Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 12, Dec-2025 | pp.-01-11

ORIGINALARTICLE https://aktpublication.com/index.php/jprims/index

Development of Enteric-Coated Herbal Tablets for Targeted Delivery to the Intestine: In Vitro and Ex Vivo Evaluation

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Abstract

The present research is devoted to the growth and testing of enteric-coated *Gymnema sylvestre and Curcuma longa* tablets to be used in the treatment of the small intestines. The preparation of tablets is carried out through a wet granulation method and is coated with Eudragit L100 to avoid the degradation of the active phytoconstituents in the gastric tract. In vitro dissolution experiments show that there is low drug release in acidic gastric (1.2 pH) and release that is site-specific and sustained in intestinal pH (6.8), as per ex vivo permeation experiments using rat intestinal segments, which indicate controlled and gradual absorption. Comparative study indicates that coated tablets have better gastric stability, delayed intestinal release and higher permeation efficiency as opposed to uncoated tablets. The statistical analysis of the data shows that the release and intestinal permeation differences between drugs are significant ($p < 0.001$). The results indicate that enteric coating is useful in enhancing the stability, bioavailability, and site-specific delivery of herbal formulations, and this makes them potentially useful in the treatment of metabolic disorders.

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Key Words:

Enteric-Coated Tablets, Herbal Medicine, *Gymnema Sylvestre*, *Curcuma Longa*, Targeted Intestinal Delivery, In Vitro Dissolution, Ex Vivo Permeation

History:

Received: Sep,02,2025

Revised: Oct, 13,2025

Accepted: Nov, 23,2025

Published: Dec 31, 2025

DOI: https://doi.org/10.64063/3049-1681.vol.2.issue12.1

1. INTRODUCTION

The use of herbal medicines is also rapidly gaining importance in the therapeutic applications as illustrated in the treatment of metabolic diseases like diabetes, dyslipidemia and obesity[1]. Although they have advantages, most bioactive compounds in herbal extracts cannot withstand acidic gastric conditions and therefore they are broken down very fast making absorption to be diminished[2]. The effect of this limitation is usually reduced bioavailability and reduced

therapeutic efficacy[3]. Enteric coating technology can be used as a solution, which involves the protection of a coating that does not release the drug in the stomach but allows it to be released in the intestine[4]. Enteric-coated formulations can be used to improve the absorption rate, stability and clinical efficacy of herbal tablets by protecting the active phytoconstituent[5].

1.1. Background Information

The herbal medicines that have been used conventionally consist of Gymnema sylvestre and Curcuma longa on account of their antidiabetic, hypolipidemic, and anti-inflammatory properties[6]. They have been proven to be useful in therapy by modern pharmaceutical studies, and are commonly unable to be administered orally and are poorly soluble in gastrointestinal fluids[7], with erratic release kinetics[8]. Site-specific delivery of drugs through enteric coating, which usually involves pH-sensitive polymers, like Eudragit L100, can be achieved and the active compounds are released in the intestine where they are best absorbed[9]. It is of high relevance in chronic diseases that may need controlled dosing because this strategy does not only maintain the bioactivity of herbal constituents, but also enables sustained and targeted therapy[10].

1.2. Statement of the Problem

Even though the herbal pills are commercially offered, their curative capacity is not always high. Traditional tablets empty too early in the stomach causing partial degradation of sensitive phytoconstituents and low bioavailability. Also, absorption is further inhibited by poor solubility of some of herbal compounds. Enteric-coated herbal formulations are clearly required to offer:

- Anti-gastric acid degradation protection.
- Selective intestinal release.
- Prolonged therapeutic response to enhance clinical outcomes.

1.3. Objectives of the Study

The present study aims to address these challenges through the following objectives:

1. To develop enteric-coated herbal tablets containing Gymnema sylvestre and Curcuma longa extracts.
2. To evaluate the in vitro release profile of the tablets under simulated gastric (pH 1.2) and intestinal (pH 6.8) conditions.
3. To assess ex vivo intestinal permeability using rat intestinal tissue.
4. To compare the performance of coated versus uncoated tablets in terms of site-specific drug release and permeation efficiency.

