# "Development and evaluation of control release tablet of metformin."

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**ABSTRACT:**

Metformin, a widely prescribed oral hypoglycemic agent, is primarily used in the treatment of Type 2 diabetes. However, its conventional immediate-release (IR) formulation requires frequent dosing, which may lead to patient non-compliance and fluctuating blood glucose levels. The aim of this study was to develop and evaluate a controlled-release (CR) formulation of metformin to provide sustained therapeutic effects, enhance patient adherence, and improve overall glycemic control. The CR metformin tablets were formulated using various excipients, including hydrophilic polymers (such as hydroxypropyl methylcellulose, HPMC), which regulate the drug release over an extended period. Several batches of tablets were prepared and evaluated for physical properties, including weight variation, hardness, friability, and drug content uniformity. In vitro drug release studies were conducted using USP dissolution apparatus, and the release kinetics were analyzed using mathematical models (zero-order, first-order, and Higuchi model). The optimized formulation exhibited a controlled and prolonged release of metformin, significantly reducing the peaks and valleys in plasma drug concentrations typically observed with immediate-release formulations. Stability studies confirmed that the CR tablets maintained their drug release profile and physical characteristics under accelerated conditions. Overall, the controlled-release metformin tablets demonstrated potential for improving patient compliance, reducing dosing frequency, and maintaining consistent therapeutic effects, making them a promising alternative to existing metformin formulations.

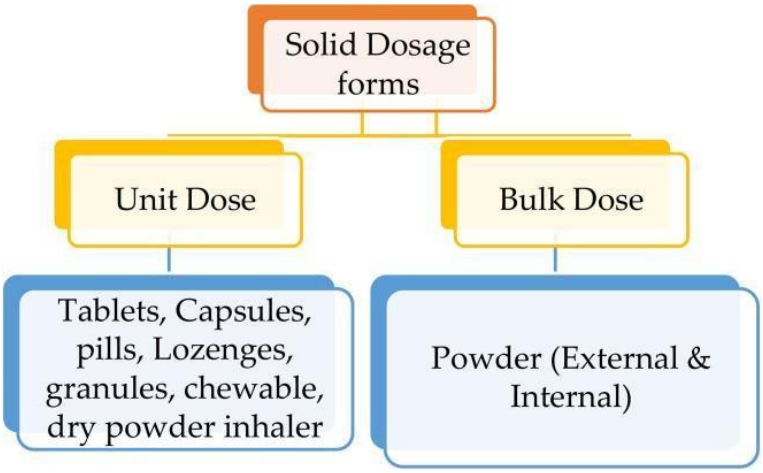
**KEY WORDS:** Control release tablet, metformin,

**INTRODUCTION :**

A drug (API) is a substance (recognized in official pharmacopoeia) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease as per the FDA. Drug delivery is a technique of delivering medication to a patient in such a manner that specifically increases

the drug concentration in some parts of the body as compared to others . The ultimate goal of any delivery system is to extend, confine and target the drug in the diseased tissue with a protected interaction. Every Dosage form is a combination of drug/active pharmaceutical ingredients (APIs) and the non-drug component called excipients/additives. APIs are the actual chemical components used to treat diseases.Generally, drug delivery systems (DDS) are preferred because direct clinical use of the active drug substances (APIs) “as they are” is very rare due to several reasons: API handling and accurate dosing can be difficult or impossible for very potent drugs (e.g., low mg and µg doses).A tablet is a solid unit dosage form that is manufactured by compression and wet/dry granulation into different shapes (round, oval or square shape). For efficient tabletting, binders, glidant and lubricants are often added as excipients. To enhance the easy break- down of tablets in the digestive tract, disintegrants are added. The tablet coating with pigments, sweeteners and flavoring agents helps to mask the taste of other ingredients and makes the tablet smoother and easier to swallow.

**solid dosage** **Classification of forms**



**Advantages and disadvantages of controlled drug delivery systems.**

- **Advantages of Controlled DDS**

Controlled or defined drug release

Target specificity

Long residence of drug

- **Disadvantages of Controlled DDS**

Possible toxicity of materials used

Dose dumping

Invasive procedure to implant or remove

**Rationale behind controlled release drug delivery systems**

## MATERIALS AND METHODS

### MATERIALS:

Metformin, Hydroxypropyl methyl cellulose K4M(HPMC K4M), Microcrystalline Cellulose, Talc, Magnesium stearate, Methanol, Ethanol, Potassium Dihydrogen Phosphate.

