



**INTERNATIONAL JOURNAL OF  
PHARMACEUTICAL SCIENCES**  
[ISSN: 0975-4725; CODEN(USA): IJPS00]  
Journal Homepage: <https://www.ijpsjournal.com>



## Research Article

# Design And Development of Co-Processed Chitin-Lactose Monohydrate as An Excipient for Oral Dispersible Tablets

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## ARTICLE INFO

Published: 04 Nov. 2024

### Keywords:

Co-processing, Direct compression, Chitin, Lactose monohydrate.

### DOI:

10.5281/zenodo.14035183

## ABSTRACT

This study describes the preparation, characterization and performance of a novel excipient for use in oral-dispersible tablets (ODT). The excipient (Cop-CLM) consists of chitin and lactose monohydrate. Specific benefits of co-processed excipients include improved flow, compressibility, disintegrating effect, and masking undesirable properties of individual excipients. The excipient with optimal physicochemical properties was obtained at a chitin: lactose monohydrate ratio of 1:2 (w/w) and produced by direct mixing. Physical properties of Co-processed chitin-lactose monohydrate (1:2 w/w) powder showed good flowability and compressibility. Differential scanning calorimetry (DSC), Fourier Transform-Infrared (FT-IR) techniques were used to characterize Cop-CLM, in addition to characterization of a powder and ODT dosage form. Heckel plot of Cop-CLM showed higher value of K (0.647) than lactose monohydrate (0.355) and chitin (0.255), which indicates more plastic material. Ondansetron ODTs were prepared, using Cop-CLM displayed excellent physiochemical properties like fast disintegration, wetting time and exceptional binding in comparison with commercially available ODT. This study concludes that Cop-CLM results in a unique multifunctional base which can successfully be used in the formulation of oral-dispersible and fast immediate release tablets.

## INTRODUCTION

Due to their ease of manufacture and self-administration, tablets are a commonly utilised drug delivery mechanism. In their preparation, a variety of excipients are employed [1].

Unfortunately, swallowing traditional tablets can be challenging for patients who are young, old, or mentally ill, which results in low patient compliance. ODT formulations have been created to address this shortcoming. In Ph. Euro., an ODT

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**Relevant conflicts of interest/financial disclosures:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



is a pill that dissolves quickly in the mouth and must be consumed in less than three minutes [2]. In recent years drug formulation scientists have recognized that single-component excipients do not always provide the requisite performance to allow certain active pharmaceutical ingredients to be formulated or manufactured adequately. Hence, there is a need to have excipients with multiple characteristics built into them such as better flow, low/no moisture sensitivity, superior compressibility and rapid disintegration ability. One such approach for improving the functionality of excipients is co-processing of two or more excipients. Co-processing of excipients refers a combination of two or more compendial or non-compendial excipients designed to physically modify their properties in a manner not achievable by simple physical mixing, and without significant chemical change [3]. Chitin is a long-chain polymer found in nature and is one of the most abundant biopolymers on Earth. Chitin is used in tablet development as a binder or disintegrant due to their high-water absorption capacity. Its mechanism involves providing structural integrity to tablets, ensuring they hold their shape, and aiding in their dissolution by promoting disintegration into smaller particles when ingested [4]. Lactose monohydrate is a form of lactose, a sugar found in milk and dairy products. Lactose monohydrate serves several functions in tablet manufacturing. As a filler or diluent, it adds bulk to the tablet, facilitating the uniform distribution of active ingredients. Its compressibility aids in the formation of tablets with the desired hardness and friability [5].

## MATERIALS AND METHODOLOGY

**Materials:** Ondansetron hydrochloride was a gift sample from Dr. Reddy's Laboratories, Bangalore. Chitin and lactose monohydrate obtained from Loba Chemie Pvt, Ltd, Mumbai. All other excipients and reagents used were of analytical grades, respectively.

## METHODOLOGY

### Preparation of Co-Processed Chitin-Lactose Monohydrate Excipient (Cop-CLM)

Three Co-Processed mixtures of chitin and lactose monohydrate of different ratios (1:1, 1:2 and 2:1 w/w) were prepared using different processing techniques, i.e., Direct mixing and solvent evaporation.