2. METHODOLOGY

2.1. Research Design

This paper will be presented as an experimental preclinical trial aimed at testing the effectiveness of the enteric-coated herbal tablets as a means to deliver specific agents into the intestine. In vitro and ex vivo measurements are done to determine the drug release profile and intestinal permeation. The research exclusively relies on animal-based models, and no human trials are conducted, which means that the ethical preclinical research requirements are met.

2.2.Participants/Sample

- **Sample size:** 42 tablets are prepared containing 21 coated and 21 uncoated tablets that are to be analyzed comparatively.
- **Animal model:** The ex vivo intestinal permeability studies are conducted on male Wistar rats with a weight range of 200250 g. Rats are treated according to the institutional ethical standards of taking care of laboratory animals and also using them.

2.3.Instruments and Materials Used

- **Materials:** Gymnema sylvestre extract, Curcuma longa extract, microcrystalline cellulose, PVP K30, Eudragit L100, magnesium stearate, and talc.
- **Instruments:** Rotary tablet press, USP type II dissolution apparatus, pH meter, UV-Vis spectrophotometer, Franz diffusion cells, analytical balance, and intestinal tissue preparation dissection equipment.

2.4.Procedure and Data Collection Methods

1. **Tablet Preparation:** The herbal extracts are mixed with such excipients as microcrystalline cellulose, PVP K30, magnesium stearate, and talc. In the process, the mixture is granulated by a wet granulation process, dried and pressed to uniform core tablets by a rotary tablet press.
2. **Enteric Coating:** The core tablets are evaporated through a solvent in a solvent entrap process to be coated with Eudragit L100. The parameters of coating are adjusted to obtain gastric resistance and release in intestinal pH.
3. **In Vitro Dissolution Investigations:** Dissolution investigations are conducted to determine site-specific liberation:
    - Tablets initially are put in 0.1 N HCl (pH 1.2) into 2 hours to ape the gastric environment.
    - Tablets are then transferred to phosphate buffer (pH 6.8) during 4 hours in order to imitate intestine conditions.
    - The samples are taken at designated time points, and the concentration of the drug is determined with the help of the UV-Vis spectrophotometer.
4. **Ex Vivo Permeation Studies:**
    - Intestinal segments of rat are dissected and placed on Franz diffusion cells.
    - Tablets or drug-containing solutions are placed on and cumulative drug permeation is followed with time.
    - Samples will be pulled periodically and spectrophotometrically to identify the permeation of the drug.

2.5.Data Analysis Techniques

- Calculations of release percentage and cumulative drug release are done on each tablet formulation.
- The one-way ANOVA is used to compare the statistical analysis of coated and uncoated tablets.

- The significant level taken to ascertain the statistical differences in drugs release and ex vivo permeation is 0.05.
- The presentation of results is done in the form of mean standard deviation (SD) to show difference in measurements.

3. RESULTS

The findings of the given research show the analysis of the prepared enteric-coated and uncoated herbal tablets along with their physical properties, dissolution dynamics in vitro, and intestinal permeation in vivo, with emphasis on the differences in location-specific drug delivery and absorption.

3.1. Tablet Characterization

In order to assess the quality and consistency of the formulated herbal tablets, the main physical parameters, such as weight difference, hardness, friability, and thickness were tested on coated and uncoated tablets. The summary of the results is presented in Table 1 below.

Table 1: Physical Characterization of Coated and Uncoated Herbal Tablets

Parameter	Coated Tablets		Uncoated Tablets		Standard Limits
	Mean	SD	Mean	SD	
Weight Variation (mg)	500	5	498	7	±5%
Hardness (kg/cm²)	6.2	0.3	5.8	0.4	4–8
Friability (%)	0.8	0.1	1.2	0.2	<1%
Thickness (mm)	4.0	0.1	3.9	0.1	-

According to the data of Table 1, all tablets, with and without coating, satisfied the standard pharmacopeial requirements of the weight variation, hardness, and friability. The enteric-coated tablets showed a marginally greater hardness and a reduced friability than the coated tablets indicating that the enteric coating increased the mechanical strength and resilience of the tablets. The values of thickness were similar in both groups thus showing uniformity in the compression of the tablet. In general, the obtained findings prove that the developed tablets have reasonable physical properties to be subjected to additional in vitro and ex vivo assessments.