**Equipment Name:** UV-Visible spectroscopy, Magnetic stirrer, Dissolution apparatus, Lyophilizer, Field emission scanning electron microscopy, Particle size analyzer, Zeta potential analyzer.

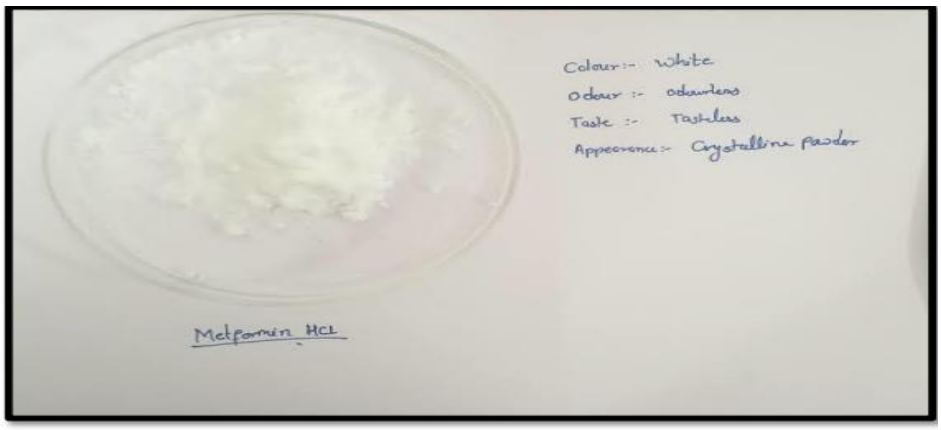
### METHODS

Control release tablets each containing 1mg of metformin was prepared by wet granulation method (using isopropyl alcohol). All the ingredients except lubricants were mixed in the order of ascending weights and blended for 10 min in an inflated polyethylene pouch and then metformin was added in this mixture then mixed for 2 min for uniform mixing. Granulation was done with binder solution of microcrystalline cellulose which was previously dissolved in isopropyl alcohol, this damp mass passed through sieve #10. The granules were dried at 40ºC for 30 min. And then passed through sieve #22-44 and lubricants such as magnesium stearate and talc were mixed and then compressed it with 10-station rotary compression machine into 850 mg tablet, to a hardness of 5-7kg/cm2 using 6 mm punch.

**RESULTS:**

**PREFORMULATION STUDY**

**1. Appearance-**




**2. Melting point:**

| **Drug name** | **Observed value** | **Reported value** |
|---|---|---|
| Metformin | 223℃ | 222-226℃ |

**3)Solubility study of metformin:**

| **Medium** | **Solubility** |
|---|---|
| Distilled water | 4.51 |
| Methanol | 3.65 |

| | |
|---|---|
| Ethanol | 2.51 |
| Phosphate buffer ph 6.8 | 3.63 |
| Phosphate buffer ph 7.4 | 3.58 |
| Acidic buffer ph 1.2 | 1.2 |

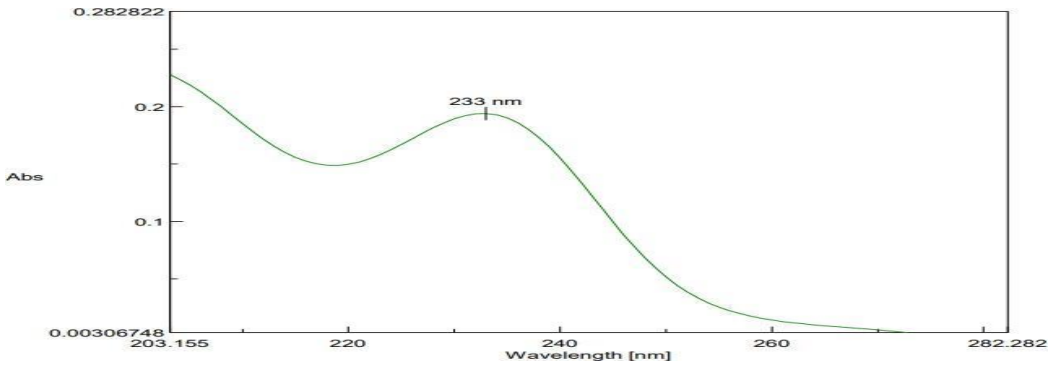
**4)Detection of Absorption Maxima (λ max)**

