION TO RHEUMATOID ARTHRITIS

Rheumatoid arthritis (RA) is a chronic, systemic autoimmune disease that primarily affects the joints, causing inflammation, pain, swelling, and stiffness. Unlike osteoarthritis, which results from wear and tear, RA occurs when the immune system mistakenly attacks the synovium—the lining of the membranes that surround the joints. This immune response can eventually lead to joint damage, loss of function, and deformities. RA commonly affects joints symmetrically, such as those in the hands, wrists, and knees, and may also impact other organs, including the lungs, heart, and eyes. The exact cause of RA is unknown, but it is believed to involve a combination of genetic, environmental, and hormonal factors. Early diagnosis and treatment are crucial to managing symptoms, preventing joint damage, and improving quality of life.



### SYMPTOMS

Rheumatoid arthritis (RA) is an autoimmune disease that causes joint pain, swelling, stiffness, and fatigue. It usually affects joints on both sides of the body, especially the hands, wrists, and knees. Morning stiffness lasting over 30 minutes is common. Over time, RA can lead to joint damage and deformity. It may also affect other parts of the body like the eyes, lungs, heart, and skin. Early diagnosis and treatment are key to managing symptoms and preventing long-term damage.

### PREDNISONE

Prednisone is commonly used as an anti-rheumatic drug, particularly in the treatment of inflammatory rheumatic diseases like: Rheumatoid arthritis (RA)

Prednisone is a glucocorticoid, a type of corticosteroid that:

- Suppresses the immune response
- Reduces inflammation

- Decreases swelling and pain
- ✓ It doesn't cure rheumatic diseases but helps control flare-ups and symptoms, especially while waiting for other disease-modifying antirheumatic drugs (DMARDs) like methotrexate to take effect.

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## MECHANISM OF ACTION

- Prednisone enters cells, binds to intracellular glucocorticoid receptors, and then alters gene expression, leading to a cascade of effects that reduce inflammation and modulate the immune system.
- The effects of glucocorticoids are mediated by both genomic and non-genomic mechanisms.
- Genomic mechanisms: involve the binding of prednisone to glucocorticoid receptors in the cell nucleus, leading to changes in gene expression and the production of proteins that inhibit inflammation.
- Non-genomic mechanisms: involve rapid effects that do not require changes in gene expression, such as the stabilization of cell membranes and the inhibition of inflammatory mediators.

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## PREFORMULATION STUDIES

### 1. Organoleptic Properties

- a. Colour: Prednisone is usually a white to off-white crystalline powder, which is ideal for incorporation into various solid dosage forms.
- b. Odor: It is odourless, reducing the likelihood of patient aversion.
- c. Taste: Slightly bitter, though this property is typically masked in oral solid dosage forms through film coating or flavoring agents in dispersible or chewable forms.

### 2. Physical Properties

- a. Physical Form: Prednisone exists in a crystalline form, which is stable under normal manufacturing conditions.
- b. Melting Point: The melting range is approximately 230–235°C, suggesting high thermal stability and suitability for processing without risk of degradation.

### 3. Micromeritic Properties

- a. Particle Size and Distribution: Fine particle size improves dissolution rate but may negatively affect flow properties. Optimizing particle size is crucial for balancing manufacturability and bioavailability.
- b. Particle Shape: Non-spherical particles like prednisone tend to have poor flow, impacting uniformity during blending and compression.
- c. Flow Properties: Poor flowability necessitates the use of flow-enhancing agents such as glidants (colloidal silicon dioxide).

### 4. Chemical Properties

- a. Solubility: Prednisone is practically insoluble in water, which may limit its absorption rate. It is soluble in organic solvents like alcohol and chloroform. Enhancement strategies include micronization, complexation, or use of surfactants
- b. pKa: ~12.6, indicating it is weakly acidic. It remains unionized at physiological pH, promoting passive membrane diffusion.
- c. LogP: ~1.6, indicating moderate lipophilicity. It has sufficient lipid solubility for membrane permeability while retaining some hydrophilic character for solubility in physiological fluids.
- d. Chemical Stability:
  - i. Oxidation: Prednisone is prone to oxidative degradation in presence of air or light; antioxidants or inert atmosphere packaging may be used.
  - ii. Hydrolysis: It does not undergo significant hydrolysis at physiological pH, which enhances oral stability.
  - iii. Isomerization: Prednisone is a prodrug that undergoes enzymatic reduction in the liver to form prednisolone, the active pharmacological form.

