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REVIEW ARTICLE ON FORMULATION AND EVALUATION OF SEASONIQUE (ETHINYLESTRADIOL AND LEVONORGESTROL) MATRIX TABLETS BY USING VARIOUS POLYMERS

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ABSTRACT

The aim of this study was to prepare matrix tablets of ethinyl estradiol and levonorgestrel using different polymers for controlled drug release in PCOS treatment. The tablets were prepared by the direct compression method. Compatibility studies showed no interaction between the drugs and excipients.The prepared tablets were evaluated for physical properties and drug content, and all results were within acceptable limits. In-vitro dissolution studies showed that the polymers helped in sustained release of the drugs for a longer time. The optimized formulation provided controlled release and good tablet quality.This study concludes that matrix tablets are a simple and effective approach for sustained delivery of ethinyl estradiol and levonorgestrel, which may improve patient compliance in PCOS management.

KEYWORDS: Ethinyl estradiol, Levonorgestrel, Matrix tablets, Polymers, Sustained release, PCOS, Oral drug delivery system.

INTRODUCTION

Drug delivery is closely linked with dosage form and route of administration, the latter of which is sometimes considered to be part of the definition.[1] Although the terms are often used interchangeably, they represent distinct concepts. The route of administration refers specifically to the path by which a drug enters the body,[2] such as oral, parenteral, or transdermal.[3] In contrast, the dosage form refers to the physical form in which the drug is

manufactured and delivered, such as tablets, capsules, patches, inhalers or injectable solutions. These are various dosage forms and technologies which include but not limited to nanoparticles, liposomes, microneedles, and hydrogels that can be used to enhance therapeutic efficacy and safety.[4] The same route can accommodate multiple dosage forms; for example, the oral route may involve tablet, capsule, or liquid suspension. While the transdermal route may use a patch, gel, or cream.[5] Common routes of administration include oral, parenteral (injected), sublingual, topical, transdermal, nasal, ocular, rectal, and vaginal. However, modern drug delivery continues to expand the possibilities of these routes through novel and hybrid approaches.[6]

ADVANTAGES OF NDDS

- Drugs are protection from physical and chemical degradation.
- It 1provide sustained delivery.
- NDDS improved tissue macrophages distribution.
- Enhancement of drug stability.
- Enhancement of pharmacological activity.

DISADVANTAGES Of NDDS

- Requires skilled man power for manufacturing,
- storage and administration
- Difficult to maintain stability of dosage forms
- Drug loading can be slow
- Dose dumping can occur.

CLASSIFICATION OF NDDS BASED ON DRUG RELEASE PROFILE

1. Immediate Release System

Example: Soluble tablets of paracetamol, aspirin.

2. Sustained Release Systems

Example: Sustained-release tablets of Diclofenac, Propranolol.

3. Controlled Release Systems

Example: Zero-order release osmotic pump systems like Glucotrol XL.

4. Delayed Release Systems

Example: Enteric-coated tablets that resist stomach acid and dissolve in the intestine (e.g., omeprazole EC tablets).

CLASSIFICATION OF NDDS BASED ON ROUTE OF ADMINISTRATION:

1. Oral Drug Delivery Systems

Examples: Osmotic pumps, Floating tablets, Colon-targeted systems

2. Transdermal Drug Delivery Systems

Examples: Transdermal patches (e.g., nicotine, fentanyl), Microneedle arrays

3. Parenteral Drug Delivery Systems

Examples: Liposomes, Nanoparticles, Depot injections

4. Ocular Drug Delivery Systems

Examples: In situ gels, Ocular inserts, Nanomicelles

5. Nasal Drug Delivery Systems

Examples: Nasal sprays, Nanoparticle suspensions

6. Pulmonary Drug Delivery Systems

Examples: Dry powder inhalers (DPI) Nebulizers, Liposomal aerosols

7. Buccal and Sublingual Systems

Examples: Mucoadhesive films, Fast-dissolving tablets

8. Rectal and Vaginal Drug Delivery Systems

Examples: Suppositories, Vaginal rings.

APPLICATIONS of NDDS

- Cancer therapy – Targeted nanoparticles, liposomes (e.g., Doxil)
- Diabetes management – Sustained-release insulin systems
- Cardiovascular diseases – Controlled-release antihypertensives
- Neurological disorders – Brain-targeted nasal or nanoparticulate delivery
- Ophthalmic diseases – Ocular inserts for glaucoma
- Infectious diseases – Sustained antibiotic release
- Hormone therapy – Vaginal rings, transdermal patches
- Vaccines – Nanocarrier-based vaccine delivery.

MATRIX DOSAGE FORM

INTRODUCTION

Historically, the oral route is considered as a most popular route in the administration of the drug. This is because of the fact the gastrointestinal physiology offers more flexibility in designing dosage form than any other route. Approximately 50% of the drug products available in the market are administered orally. Tablets are the most commonly and widely

used dosage form. This type of drug delivery system is called conventional drug delivery system and is known to provide an immediate release of the drug. Such immediate release products result in relatively rapid drug absorption and the onset of accompanying pharmacodynamics effect.

ADVANTAGES OF ORAL MATRIX SYSTEMS

- Easy to Manufacture
- 'Dose dumping' and toxic effects due to high plasma concentration are reduced.
- Improvement in patient compliance.
- . Better control of therapeutic drug concentration.
- Improvement in bioavailability of some drugs.

Disadvantages of Oral Controlled Release Formulations

- The drug release rate can be altered by food and gastric transit time; as a result, differences may arise in the release rate between doses.
- If the formulations are crushed or chewed, it can lose the 'slow release' characteristics and possess toxicity

POLYMERS USED IN MATRIX TABLETS

Polymers used for matrix tablets may be classified as.