#### Direct Mixing

The three mixtures were separately Sieve through mesh no. 18 and then mixed for 5min at 10 rpm using a 1 L cubic blender equipped with a motor drive machine [6].

#### Solvent Evaporation

Weigh and combine the coprocessed mixture, then dissolve it in a solvent (water). Agitate the mixture until the solvent evaporates, allowing the coprocessed mixture to dry [7].

### Physical Properties of Co-Processed Chitin-Lactose Monohydrate Powder

**Bulk density:** It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the 20 g powder (passed through standard sieve # 20) into a 100 ml measuring cylinder and initial volume was noted. From this the bulk density is calculated according to the formula mentioned below. It is expressed in g/ml.

$$Db = M / Vb$$

Where, M is the mass of powder, Vb is the bulk volume of the powder.

#### Tapped density

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted, it is expressed in g/ml and is given by the formula [8]

$$Dt = M / Vt$$

Where, M is the mass of powder.

Vt is the tapped volume of the powder.

#### Angle of repose



It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane and it can be calculated by the following formula.

$$\tan(\theta) = h / r$$

$$\theta = \tan^{-1}(h/r)$$

where,  $\theta$  = Angle of repose

h = Height of the pile.

r = Radius of the pile.

#### **Carr's index (or) % compressibility**

It indicates powder flow properties. It is expressed in percentage and is given by the formula.

$$I = \frac{D_t - D_b}{D_t} \times 100$$

$$I = \frac{D_t - D_b}{D_t} \times 100$$

$D_t$

Where,  $D_t$  is the tapped density of the powder and

$D_b$  is the bulk density of the powder.

#### **Hausner ratio**

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula

$D_t$

$$\text{Hausner ratio} = \frac{D_t}{D_b}$$

$D_b$

Where,  $D_t$  is the tapped density.

$D_b$  is the bulk density.

#### **pH measurement**

The pH of powder was determined using digital pH-meter (Infra Digi, Raipur). About 1 g of the powder was weighed and dissolved in 100 ml of distilled water [9].

#### **Characterization of Co-processed chitin-lactose monohydrate excipient**

##### **Fourier transform infrared spectroscopy (FT-IR):**

FT-IR measurements were performed using an FT-IR instrument (Paragon 1000, Perkin Elmer, Llantrisant, UK) by means of thin pellets containing 1 mg of each sample dispersed in 100 mg of KBr. The spectra were recorded at room temperature as an average of 3 scans, in the 400–4000  $\text{cm}^{-1}$  range with a spectral resolution of 1  $\text{cm}^{-1}$ . In order to minimize the effects of traces of

$\text{CO}_2$  and water vapour from the atmosphere of the sample compartment, the spectrometer was purged with nitrogen [10].

**Differential scanning calorimetry (DSC):** DSC is used to investigate the physical and chemical interactions between the excipients. Samples (~5 mg) were hermetically sealed in aluminium pans and scanned over a range temperature of 0–300°C at a rate of 5 °C/min. The instrument was calibrated using indium and the calorimetric data were analysed [11].

#### **Powder Compressibility**

Chitin, Lactose Monohydrate and Cop-CLM powder samples were compressed using a universal testing machine (RKM 50, PR-F system, ABS Instruments, Tamilnadu, Germany) equipped with 12 mm round, flat face upper and lower punches as well as dies; punch speed was fixed at 10 mm/min. Different compression forces from were applied. Three tablets were prepared to ensure reproducibility. Compression was carried out at 400 mg tablet weight. The compression behavior of the samples was evaluated using the Heckel equation. The Heckel equation is widely used to determine the relative density of a powder bed during compression. The Heckel equation is expressed as,

$$\ln [1/(1-D)] = KP+A$$

Where,

D is the relative density of the tablet, P is the applied pressure, K is the slope, A is the intercept. Heckel plots of  $\ln [1/(1-D)]$  against the applied pressure were constructed [12].