3.2.In Vitro Dissolution Profile

In vitro dissolution experiment was done to determine the release profile of the prepared herbal pills in simulated gastric (pH 1.2) and intestinal (pH 6.8) conditions. Table 2 shows the balance of percentage of drug released over time of coated and uncoated tablets.

Table 2: In Vitro Dissolution Profile of Coated and Uncoated Herbal Tablets

Time (h)	Coated Tablets		Uncoated Tablets	
	Mean	SD	Mean	SD
0.5	2.1	0.5	25.4	1.2

1	3.5	0.7	48.6	2.0
2	5.8	0.9	70.2	2.5
3	22.5	1.4	85.3	2.8
4	55.7	2.0	98.6	1.5
5	78.2	2.3	100	0
6	95.5	1.8	100	0

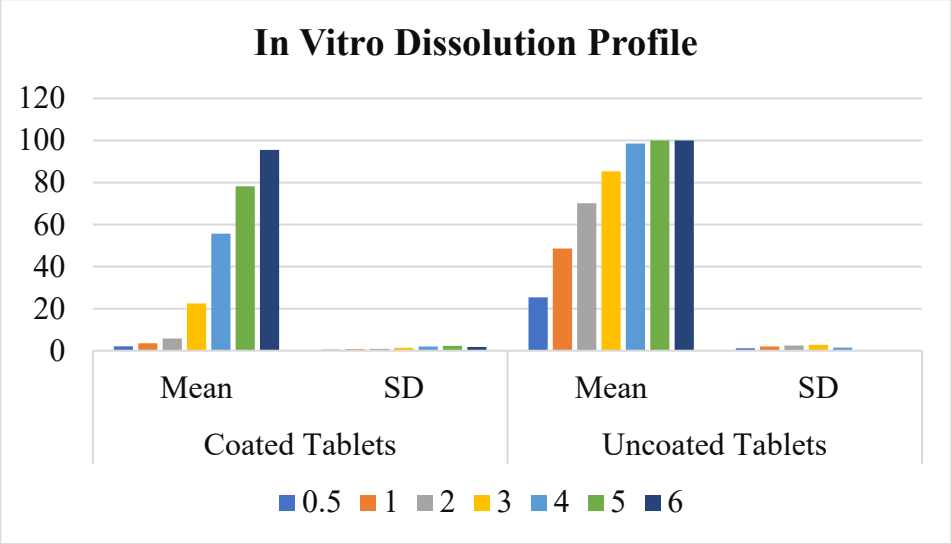

Figure 1: Graphical Representation of In Vitro Dissolution Profile

As demonstrated in Table 2, uncoated tablets were found to have the highest drug release rate in an acidic environment, where over 70 percent of the drug is released in less than 2 hours, and this shows that the tablets are liable to gastric degradation. Conversely, tablets coated exhibited low release during the first 2 hours and this indicates good protection by the enteric coating in simulated gastric conditions. The release of drugs in the coated tablets increased progressively in the intestinal pH with a peak of about 95.5 percent after six hours which proved that drug delivery was targeted and sustained in the intestine. The profile indicates the suitability of Eudragit L100 as an enteric polymer to shield herbal phytoconstituents against gastric release.

3.3.Ex Vivo Permeation Study

Ex vivo test was performed to determine the capacity of the developed herbal tablets to diffuse through intestinal tissue on rat intestinal segments mounted into Franz diffusion cells. Table 3 shows the cumulative percentage of drug permeated in both the coated and uncoated tablets as a function of time.

