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PREPARATION AND EVALUATION OF MEBENDAZOLE TABLET

Mrs. M. Shiroja*[1], Dr. Chandrasekhara Rao Baru[2], J. Aarthi[3], Kaish Ansari[4], Shaik Shadab Ahmad[5], Shravani[6], D. Mayuri[7]

[1]Assistant Professor and Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, 500075.

[2]Principal and Professor and Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, 500075.

[3-7]Student, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, 500075.

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***Corresponding Author**

Mrs. M. Shiroja

Assistant Professor and Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, 500075.

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ABSTRACT

Mebendazole is a broad-spectrum anthelmintic drug widely used for the treatment of helminthic infections. However, its conventional oral dosage forms may present swallowing difficulties, especially for pediatric and geriatric patients. The present study aimed to formulate and evaluate oral disintegrating tablets (ODTs) of mebendazole using different super disintegrants to enhance patient compliance and achieve rapid tablet disintegration. Mebendazole ODTs were prepared by the direct compression method using various concentrations of super disintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate. The prepared formulations were evaluated for pre-compression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio. Post-compression studies included weight variation, hardness, friability, drug content uniformity, wetting time, water absorption ratio, disintegration time, and invitro dissolution studies. The results demonstrated that all formulations complied with pharmacopeial specifications for tablet quality. Among the super disintegrants tested, formulations containing crospovidone showed the shortest disintegration time and highest drug release profile compared to other formulations. Rapid tablet disintegration was attributed to the superior wicking and swelling properties of the super disintegrant. The optimized formulation exhibited acceptable mechanical strength, uniform

drug content, rapid disintegration, and enhanced dissolution characteristics.

KEYWORDS: Mebendazole, Oral Disintegrating Tablets, Direct Compression, Super disintegrants, Crospovidone, Rapid Disintegration. Dissolution, Anthelmintic.

INTRODUCTION

Tablets are one of the most widely used solid dosage forms in pharmaceuticals, offering a convenient and effective way to administer active pharmaceutical ingredients (APIs) to patients. A tablet is a compact, solid unit containing one or more APIs mixed with excipients, prepared by compression or molding. The history of tablets dates to ancient times, but modern tablet manufacturing has evolved significantly with advances in technology and formulation science. Tablets are designed to deliver APIs systemically, locally, or for specific targeting, catering to diverse therapeutic needs. They can be formulated for immediate release, sustained release, or controlled release, depending on the desired pharmacokinetic profile. The popularity of tablets stems from their ease of use, accurate dosing, stability, and cost-effectiveness. The design and development of tablets involve careful selection of excipients, manufacturing processes, and evaluation parameters to ensure optimal product quality and performance.

Excipients play a crucial role in tablet formulation, influencing properties like compressibility, disintegration, and dissolution. With the growing demand for patient-centric and personalized medicines, tablet development has become increasingly sophisticated, incorporating novel technologies and strategies to enhance bioavailability, reduce side effects, and improve patient compliance.

Tablets are small, lightweight, and easy to carry, making them convenient for patients to use anywhere.

Ease of Administration. They are simple to take, especially oral tablets, and do not require any special preparation. Good Stability Tablets have better physical, chemical, and microbiological stability compared to liquid dosage forms, leading to a longer shelf life.

ADVANTAGES OF TABLETS

- **Accurate dose** – each tablet has a fixed amount of drug.
- **Easy to use** – portable, simple to swallow or administer.
- **Stable** – longer shelf life compared to liquids.
- **Cost-effective** – cheaper to produce than capsules/injections.
- **Versatile** – can be made as immediate-release, extended-release, enteric-coated, chewable, or dissolving forms.
- **Better compliance** – patients prefer tablets due to convenience.

DISADVANTAGES OF TABLETS

- **Swallowing difficulties** – some patients (children, elderly) struggle with solid tablets.
- **Slow onset of action** – compared to injections, tablets take longer to act.
- **Taste issues** – bitter drugs may be hard to mask in tablet form.
- **Risk of irritation** – some tablets can irritate the stomach lining.
- **Fixed dose only** – cannot easily adjust dose once manufactured.
- **Moisture sensitivity** – tablets may lose potency if not stored properly.