#### **Formulation of ondansetron HCl oral dispersible tablet using the prepared co-processed excipients**

The ODT for the Ondansetron HCl drug were prepared using a direct compression method. In this method, Ondansetron HCl and all excipients, except Magnesium stearate, were first mixed for 2 min and then magnesium stearate was added and further mixed for another 2 min. About 250 mg of



the powder mix was weighed accurately and fed into die of single punch machinery and compressed using 12mm flat-surface punches.

**Table 1. Composition of ondansetron HCl oral-dispersible tablets**

Material	Composition (% w/w)
Ondansetron HCl	03.50
Cop-CLM (1:2)	90.00
Magnesium stearate	01.00
Sodium starch glycolate	03.00
Aspartame	00.50
Strawberry powder flavour	02.00

### Evaluation of physical properties of ondansetron HCl oral dispersible tablets formulated using the prepared co-processed excipients

**1. Friability:** Twenty tablets were weighed collectively (W1) and loaded into the friabilator (EF - 2 Electrolab, Mumbai), which was set to rotate for four minutes at a speed of 25 rpm. The tablets were then dusted, re-weighed (W2), and the percentage of friability (F) was computed as follows:

$$\% \text{ friability} = \frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \times 100$$

**2. Disintegration test:** Disintegration time was determined using 6 tablets per batch in the disintegration tester (Erweka ZT4-4, Germany) containing distilled water at a temperature of  $37 \pm 0.5^\circ\text{C}$  [13].

**3. Tablet hardness:** Using the hardness tester (Tablet hardness tester, Monsanto), the hardness (kg) of three (3) randomly chosen tablets was assessed, and the mean was computed [14].

**4. Wetting time:** A piece of tissue paper folded twice was placed in a Petri dish (8.5 cm in diameter) containing 6 mL of water. One tablet was carefully placed on the surface of the tissue paper and allowed to wet completely. The time required for the water to reach the upper surface of the tablet was recorded as the wetting time [15].

**5. Thickness:** Thickness was measured using Vernier Callipers. It was determined by checking the thickness of three tablets of each formulation.

**6. IN-VITRO DRUG RELEASE STUDY:** The *in-vitro* dissolution studies were carried out using USP type -1 Dissolution apparatus for up to 12 minutes. Ondansetron HCl oral-dispersible tablets was placed in dissolution apparatus containing 900ml 6.8 pH phosphate buffer which was maintained at  $37 \pm 0.5^\circ\text{C}$  and at a stirring speed of 50 rpm. 5ml samples were withdrawn at predetermined time intervals and the same volume of fresh medium was replaced into the basket. Sample was withdrawn at time intervals of 2, 4, 6, 8, 10, 12 minutes. The concentration of drug released was estimated by using UV spectrophotometer at  $\lambda_{\text{max}}$  310nm [16].

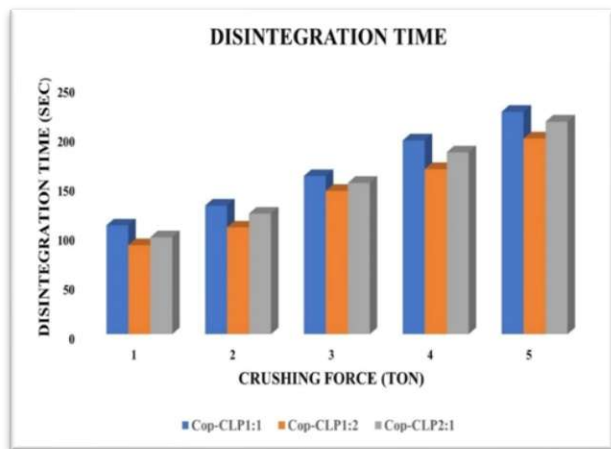
### RESULT AND DISCUSSION:

