World Journal of Pharmaceutical Science and Research

www.wjpsronline.com

Research Article

ISSN: 2583-6579
SJIF Impact Factor: 6.916
Year - 2026
Volume: 5; Issue: 3
Page: 473-485

IMPACT OF INTRA-GRANULAR METHOD OF DISINTEGRANT INCORPORATION ON FORMULATED PARACETAMOL TABLETS DISSOLUTION

Ucheokoro Adaeze S.*, Ugoeze Kenneth C., Abali Sunday O.

Department of Pharmaceutics and Pharmaceutical Technology, University of Port Harcourt, Port Harcourt 500004, Nigeria.

Article Received: 22 January 2026 | | Article Revised: 12 February 2026 | | Article Accepted: 4 March 2026

***Corresponding Author: Ucheokoro Adaeze S.**
Department of Pharmaceutics and Pharmaceutical Technology, University of Port Harcourt, Port Harcourt 500004, Nigeria.
DOI: https://doi.org/10.5281/zenodo.19050157

How to cite this Article: Ucheokoro Adaeze S., Ugoeze Kenneth C., Abali Sunday O. (2026) IMPACT OF INTRA-GRANULAR METHOD OF DISINTEGRANT INCORPORATION ON FORMULATED PARACETAMOL TABLETS DISSOLUTION. World Journal of Pharmaceutical Science and Research, 5(3), 473-485.

ABSTRACT

Background: Disintegrants are essential excipients in immediate-release tablets because they facilitate tablet breakup and promote rapid drug dissolution and bioavailability. Although synthetic superdisintegrants such as sodium starch glycolate (SSG) are widely used, there is increasing interest in natural, biodegradable, and locally sourced alternatives. Lentinus tuber regium, an edible mushroom, has shown potential as a pharmaceutical excipient, but its disintegrant performance depends on processing and formulation conditions.

Objective: This study evaluated the effect of processing and intra-granular incorporation of Lentinus tuber regium powder on the dissolution performance of formulated paracetamol tablets.

Methods: Natural Lentinus tuber regium powder (NLT) was processed by bleaching to obtain bleached LT (BLT) and by solvent purification to obtain solvent-purified LT (SPLT). Each powder was incorporated intra-granularly at concentrations of 3.0%, 7.0%, and 10.0% w/w using the wet granulation method. Sodium starch glycolate served as the reference superdisintegrant. Paracetamol tablets were compressed under uniform conditions and evaluated for dissolution using the USP paddle apparatus in suitable dissolution medium maintained at 37 ± 1 °C. Dissolution profiles were analyzed to determine the influence of processing method and concentration on drug release.

Results: Tablets containing NLT exhibited slow and incomplete drug release at all concentrations, indicating limited hydration and disintegration efficiency of the unprocessed powder. In contrast, BLT formulations showed significantly enhanced dissolution, particularly at low concentration, while SPLT exhibited optimal dissolution at moderate concentration. At higher concentrations, both BLT and SPLT showed reduced dissolution, possibly due to excessive swelling and restricted diffusion pathways within the tablet matrix. Generally, processed LT powders performed comparably to, and in some cases better than, SSG.

Conclusion: Processing and intra-granular method of incorporation significantly improved the disintegrant performance of Lentinus tuber regium. The results support the potential of processed Lentinus tuber regium as a natural, cost-effective alternative superdisintegrant for immediate-release tablet formulations.

KEYWORDS: *Lentinus tuber regium*, natural superdisintegran, intra-granular incorporation, paracetamol tablets, dissolution profile.

1. INTRODUCTION

Oral drug delivery has been recognized for decades as the furthermost broadly used route of administered amongst all the routes that have been working for the systemic distribution of drug via numerous pharmaceutical products of diverse dosage forms. The motives that the oral route attained such approval may be in part accredited to its ease of administration. Oral sustained drug delivery system is difficult by partial gastric residence times (GRTs). Speedy GI transit can avoid comprehensive drug release in the absorption region and decrease the effectiveness of the administered dosage.[1]

Fast dissolving tablets (FDTs) have gained significant attention in the pharmaceutical industry due to their numerous advantages such as ease of administration, rapid onset of action, and improved patient compliance. Super disintegrants play a crucial role in the formulation of FDTs by facilitating rapid disintegration of the tablet matrix upon contact with saliva.[2,3]

Natural super disintegrants have gained attention in recent years due to their biocompatibility, sustainability, and cost-effectiveness.[4] Therefore, this study aims to explore various natural super disintegrants for the formulation of FDTs to enhance the dissolution rate and overall bioavailability of the drug. These natural ingredients are preferred in pharmaceutical formulations due to their biocompatibility, safety profile, and environmental friendliness.[5,6]