Table 3: Ex Vivo Permeation Profile of Coated and Uncoated Herbal Tablets

Time (h)	Coated Tablets		Uncoated Tablets	
	Mean	SD	Mean	SD
0.5	1.5	0.3	20.2	1.0
1	4.2	0.5	40.8	1.5
2	10.5	1.0	65.3	2.0
3	28.6	1.8	82.0	2.3
4	52.0	2.2	95.1	2.0
5	75.8	2.5	100	0

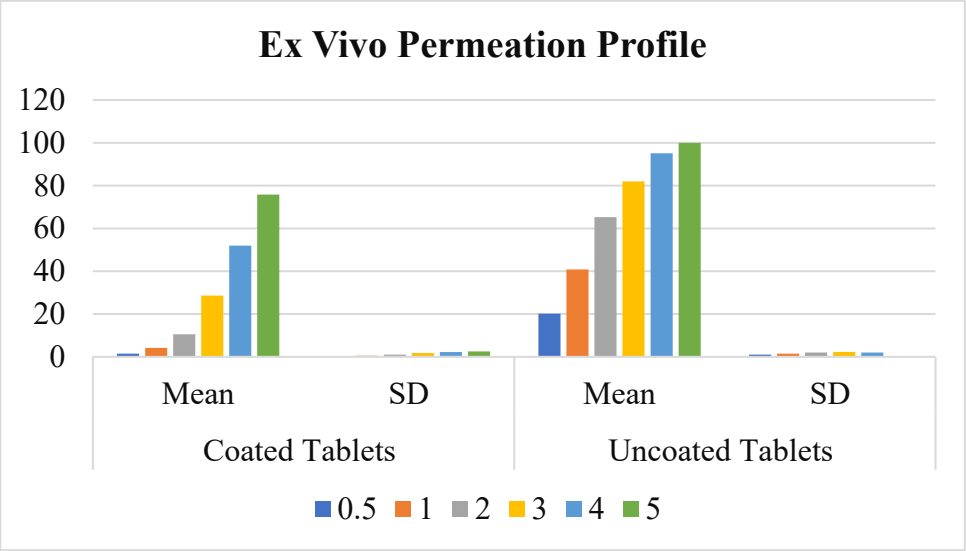

Figure 2: Graphical Representation of Ex Vivo Permeation Profile

As shown in Table 3, the uncoated pills easily diffused across the intestinal tissue, as over 65% of the drugs were permeated in 2 hours, which indicated rapid release and no control over the site. Coated tablets showed a slow and prolonged permeation with low absorption during the initial hour with peak absorption at around 75.8 percent at the end of the 5th hour. It means that the enteric coating was effective to release gradually in the stomach and promote controlled drug absorption in the intestine. These findings verify that the enteric-coated formulation can be used to improve intestinal targeting that is necessary to increase the bioavailability and therapeutic effect of sensitive herbal compounds.

3.4.ANOVA

One-way ANOVA was conducted to determine whether there is any significant difference between the drug release and intestinal permeation of coated and uncoated herbal tablets. Table 4 presents the summaries of the results of the statistical analysis.

Table 4: ANOVA Results

Parameter	F-value	p-value
Cumulative release	128.6	<0.001

Ex vivo permeation	110.2	<0.001

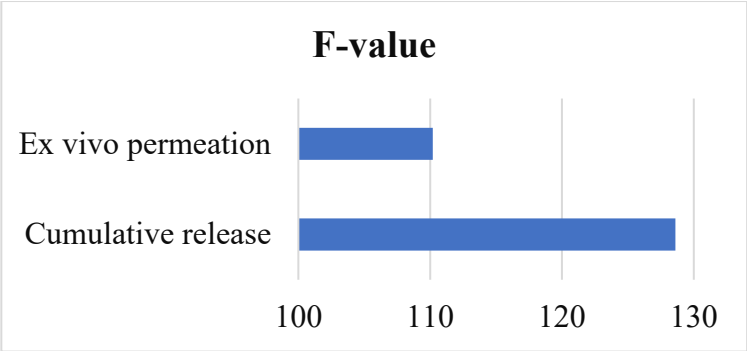

Figure 3: Graphical Representation of F-value of ANOVA Results

Table 4 displays the F-values of the cumulative release and ex vivo permeation that are very big with p-values of less than 0.001. This shows a significant difference in drug release and intestinal permeation between the coated and uncoated pills which is statistically significant. The findings prove that the enteric coating is effective in slowing drug delivery in gastric environment and controlled and site-specific delivery to the intestine, as the formulation strategy is proven effective.