#### Selection of Processing Methods and Ratios for Co-Processed Chitin–Lactose Monohydrate (Cop-CLM) Excipient

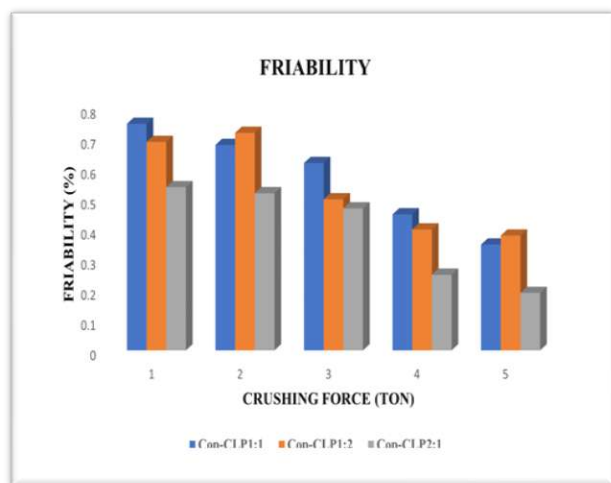
In order to select the optimal ratio and process for co-processed excipient preparation, three different ratios of chitin and lactose monohydrate (1:1, 1:2, 2:1 w/w) and two different processing techniques i.e., solvent evaporation, direct mixing were used. The prepared excipients were lubricated with magnesium stearate (1.0% w/w) and compressed at different tablet crushing forces. The tablets obtained were tested for friability, disintegration and wetting times versus the corresponding crushing forces. The preliminary results of the aforementioned experiments indicated that solvent evaporation method was unsuitable because the mixtures prepared by solvent evaporation displayed unacceptable physical properties (e.g., poor flow and powder non-uniformity). The difference in bulk densities of chitin ( $\sim 0.2 \text{ g/cm}^3$ ) and lactose monohydrate ( $\sim 0.5 \text{ g/cm}^3$ ) is the reason underlying such unacceptable physical properties. In case of direct mixing displayed acceptable physical properties. However, direct



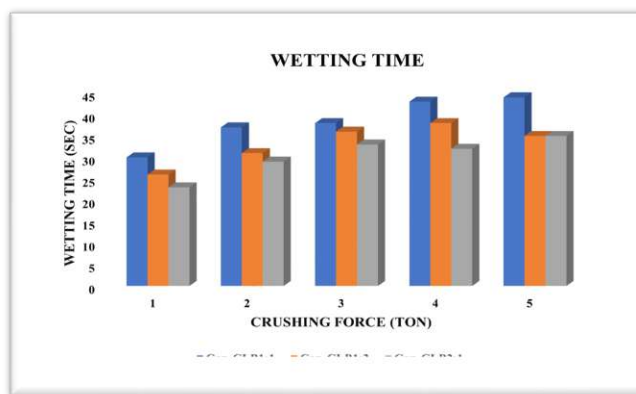
mixing gave reasonable results. The data in Figure 1 shows the effect of crushing force on the friability, disintegration and wetting times of tablets produced. Up to a crushing force of 5 tons, all chitin: lactose monohydrate ratios showed acceptable physical properties (low friability and fast disintegration and wetting times). Using chitin: lactose monohydrate ratios 1:1, 1:2 and 2:1 (w/w) over all the investigated range of crushing forces produced tablets with acceptable physical properties. However, a ratio of chitin and lactose monohydrate of 1:2 (w/w) was chosen to obtain beneficial lactose monohydrate taste properties and to reduce the amount of insoluble chitin in ODT preparation.



a



b



c

**Figure 1. Plots of the crushing force (N) versus (a) disintegration time; (b) friability; and (c) wetting time for compacted mixtures prepared using different ratios of chitin and lactose monohydrate (1:1, 1:2, and 2:1 w/w).**