### 5. Stability Studies

- a. Thermal Stability: Stable at standard processing temperatures used in granulation and compression.
- b. Light Sensitivity: Degrades when exposed to light; packaging in amber bottles or opaque blister packs is essential.

- c. Moisture Sensitivity: Being hygroscopic, prednisone absorbs moisture, leading to potential degradation. Storage in tight containers with desiccants is advised.
- d. Storage Conditions:
  - Recommended storage at controlled room temperature (15°C–25°C).
  - Avoid exposure to direct light and high humidity.
  - Label should indicate: 'Store in a dry place, protected from light.'

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## FORMULATION OF PREDNISONE TABLET

### DIRECT COMPRESSION METHOD

Direct compression is a process by which tablets are compressed directly from the powder blend of active pharmaceutical ingredients (APIs) and excipients, without any preliminary granulation steps.

#### Why Direct Compression for Prednisone?

Prednisone is potent, meaning small doses are used (e.g., 1 mg to 50 mg), and it's chemically stable. This makes it a good candidate for direct compression. However, prednisone has poor flowability and compressibility, so formulation with proper excipients is critical.

#### Steps in Direct Compression of Prednisone Tablets

##### Step 1: Pre-mixing / Sieving

- Prednisone and other ingredients are sieved to break up lumps and ensure uniform particle size.
- This ensures uniform distribution and content uniformity, which is important for low-dose drugs like prednisone.

##### Step 2: Blending

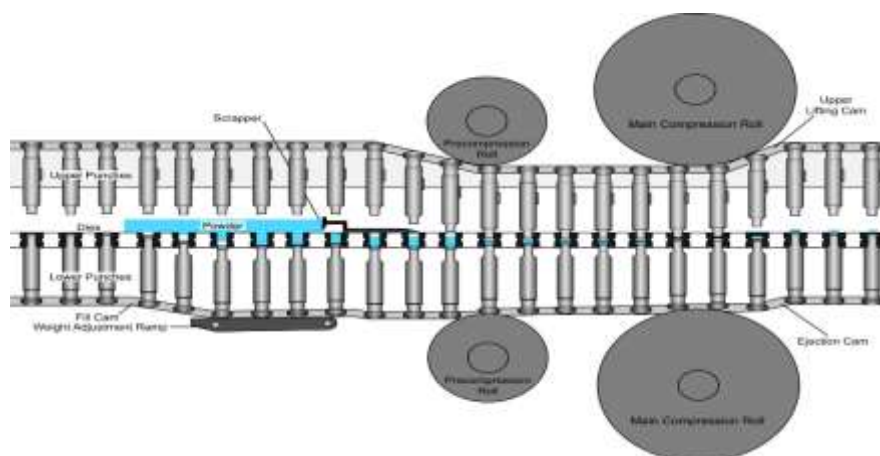
The API (prednisone) is mixed with functional excipients, including:

- Diluent/filler (e.g., microcrystalline cellulose, lactose): Improves bulk and flow.
- Binder (e.g., MCC also acts as binder in DC): Helps particles stick together.
- Disintegrant (e.g., sodium starch glycolate, croscarmellose sodium):
  - Ensures the tablet breaks down quickly in the digestive tract.
  - Lubricant (e.g., magnesium stearate): Prevents sticking to the die and punch.
  - Glidant (e.g., colloidal silica): Improves powder flow.

- ✓ Blending is done in a tumble blender or V-blender to ensure uniform distribution of prednisone throughout the mix.

##### Step 3: Compression

- The blended powder is directly fed into a tablet press.
- The press compresses the powder into tablets of uniform weight, hardness, and content.
- No granulation or drying steps are needed.



## EVALUATION OF PREDNISONE TABLETS

### 1. Organoleptic characters

Purpose: Check for any deviations or defects in appearance, odor, texture

Method: Visual Inspection

### 2. Uniformity of Dosage Units

Purpose: Ensure each dosage unit delivers intended amount of drug

Methods:

- Weight variation test (for tablets with high drug load):  $\pm 5\%$  of average weight
- Content uniformity test (for low-dose tablets): 85% - 115% of labeled amount

### 3. Assay

Purpose: Determine the actual amount of prednisone per tablet.