The medication can then be absorbed partially or entirely into the systemic circulation from blood vessels in the sublingual mucosa, or it can be swallowed as a solution to be absorbed from the gastrointestinal tract. Tablet disintegration has received considerable attention as an essential step in obtaining faster drug release. The oral route of administration is central for the delivery of a large number of the important drug in the various therapeutic area, many patients prefer standard oral dosage form as well as advanced oral drug delivery system over other dosage form.[7]

Superdisintegrants: The term super-disintegrants refer to substances which achieve disintegration faster than the substances conventionally used. A tablet or a capsule content breaks up or disintegrates into a smaller particle that dissolves more rapidly than in the case of the absence of such disintegrates. Super-disintegrants are granules used at a low level in the solid dosage form, typically from 1 to 10 % of the total weight of a given unit dosage. Many factors are considered in the selection of Superdisintegrants: Quantity of disintegrates present in preparation, Kind of addition and mixing, Drug nature, Good flowability, The occurrence of surface-active agents.[8]

Super disintegrants are ingredients that are added to tablet formulations in order to facilitate quick dissolution and disintegration. Although synthetic super disintegrants have been widely used, due to their biocompatibility, safety, and environmental friendliness, there is growing interest in investigating natural alternatives. Plant-based compounds, which are natural super disintegrants, present a promising option with potential advantages.[9]

2. MATERIALS AND METHOD

2.1 Materials

Table 2.1: Materials Used.

Materials	Manufacturer	Country	Grade
Sodium Starch Glycolate	Tribute Pharma	India	Analytical
Gelatin	Titan biotech	India	Analytical
Talc	Titan biotech	India	Analytical

Magnesium Stearate	JHD	China	Industrial
Lactose	Titan biotech	India	Analytical
Sodium hypochlorite	FMCG	Nigeria	Industrial
Ethanol	JHD	China	Analytical
Chloroform	JHD	China	Analytical/Industrial
Acetone	Loba Chemie	India	Analytical/Industrial
n-hexane	JHD	China	Analytical
Nitric acid	JHD	China	Industrial
Dilute hydrochloric acid	Loba Chemie	India	Analytical
Methanol	JHD	China	Industrial
Potassium sulphate	JHD	China	Industrial
Potassium chloride	JHD	China	Industrial
Sodium chloride	Kermel	China	Industrial
Magnesium nitrate	Kermel	China	Industrial
Disodium hydrogen phosphate dehydrate	JHD	China	Analytical
Potassium dihydrogen phosphate	JHD	China	Analytical

2.2 Plant sample Collection and Identification

The plant sample was sourced from Agazi, Ahia-Ohuru, Aba, Abia State, and was identified botanically as *Lentinus tuber regium* was deposited in the University of Port Harcourt herbarium with identification number E-HERBARIUM ID.NO: EH-P-O53, EH-C-013.

2.3 Processing of Plant Sample

The natural tubers of *Lentinus tuber regium* were peeled, sliced, air-dried, pulverized and passed through a 250 µm stainless sieve (coded NLT). A 250 g of the NLT powder was submerged in sufficient sodium hypochlorite (3.5 % w/v) and stirred for 30 min, washed in deionized water until neutral to litmus. The wet mass was submerged in sufficient alcohol (96 % v/v), slurred for 30 min, dried at 60 ^{o}C. It was pulverized and classified to 250 µm size (BLT). A 250 g of the NLT was treated in turns in a Soxhlet apparatus using chloroform and acetone respectively. The powder obtained was submerged in enough sodium hypochlorite (3.5 % w/v) and blended for 30 min. It was washed with deionized water until neutral. The mass was slurred in alcohol (96 % v/v), dried at 60 ^{o}C, pulverized to 250 µm sieve size (SPLT).

2.4 Evaluation of *Lentinus tuber regium* powders (NLT, BLT, SPLT)

The physicochemical properties of these powders were determined as follows and all determinations were carried out in triplicate.

2.4.1 Organoleptic test

The respective powder samples were tested and observed for colour, taste, texture and odour organoleptically.

2.4.2 pH of 1%w/w aqueous dispersion

A 1g quantity of each powder sample; NLT, BLT and SPLT respectively was dispersed in a 100mls of deionized water and was tested with a pH meter (Hanna, India), the readings were recorded.

2.4.3 Solubility profile

The solubility of 0.1g of the respective samples; NLT, BLT and SPLT were carried out at room temperature and at 40°C (in water bath) using 10 ml of water, ethanol, methanol, acetone, chloroform, n-hexane and dilute mineral acids such as nitric, hydrochloric acids.