### Physical Properties of Cop-CLM Powder

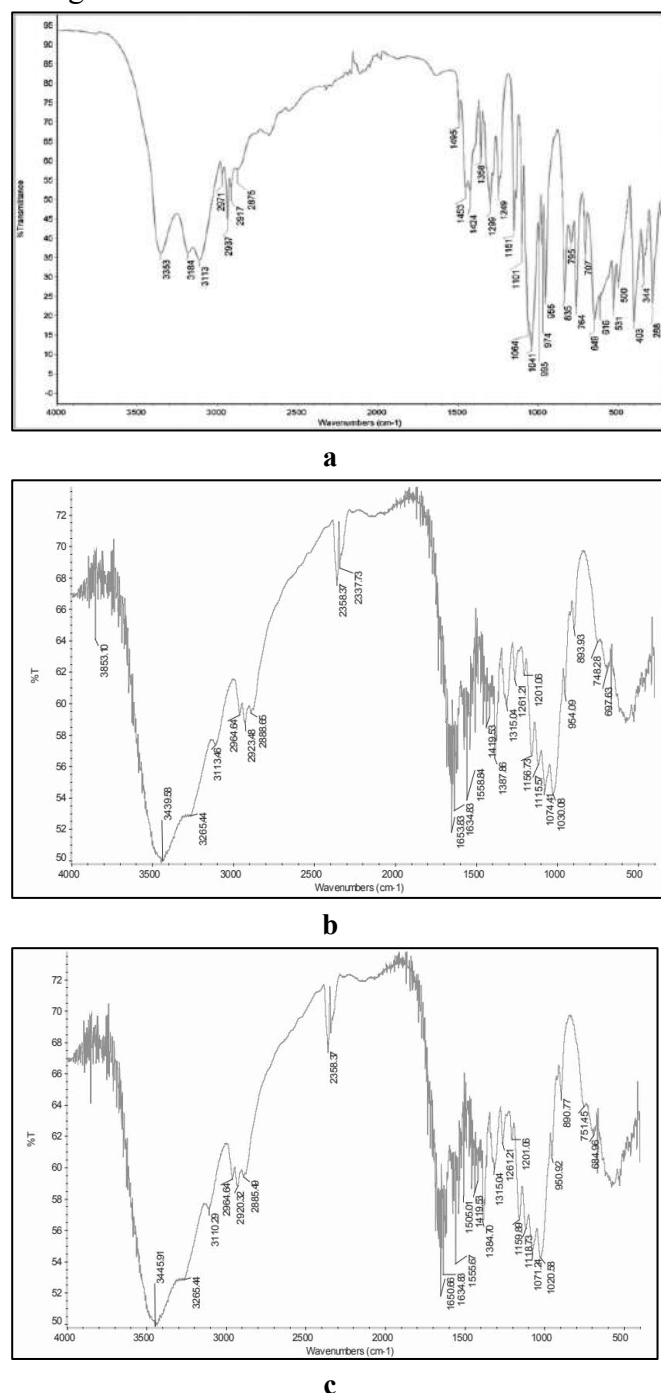
The Cop-CLM powder have a water content of about 1.7 W/W% and pH of about 6.6. The Cop-CLM have a bulk density of about 0.53 gm/ml. A higher bulk density is advantageous in tableting because of a reduction in the powder-fill volume of the die. Tap density of about 0.60 gm/ml. The Carr Index calculated from the density data showed a value less than 12, and Hausner ratio of less than 1.13 further indicating the good flowability, which is an important factor for DC powders. Angle of repose of about 34° indicates good flow. The Hausner Ratio, Carr Index and Angle of Repose values for Cop-CLM powder are shown in Table 2. From the data obtained, Cop-CLM powder showed good flowability and compressibility.

**Table 2. Physical properties of Co-processed chitin-lactose monohydrate (1:2 w/w) excipient (Cop-CLM)**

Parameters	Value
Water content (w/w%)	1.7
pH	6.6
Bulk density (gm/ml)	0.53
Tapped density (gm/ml)	0.60
Hausner Ratio	1.13
Carr Index	11.66
Angle of Repose (degree)	34°