Table No. 1: Polymers used in matrix tablets.

POLYMERS USED IN MATRIX TABLETS	EXAMPLES
hydrogels	Polyhydroxy ethyl, polyethylene oxide
Soluble polymers	Polyethylene glycol, hydroxy propyl, methyl cellulose, polyvinyl alcohol
Biodegradable polymers	Polylactic acridology glycolic acid, polyanhydrides
Non-biodegradable polymer	Polyethylene vinyl acetate, poly vinyl acetate, poly vinyl chloride, cellulose acetate
Muco-adhesive polymer	Polycarbophil, tragacanthin, methyl cellulose pectin
Natural gums	Xanthan, guar gum, karaya gum, gum Arabic locust bean gum

METHOD OF PREPARATION

1. Direct Compression Method
2. Wet Granulation Method
3. Melt Granulation (Thermal Fusion Method)

Other Methods (Less Common).

- Hot-Melt Extrusion
- Spray Drying
- Ionotropic Gelation (for polysaccharide matrices like alginate).

Manufacturing Steps

- ❖ Mixing: Drug + polymer + diluents
- ❖ Granulation: Wet or dry granulation (based on excipients)
- ❖ Drying: If wet granulated
- ❖ Sieving: For uniform granule size
- ❖ Blending: With lubricant and glidant
- ❖ Compression: Using tablet press.

Evaluation Parameters

1. Weight variation
2. Hardness
3. Friability
4. Drug content
5. In vitro drug release
6. Swelling index (for hydrophilic matrices[).]

POLYCYSTIC OVARY SYNDROME (PCOS)

INTRODUCTION

Polycystic ovary syndrome, or polycystic ovarian syndrome, (PCOS) is the most common endocrine disorder in women of reproductive age. The name is a misnomer, as not all women with this condition develop cysts on their ovaries. The name originated from the observation of cysts which form on the ovaries of some women with this condition. However, this is not a universal symptom and is not the underlying cause of the disorder.

Table No. 2: pcos.

POLYCYSTIC OVARY SYNDROME	
Other names	Hyperandrogenic anovulation (HA) Stein-Leventhal syndrome
Specialty	Gynecology, endocrinology
Symptoms	Irregular menstrual periods, heavy periods, excess hair, acne.
Complications	Type 2 diabetics, obesity, obstructive sleep apnea, heart disease
Duration	Long term

Causes	Genetic and environmental factors
Risk factors	Obesity, not enough exercise, family history
Diagnostic method	Based on anovulation, high androgen levels, ovariancysts
Differential diagnosis	Adrenal hyperplasia, hypothyroidism, high blood levels of prolactin
Treatment	Weight loss, exercise
Medication	Birth control pills, metformin, GLP-1, anti-androgens
Frequency	2% to 20% of women of childbearing age

DRUG AND EXCIPIENTS

Ethinylestradiol

Chemical data

- **Molecular formula:** $c_2oh_{24}o_2$
- **Molecular weight :**296.403g/mol
- **Melting point**:182-184˚c
- **P^{ka} value**: p^{ka} (strongest acidic)10.33

  p^{ka} (strongest basic)1.7
- **Physical state**: solid
- **Water solubility**: 4.8-11.3mg/L

Levonorgestral

Chemical data

Molecular formula:c21h28o2

Molecular weight:312.446

Melting point:232˚c-239˚c

P^{ka} value: pka (strongest acidic)17.91

p^{ka} (strongest basic)-1.5

Physical state: crystalline powder

Solubility: slightly soluble in ethanol and acetone and sparingly soluble in methylene chloride, insoluble in water.

Polymer profile: HPMC K4M, CARBOPOL, SODIUM CARBOXY METHYL CELLULOSE(SCMC)

DILUENT PROFILE: Micro crystalline cellulose(mcc)

LUBRICANTS: Talc

SWEETENING AGENT: Lactose

BINDING AGENT: PVP (poly vinyl pyrrolidine**)**

Plan of work

1. Preformulation Study

- APICharacterization
- Physical Appearance
- Solubility studies
- Sieve Analysis
- Drug-Excipient Compatibility Studies
- Physical Compatibility
- IR spectrophotometry
- Analytical Method development.

2. Formulation development

3.Evaluation parameters of Matrix tablet

- Physical Description
- Sieve Analysis
- Bulk Density and Tap Density
- Compressibility index
- Angle of repose
- Weight variation
- Hardness
- Thickness
- Friability
- Disintegration time
- Assay of HPLC
- Dissolution by UV.

4. Comparision of Dissolution profile of trail formulations with innovator

5. To perform stability studies of selected formulation

SUMMARY

Formulation development was undertaken to design matrix tablets of Ethinyl Estradiol and Levonorgestrel using various polymers with the objective of achieving controlled drug release and improving therapeutic efficacy in the management of Polycystic Ovary Syndrome (PCOS). Matrix tablet technology was selected to maintain steady hormone`e levels, reduce

dosing frequency, and improve patient compliance. Based on literature review, suitable hydrophilic and hydrophobic polymers such as HPMC (various grades), ethyl cellulose, sodium carboxymethyl cellulose, and Carbopol were selected. Different formulations were prepared by direct compression method, varying the type and concentration of polymers to optimize the release profile. Preformulation studies were carried out to evaluate drug–excipient compatibility using physical observation and FT-IR studies, which confirmed the absence of any significant interaction between the drugs and selected excipients.

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