TYPES OF TABLETS

- **Compressed Tablets** – the most common, made by compressing drug + excipients.
- **Sugar-Coated Tablets** – coated with sugar to mask taste and protect drug.
- **Film-Coated Tablets** – thin polymer coating for protection and controlled release.
- **Enteric-Coated Tablets** – resist stomach acid, dissolve intestine.
- **Effervescent Tablets** – dissolve in water, release gas for quick action.
- **Chewable Tablets** – designed to be chewed, useful for children/elderly.
- **Buccal/Sublingual Tablets** – dissolve in mouth for rapid absorption.
- **Orally Disintegrating Tablets (ODTs)** – dissolve quickly on the tongue without water.
- **Extended-Release Tablets** – release drug slowly over time.
- **Vaginal Tablets** – inserted for local treatment.
- **Implant Tablets** – placed under skin for long-term release.

MATERIALS AND METHODS

DIRECT COMPRESSION METHOD

Direct compression involves compressing a uniform blend of drug and excipients directly into tablets without any preliminary granulation process.

Process steps

- Weighing of ingredients
- Addition of lubricants and glidants
- Compression using tab let punching

Machine Requirements

- Good flow propertes
- Adequate compressibility
- Uniform particle size distribution

Advantages

- Fewer processing steps, reducing manufacturing time Cost-effective and energy-efficient
- Suitable for heat-and moisture sensitive drugs.

Disadvantages

- Limited to drugs with good compressibility
- Risk of content uniformity issues due to segregation
- Not suitable for low-dose dugs without proper diluent

Applications

- Widely used for modem formulations using directly compressible excipients
- Minimizes stability issues

MATERIALS

S.NO	INGREDIENTS	CATEGORY
1	Mebendazole	Active pharmaceutical ingredient
2	Maize starch	Diluent/Binder
3	Sodium starch Glycolate	Disintegrating agents
4	SLS [Sodium Lauryl Sulfate]	Wetting agents
5	Sodium Saccharin	Sweetener
6	Magnesium Stearate	Lubricant
7	Talc	Glidant
8	Povidone K 30	Binder

FORMULATION DEVELOPMENT

S.NO	INGREDIENTS	F1[mg]	F2[mg]	F3[mg]	F4[mg]	F5[mg]
1	Mebendazole	500	500	500	500	500
2	Maize starch	40	40	40	40	40
3	Sodium starch glycolate	20	25	30	35	40
4	SLS [sodium lauryl sulfate]	10	12	14	16	18
5	Povidone K 30	15	17	19	21	23
6	Sodium saccharin	5	5	5	5	5
7	Magnesium stearate	5	5	5	5	5

RESULTS AND DISCUSSIONS

EVALUTION TEST

1. Thickness

Thickness is the physical dimension representing the distance between two opposite surfaces of an object. It typically measures the smallest of an object three dimensions [length, width and thickness].

Standard range

The standard range of thickness for a mebendazole tablet generally falls between 3.0 mm and 5.0mm.

2. Weight variation

The Mass Variation (Weight Variation) test is a pharmacopeial quality control test used to ensure uniformity of dosage unit

Calculations

Total weight of 20 tablets = 14,000 mg Average weight:

Permissible limit:

Acceptable weight range:

Result: -

All tablets were found within the acceptable range of 665-735 mg. Therefore, the batch of Mebendazole 5D

mg tablets comply with the pharmacopeial requirements for the Weight Variation Test.

3. Hardness test

A hardness evaluation test is a mechanical procedure used to determine a materials resistance to permanent surface deformation, such as scratching, abrasion, or indentation. Calculations

Average Hardness Acceptance Criteria

Mebendazole 500 mg tab lets are typically expected to have hard ness in the range of 6-10 kg/cm 2 to ensure

adequate strength and acceptable disintegration.

Result:

The average hardness of the Mebendazole 500 mg tablets was found to be 8 35 kg/cm2.

4. Friability test

Friability in the tendency of a solid materials easily break, crumble, or reduce into smaller pieces or powder under pressure friction, or tubbing

Calculation:-Result Table

Test	Specification	Observed value
Friability	NMT 1.0%	0.50%

[NMT=Not More Than]

Acceptance Criteria

According to pharmacopeial requirements

- Friability should be no more than 1.0%.
- Tablets should show no evidence of cracking, capping, or breaking.