## Characterization of Cop-CLM Powder

**FT-IR:** The FT-IR spectra of lactose monohydrate, chitin and Cop-CLM are presented in Figure 2a-2c

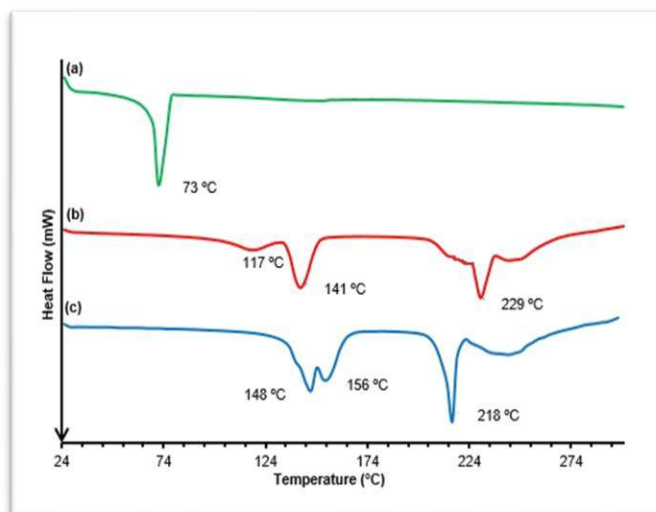


**Figure 2. FT-IR spectra of (a) lactose monohydrate; (b) chitin; and (c) co-processed chitin-lactose monohydrate (1:2 w/w) excipient (Cop-CLM).**

FTIR spectroscopy is a quick and simple technique for identifying any chemical changes or interactions. FTIR spectra of lactose monohydrate showed a characteristic peak at 3353 cm<sup>-1</sup> due to O-H stretching, CH stretching at 2875 cm<sup>-1</sup> and CO stretching at 1064 cm<sup>-1</sup>. A bending vibration at 1424 cm<sup>-1</sup> was observed due to CH<sub>2</sub> bending. FTIR spectra of chitin showed a characteristic peak at 3439.58 cm<sup>-1</sup> due to O-H stretching, CH stretching at 2888.65 cm<sup>-1</sup> and CO stretching at 1074.41 cm<sup>-1</sup>. A bending vibration at 1419.5 cm<sup>-1</sup> was observed due to CH<sub>2</sub> bending. The two bands 1653.83 and 1558.84 cm<sup>-1</sup> range, corresponding to the amide 1 and amide 2 vibrational modes of chitin. FTIR spectra of co-processed excipients showed retention of all the major peaks of individual polymers which indicate the absence of chemical interaction between polymers during processing as shown in figure 2.

## Differential scanning calorimetry

The differential scanning calorimetry of chitin, lactose monohydrate and Cop-CLM are presented in the figure 3a-3c.