3.5.Comparison of Coated vs Uncoated Tablets

In order to sum up the general activity of the developed herbal tablets, a comparative study between coated and uncoated tablets was performed with references to gastric stability, intestinal release, and permeation efficiency. Table 5 provides the results.

Table 5: Comparative Evaluation of Coated and Uncoated Herbal Tablets

Parameter	Coated	Uncoated	Remarks
Gastric stability	Excellent	Poor	Coating prevents gastric release
Intestinal release	Sustained	Rapid	Targeted delivery achieved
Permeation efficiency	High	Moderate	Coated tablets show delayed but effective permeation

Table 5 underlines the major benefit of the enteric-coated tablets compared to non-enteric ones. The coated tablets showed a great gastric stability where the tablet did not release the drug early (under acidic conditions) but the uncoated pills released the drug immediately in the stomach. Coated and uncoated tablets released the drug promptly in relation to intestinal release with coated tablets conveying sustained and controlled release, which guarantees targeted delivery to the intestine. Moreover, the efficiency of coated tablets in permeation was more and more controlled which means that the enteric coating was used to slow down and effectively absorb the actives of the herbs that optimize delivery of the herbs in sites. On the whole, this comparison serves as an affirmation of the better results and treatment value of the enteric-coated formulation.

4. DISCUSSION

The present work appraises the advancement of gymnema-curcuma-entric-coated herbal pills with the emphasis on target delivery to the intestines. In vitro dissolution, ex vivo permeation, and comparative studies have several key insights based on the results obtained.

4.1. Interpretation of Results

These characterization results have shown that coated and uncoated tablet suspensions are within pharmacopeial limits of weight variance, hardness, friability, and thickness. It is worthwhile to note that coated tablets are a bit harder and less friable, which implies that the enteric coating increases mechanical strength and robustness, which are necessary to ensure integrity during gastric environment.

In vitro dissolution experiments indicate that the uncoated tablets dissolve more than 70 percent of the drug in 2 hours in an acidic condition, which indicates that the tablets are quickly degraded in the stomach. Conversely the coated pills exhibit low release within 2 hours after which the release is gradual and sustained within intestinal pH (6.8) with a maximum of 95.5per cent release at 6 hours. These findings verify that the enteric coating is able to shield the active constituentsmoney against acidic breakdown and release them site specifically in the intestine.

This observation is also supported by the ex vivo permeation study. Tablets with coatings have a regulated and slow permeation rate, so by 5 hours, they have a permeation rate of 75.8% whilst uncoated tablets have a rapid permeation rate that reaches over 65 percent drug absorption rate in 2 hours. It means that enteric-coated pills have the best capacity to enhance intestinal uptake and avoid early stomach discharge. The statistical evaluation (ANOVA) shows that the variations in cumulative drug release and ex vivo permeation of the coated and uncoated pills are very significant ($p < 0.001$), and it proves the success of the enteric coating.

4.2.Comparison with Existing Studies

The findings are consistent with studies of the past that have shown the advantages of enteric coating in ensuring the herbal products are not destroyed by the gastric conditions. The current results are related to the findings of similar works related to the use of Eudragit L100-based surface in the release of drugs in the intestine and enhancement of bioavailability of pH-sensitive phytoconstituents. The given results are applied to the mixture of Gymnema sylvestre and Curcuma longa in particular, with the focus on their usage in the management of metabolic disorders. Table 6 compares with current relevant studies.