Criteria: Typically, 90%–110% of the label claim.

Methods: HPLC or UV spectrophotometry.

### 4. Hardness (Crushing Strength)

Purpose: Evaluate mechanical strength for handling and transport.

Optimal Range: Depends on formulation but often 4 -10 kg/cm<sup>2</sup>

### 5. Friability

Purpose: Assess tablet resistance to chipping or breaking.

Limit: Less than 1% weight loss after rotation in a friabilator.

### 6. Disintegration Test

Purpose: Ensure the tablet breaks down into smaller fragments in liquid medium in a specified time.

Typical Limit: Tablets must disintegrate within 15–30 minutes.

### 7. Dissolution Testing

Purpose: Measure the rate and extent to which prednisone dissolves from the tablet.

USP Standard: Often requires  $\geq 80\%$  of drug to be released within 30–45 minutes.

Method: USP Apparatus II (paddle method), with spectrophotometric or chromatographic analysis.

### 8. Stability Testing

Purpose: Determine shelf-life and appropriate storage conditions.

Conditions:

- Long-term (25°C/60% RH)
- Accelerated (40°C/75% RH)

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## PACKAGING, STORAGE AND LABELING

Packaging:

- Primary: Blister packs, HDPE bottles
- Secondary: Cartons
- Needs: Moisture/light protection, regulatory compliant

Labeling:

- Includes name, strength, dose, route, storage, warnings, batch & dates
- Must be clear & durable

Storage:

- Temp: 15–25°C
- Dry place, protect from light
- Use tight, opaque containers

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## DOCUMENTATION

### 1. BATCH FORMULA RECORD

A Batch Formula Record (BFR) documents the specific formulation and manufacturing instructions for a particular batch of a product, typically in the pharmaceutical or chemical industry.

It include,

1. Batch Details
2. Ingredients
3. Manufacturing Process
4. Quality Control
5. Packaging and Labeling
6. Documentation and Signatures

### 2. MASTER FORMULA RECORD

A Master Formula Record (MFR) is a comprehensive document in pharmaceutical manufacturing that outlines the details of a product's manufacturing.

It includes,

1. Chemical and Physical Data
2. Formulation Details
3. Manufacturing Process
4. Quality Control
5. Other Important Information

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## REFERENCES

1. Aulton, M. E., & Taylor, K. (2017). Aulton's Pharmaceuticals: The Design and Manufacture of Medicines (5th ed.). Elsevier Health Sciences.

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2. Allen, L. V., Popovich, N. G., & Ansel, H. C. (2013). *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems* (10th ed.). Wolters Kluwer.
  3. Rowe, R. C., Sheskey, P. J., & Owen, S. C. (2006). *Handbook of Pharmaceutical Excipients* (6th ed.). Pharmaceutical Press.
  4. Smolen JS, Aletaha D, McInnes IB. Rheumatoid arthritis. *Lancet*. 2016
  5. Bullock J, Rizvi SAA, Saleh AM, Ahmed SS, Do DP, Ansari RA, Ahmed J. Rheumatoid Arthritis: A Brief Overview of the Treatment. *Med Princ Pract*.
  6. Pawar VA, D'mello PM. Formulation and evaluation of prednisone tablets using direct compression method. *Int J Pharm Tech Res*. 2011.
  7. Goudanavar PS, Patil MB. Formulation and evaluation of prednisone matrix tablets using natural polymers. *Int J Pharm Sci Rev Res*. 2010.
  8. Desai J, Koli A, Joshi S, Shaikh T. Formulation and evaluation of prednisone tablets by direct compression method. *Int J Pharm Sci Invent*. 2014.
  9. Patel JP, Shah JS. Formulation and in vitro evaluation of sustained release matrix tablets of prednisone using hydrophilic polymers. *Int J Pharm Sci Res*. 2013.
  10. Kulkarni U, Suresh S, Mahesh M, Hiremath D. Formulation development and evaluation of oral sustained release matrix tablets of prednisone. *Int J Res Pharm Chem*. 2011.