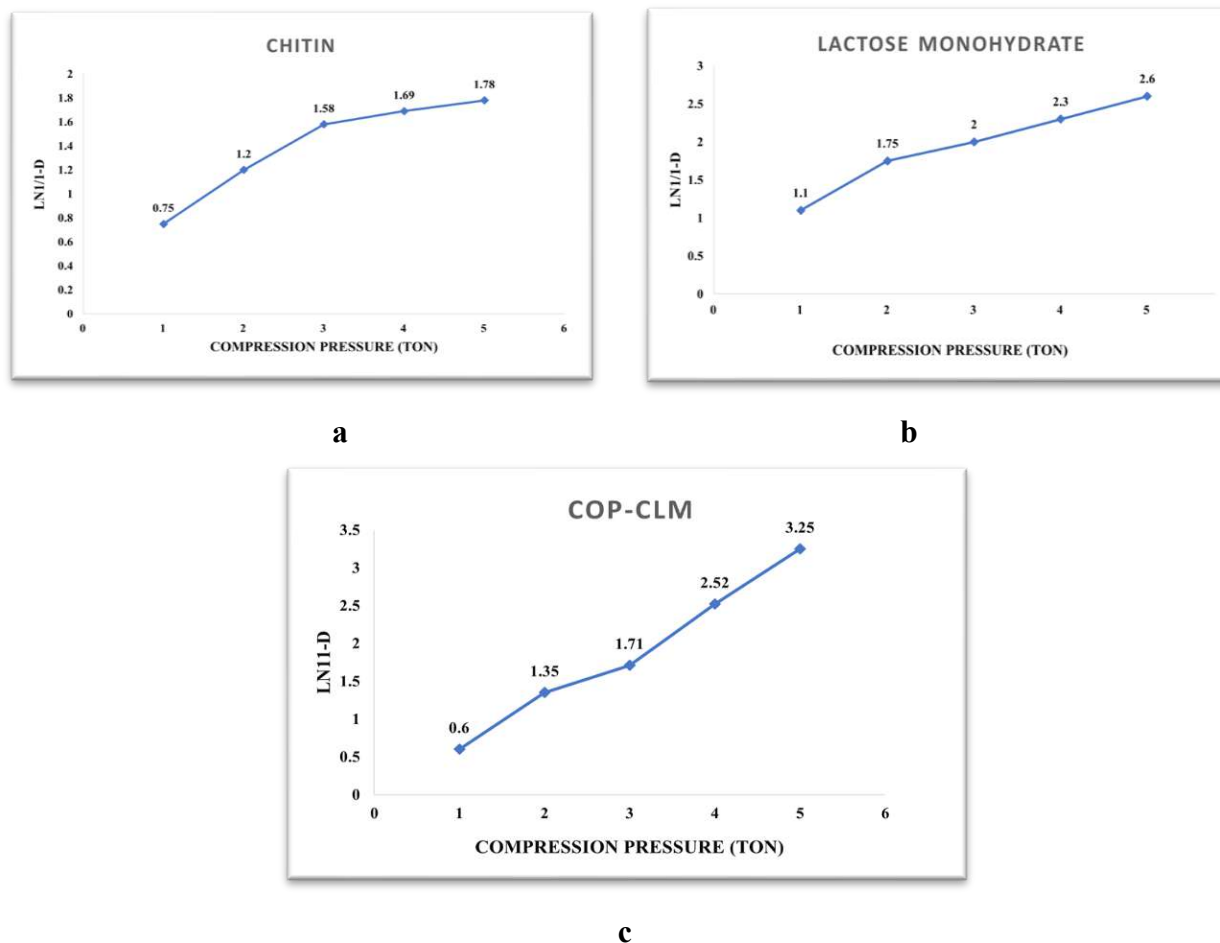


**Figure 3. DSC curves for (a) chitin (b) Lactose monohydrate (c) Co-processed chitin-lactose monohydrate (1:2) excipient (Cop-CLM)**

DSC of chitin exhibits an endothermic peak at 73°C and this can be ascribed to the loss of water. DSC of lactose monohydrate shows endotherms at

117°C, 141°C are believed due to the dehydration of the crystalline water. The endotherms at 229°C are believed correspond to the melting point. DSC thermograms of co-processed excipients showed negligible difference in terms of peak shift of the individual components.

**Powder Compressibility:** The compression behaviour of the chitin, lactose monohydrate and Cop-CLM powder samples was evaluated using the Heckel equation shown in the below figures 4a-4c. Compressional pressure was applied in Tons.



**Figure 4. Heckel plot of (a) chitin; (b) lactose monohydrate; and (c) co-processed chitin-lactose monohydrate (1:2 w/w) excipient (Cop-CLM).**

- ❖ Chitin is a type C material. When the initial compression pressure is applied it shows linear region which becomes superimposed, this superimposed region flattens out as the applied compression pressure is increased. This behaviour was ascribed due to the absence of a rearrangement stage. Densification occurs due to plastic deformation and asperity melting.
- ❖ Lactose monohydrate is a type b material. When the initial compression pressure applied it shows curved region followed by a straight line, indicates that the particle is fragmenting at the early stages of the compression process. Brittle fracture occurs because of the preceds plastic flow of the material. These types of materials required high yield pressure.
- ❖ In Cop-CLM, When the compressional pressure is applied it shows initial curve indicates rearrangement and fragmentation occurs. As compression progresses, the high

linear obtain indicates that plastic deformation is taking place due to densification by brittle fracture. Such high linearity is often experienced with comparatively soft materials that undergo plastic deformation while retaining different degrees of porosity, depending on the initial packing arrangement in the die.

- ❖ Heckel plot of Cop-CLM shows higher value of K (0.647) than lactose monohydrate (0.355) and chitin (0.255), which indicates more plastic material.