Result

The friability of the Mebendazole 500 mg tablets was found to be 0.50%, which is within the acceptable pharmacopeial limit of not more than 1.0%. Therefore, the tablets pass the friability test and possess satisfactory mechanical strength.

5. Disintegration Test

Disintegration refers to the process of breaking apart into smaller fragments, crumbling, or gradually falling apart. It signifies a loss of structural integrity, cohesion, or unity, and can apply to physical objects, organizations, or concepts.

Acceptance Criteria

For uncoated tablets, the pharmacopeial limit is generally:

Not more than 15 minutes

All six tablets should disintegrate completely within the specified time.

Result

The average disintegration time of Mebendazole 500 mg tablets was found to be 4 minutes, 43 seconds. All tablets disintegrated completely within the pharmacopeial limit of 15 minutes.

Therefore, the tablets pass the disintegration test and comply with the specified requitements

6. Dissolution test

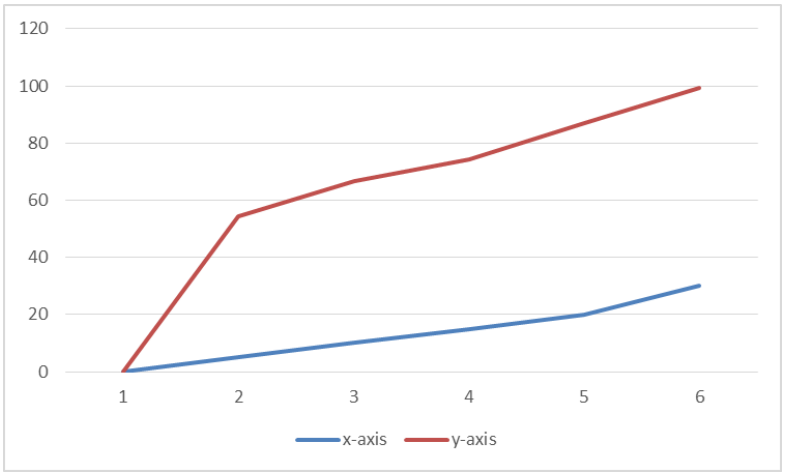
Dissolution is a process in which sold substance solubilizes in each solvent [i.e]., mass transfer from the solid surface to the liquid phase,

Standard Calibration Dissolution study

Parameter	Condition
Apparatus	USP type II [paddle]
Medium	900ml 0.1N HCL
Temperature	37±0.5°C
Paddle speed	50rpm
Sample Volume	5ml
Wavelength	234nm
Test duration	30mins

INVITRO DRUG RELEASE STUDIES OF MEBENDAZOLE TABLET

Time[min]	F1[%drug release]	F2[%drug release]	F3[% drug release]	F4[%drug release]	F5[%drug release]
0	0	0	0	0	0
5	52.26	55.38	54.18	45.34	54.42
10	65.86	63.99	69.85	60.49	66.87
15	74.97	79.12	80.49	78.15	74.43
20	82.67	89.2	90.23	85.25	86.86
30	89.49	91.52	95.79	97.2	99.25



% drug release for F5 Formulation

CONCLUSION

The present study was successfully carried out for the preparation and evaluation of Mebendazole tablets using suitable excipients and standard pharmaceutical techniques. The prepared formulations were evaluated for various pre-compression parameters such as angle of repose, bulk density, tapped density, Car's index, and Hausner ratio, which indicated good flow properties and compressibility of the powder blend. The compressed tablets were further evaluated for post-compression parameters including hardness, thickness, weight variation, friability, disintegration time, dug content uniformity, and dissolution studies. The results obtained for all formulations were found to be within acceptable pharmacopeial limits. Among all the formulations, formulation F6 showed better overall performance with satisfactory hardness and low friability uniform drug content acceptable disintegration time, and better drug release profile. The stability studies revealed that the optimized formulation remained stable without significant changes in physical and chemical properties during the study period from the overall evaluation and results, was concluded that formulation F6 was the optimized formulation and can be considered suitable for effective oral delivery of Mebendazole.

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