The observed λmax for metformin was 233 nm, which closely matches the reported value of 234 nm. This minor discrepancy of 1 nm indicates that the UV spectra obtained for metformin in distilled water aligns well with the expected behavior of the compound. The agreement between the observed and reported λmax values suggests that the metformin sample is correctly identified and free from significant impurities, confirming the reliability and accuracy of the analytical method used.

**Observation of λmax**

| **Drug Name** | **Observed Value** | **Reported Value** |
|---|---|---|
| **Metformin** | **233** | **234** |

**UV spectra of Metformin in Distilled water**



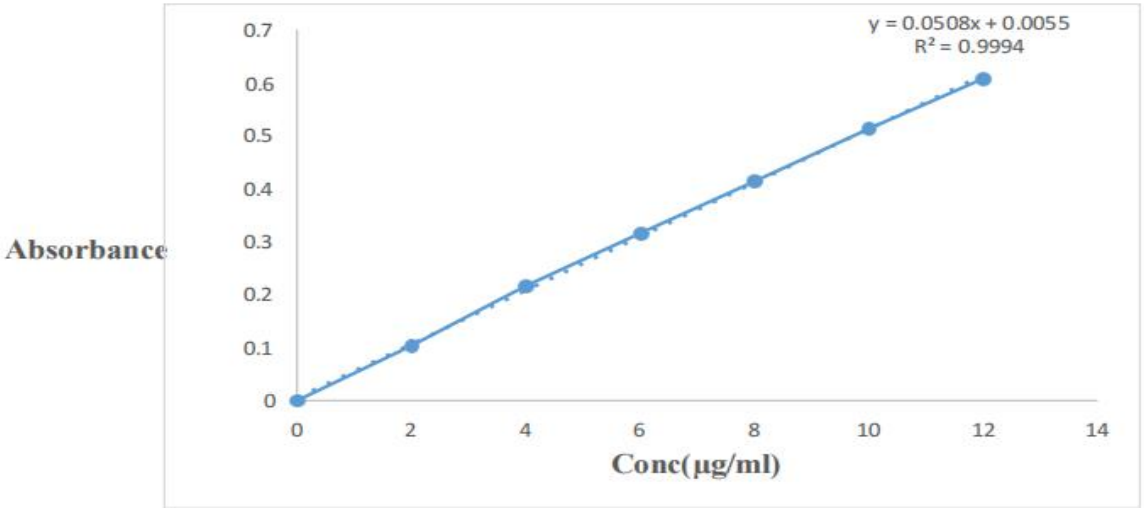

**5) Calibration curve-**

Calibration curve in Distilled water:

The calibration curve in distilled water, based on the provided data and equation, demonstrates a strong linear relationship between concentration and absorbance. The equation for the calibration curve is y=0.0508x+0.0055, where y represents absorbance and xxx represents concentration in µg/ml. The correlation coefficient ($R^2$) of 0.9994 indicates an excellent linear fit,suggesting that the method used for determining the concentration of the substance in distilled water is highly accurate and reliable. This high correlation coefficient means that nearly all the variability in absorbance can be explained by the changes in concentration, validating the use of this calibration curve for precise quantitative analysis.

**Calibration curve in Distilled water**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 0 | 0 |
| 2 | 0.103 |
| 4 | 0.216 |
| 6 | 0.313 |
| 8 | 0.414 |
| 10 | 0.513 |
| 12 | 0.608 |




**Calibration curve in Distilled water**

## CONCLUSION

The study began with a comprehensive Preformulation assessment of Metformin, focusing on its physical and chemical properties. The API was successfully identified and characterized through melting point determination, solubility studies, and UV spectroscopy, confirming its purity and suitability for formulation. Calibration curves demonstrated high linearity across various solvents, validating UV spectroscopy as a reliable method for quantification.

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