### Evaluation of Ondansetron HCl oral-dispersible tablets

**Table 3. Physical properties of Ondansetron HCl oral-dispersible tablets formulated using the prepared co-processed excipients**

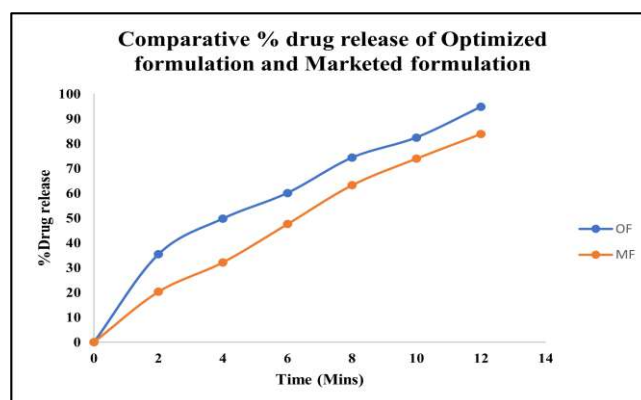
Parameters	Formulation code	
	Optimized formulation	Marketed formulation
Hardness (kg)	3.7±0.10	4±0.15
Thickness (mm)	3.40±0.17	2.90±0.30
Friability (%)	±0.36	±0.43
Disintegration Test (Sec)	24±0.12	28±0.23
Wetting Time (Sec)	41±0.28	50±0.21
Drug Content (%)	99.45±0.01	98.92±1.57

All the values are expressed as mean± SD, n=3  
 In the present work, co-processed mixture of chitin and lactose monohydrate (Cop-CLM) by DC is used as a multi-functional excipient. Although a limited number of excipients were used with Cop-CLM as ODT base to improve the taste and to prevent sticking of powder on punches and dies during tablet compression, the fast disintegration properties (24 s) was attained when compared to marketed formulation. The results indicate that Cop-CLM is compressible and preserves its functionality when utilized in DC formulation. Hence, it can be used as a multifunctional base (binder, filler and disintegrant) in ODT formulations.

**Comparative dissolution study of optimized formulation and marketed formulation:** The dissolution profile of optimized formulation was compared with marketed Ondansetron HCl orally disintegrating tablet. The comparative drug release profiles are shown in table:4 and fig:5.

**Table 4. Comparative In Vitro Release Data of Optimized Formulation and Marketed Ondansetron HCl oral dispersible tablet**

Time (min)	Percentage Drug Release (%)	
	Optimized formulation	Marketed Formulation
2	35.40±0.60	20.29±0.48
4	49.80±0.26	32.16±0.70
6	60.10±0.98	47.57±0.43
8	74.32±0.67	63.23±0.28
10	82.45±0.11	73.98±0.16
12	94.78±0.46	83.92±0.15



**Figure 5. Comparative In Vitro Release profile of Optimized Formulation and Marketed Ondansetron HCl Oral dispersible tablet in phosphate buffer pH 6.8**

The percentage drug release of optimized formulation and marketed product was found to be 94.78% and 83.92% at 12 minutes. The drug release of optimized formulation of Ondansetron HCl orally dispersible tablets was found to be greater than that of marketed product. The percentage drug release was found to be increased by 10.86% at 10 minutes interval in optimized formulation compared to the marketed product.

## CONCLUSION

Co-processing of chitin with lactose monohydrate by DC offers an excellent multifunctional base for ODT formulations. The novel excipient displayed fast disintegration and wetting properties over a wide range of tablet crushing force values. Regardless of the preparation method the functionality of the novel excipient was preserved. Moreover, the excipient can accommodate a high amount of drug without affecting its functionality. Utilization of the novel excipient in ODT containing active pharmaceutical ingredients offers very fast disintegration and wetting rates, excellent chemical stability and binding properties in comparison with commercially available ODT bases.

**Acknowledgement:** We sincerely acknowledge the Guide, Management, Principal, HOD, Teaching and Non-teaching staff of Sarada Vilas College of pharmacy, Mysuru for their endless support and suggestions throughout the research work.

## List of Abbreviations:

Cop-CLM: Co-processed chitin-lactose monohydrate

ODT: Oral dispersible tablet.

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**HOW TO CITE:** Prajwal K.\*, Parthasarathi Kulkarni, Nagendra R., Venkatesh, K. Hanumanthachar Joshi, Design And Development of Co-Processed Chitin-Lactose Monohydrate as An Excipient for Oral Dispersible Tablets, *Int. J. of Pharm. Sci.*, 2024, Vol 2, Issue 11, 239-248. <https://doi.org/10.5281/zenodo.14035183>