Table 6: Comparison of Enteric-Coated Herbal/Formulation Studies

Author's Name	Herbal/Drug Model	Formulation Type	Target Delivery Site	Key Findings
Strich, (2023)[11]	General polysaccharide-based drugs	Oral polysaccharide-based enteric delivery systems	Colon	Polysaccharide coatings effectively protect drugs from gastric degradation and target colon delivery
Taymouri	Colchicine	Enteric-coated zein	Colon	Enhanced site-specific

et al., (2025)[12]		nanoparticles in capsules		release and stability in gastric environment
Thomas & Koland, (2022)[13]	Curcumin + Piperine	Enteric-coated chitosan microspheres	Small intestine	Improved transepithelial permeation in Caco-2 cells and sheep intestinal mucosa
Wang et al., (2023)[14]	Panax notoginseng saponins	Self-double-emulsifying drug delivery system with enteric-coated capsules	Small intestine	Improved oral bioavailability and anti-inflammatory activity
Zhao et al., (2021)[15]	Panax notoginseng flower saponins	Enteric-coated sustained-release pellets	Small intestine	Sustained drug release with strong in vitro–in vivo correlation

4.3.Implications of Findings

The research shows that enteric coated herbal tablets have the ability to:

- Keep away early gastric leeching and decaying of active herbal compounds.
- Achieve prolonged and regulated release in the intestinal site.
- Increase intestinal permeation that might stimulate bioavailability and therapeutic efficacy.

These results demonstrate a possible prospect of coming up with herbal-specific treatments of chronic metabolic conditions, which is a good alternative to traditional oral herbal preparations.

4.4.Limitations of the Study

- The research solely involves the use of rat intestinal models which are not necessarily representative of the human gastrointestinal physiology.
- Long-term studies on the coated tablets were not conducted.
- The study lacks in vivo therapeutic or pharmacokinetic assay in larger models.

4.5.Suggestions for Future Research

- Perform in vivo pharmacokinetic and pharmacodynamic research on the appropriate animal models to confirm bioavailability and drug efficacy.
- Determine stability of enteric-coated tablets in different storage conditions at a long period of time.
- Investigate alternative coating polymers and optimization to further increase the site-specific delivery and controlled release profiles.
- Determine the possible synergies between using a combination of various herbal extracts in enteric-coated formulations to manage metabolic disorders.

5. CONCLUSION

5.1.Summary of Key Findings

The present research manages to prepare enteric-coated herbal tablets made of extracts of Gymnema sylvestre and Curcuma longa. Characterization of tablet Tablet characterization

establishes that both coated and uncoated tablets comply with pharmacopeia standards in terms of weight variation, hardness, friability and thickness with coated tablets proving to be stronger mechanically. In vitro dissolution data indicates that coated tablets are resistant to gastric degradation and have a slow release in intestinal pH to an apogee release of about 95.5% at 6 hrs. The ex vivo permeation of coated tablets also indicated a controlled intestinal absorption as the cumulative permeation of coated tablets reaches approximately 75.8% at 5 hours whereas uncoated tablets release and permeate at a fast rate. The statistical analysis confirms the presence of significant differences between coated and uncoated formulations ($p < 0.001$), which indicates that enteric coating is an effective coating method to deliver drugs to the target intestine.

5.2.Significance of the Study

It is evident that enteric-coated herbal preparations have the potential to address typical shortcomings of oral herbal tablet preparations, including early gastric emptying, inadequate solubility, and bioactive degradation. The coated tablets will improve bioavailability and therapeutic efficacy of herbal extracts by delivering site-specific and sustained intestinal delivery, and thus, it is applicable in the treatment of chronic metabolic syndrome such as diabetes and dyslipidemia.

5.3.Final Thoughts or Recommendations

The experiment shows that enteric coating of herbal tablets is possible and beneficial, which is the case with Gymnema sylvestre and Curcuma longa. Future studies ought to entail in vivo pharmacodynamics and pharmacokinetics, long-term stability assay, and investigation of alternative polymers to be used in coating to streamline targeted delivery. These findings suggest that more research and possible clinical conversion of enteric-coated herbal tablets are viable and trustworthy curative investigations of metabolic conditions.

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