2.4.4 Moisture content

A 5.0g weight of the respective powder sample; NLT, BLT and SPLT was weighed in a crucible and left in a hot air oven at 105°C. The samples were reweighed after each 30 min. to monitor the reduction in weight. The final weight was recorded when there was no more reduction in weight of the respective samples. The moisture loss was calculated as a percentage after triplicate repetition (Reeb J. and Milota M., 1999)

2.4.5 Hydration capacity

Empty centrifuge tubes were weighed and a 1.0 g weight of NLT, BLT and SPLT powders respectively were weighed and transferred into the respective tubes and then labelled and weighed. 10 ml of water was transferred into each of the tubes and these were vigorously shaken then observed for 10 min. The tubes were placed in the centrifuge which was operated at 3000 rotation per minute (rpm) operated for 10 min. The supernatant were carefully decanted and sediment weighed. This was carried out in triplicate for all the samples.

Hydration capacity was calculated using the formula stated below:

$$Hydration\ capacity = x/y \quad \text{..... (1)}$$

Where:

y =weight of dry powder

X = weight of moist powder after centrifugation (Fleming, *et al.*, 1974).

2.4.6 Swelling Index

A 10ml measuring cylinder was used to collect a 1.0g weight of NLT, BLT and SPLT respectively and the cylinder was tapped on a levelled base until a constant volume of powder was maintained and the first reading known as the initial volume was taken and then 5mls of water was introduced and the measuring cylinder was vigorously shaken until a well blend of mixture was obtained then it was allowed for a minimum of 3 days and the final volume was determined and recorded, this was done in triplicate and the procedure was repeated for all the samples.

Swelling Index is expressed as:

$$Swelling\ index = Vv/Vx \quad \text{..... (2)}$$

Where: Vv = volume of sediment

Vx =tapped volume occupied by powder (Rauh, F *et al*., 2006)

2.5 Determination of densities

2.5.1 Bulk Density

A 100ml measuring cylinder was used to hold a 20g weight of the respective samples of NLT, BLT and SPLT powders. The bulk volume of the powders were noted and this process was repeated in triplicate for all the samples.

Bulk density was expressed as:

$$\text{Bulk Density} = Mass/Bulk\ Volume \quad \text{..... (4)}$$

(Hunt N. and Gilkes R., 1992)

2.5.2 Tapped Density

A 100ml measuring cylinder was used to hold a 20g weight of the NLT, BLT and SPLT powders. The initial volume noted and recorded. The measuring cylinder was tapped on the desk several time until a constant volume was maintained and the final volume noted and recorded as well. Three determination was taken and recorded for all the samples and the readings for the initial and final volumes recorded respectively.

Tapped density is expressed as:

Tap density = $\frac{Mass\ of\ Powder}{Tapped\ Volume\ of\ Powder}$ ………………………………………………. (5)

(Hunt N. and Gilkes R., 1992)

2.5.3 True Density

An empty 25ml volume pycnometer was weighed. It was filled with n-hexane and capped, wiped off excess fluid on its body and weighed. A 0.5 g quantity of each of the samples of *Lentinus tuber regium* was weighed into the n-hexane filled pycnometer. It was capped, the spilled n-hexane wiped off the pycnometer and the weight taken.

Three determinations were taken and the true density calculated as follows:

True density $\rho = w2 \times w3/v(w3 - w4 + w2 + w)$ …………………………………….. (6)

Where;

V = 25ml (volume of pycnometer)

W=weight of empty pycnometer

W1= weight of pycnometer and n- hexane

W2= the difference between the W and W1

W3= weight of sample powder

W4= weight of sample + n - hexane + pycnometer (L´opez-Ortiz A. and Rodriguez-Ram´ırez J., 2011)

2.5.4 Flow Rate

To determine flow rate, a funnel was tightly clamped on a retort stand at 7cm from the flat base, cotton wool was used to block the funnel orifice and after a 20g of NLT, BLT and SPLT powder respectively were loaded into the funnel the orifice was allowed to open to let the powder freely flow. Flow rate was calculated for all the samples after three determinations were carried out.

Flow rate was expressed as:

Flow rate = $Mass\ of\ powder / Time$ ……………………………………………………… (7)

(Kanig J L., 1986)

2.5.5 Angle of Repose

The constant powder heap height method was adopted. The *L t regium* powder was used to fill a funnel clamped on a retort stand on a flat surface whose plugged orifice was a distance of 3 cm above the flat surface. A 20g of *L t regium powder* was poured until the cone formed by the discharged powder touched the orifice tip of the funnel. The height

and diameter of the powder cone were measured. Experiment was done in triplicate. Each of the processed or modified *L t regium* was used.

Angle of repose θ is expressed as:

$$\theta = \tan^{-1} h/r \quad \ldots\ldots (8)$$

Where h= height of powder heap

r = radius of powder heap. (Gold G., 1966)

2.6 Formulation of tablets by wet granulation method

Table 2.2: Formula for Paracetamol Tablet Formulation

Concentration	**3% $^{w}/_{w\,(IG)}$**	**`7% $^{w}/_{w\,(IG)}$**	**10% $^{w}/_{w\,(IG)}$**
Ingredient	**Amt/Tablet (mg)**	**Amt/Tablet (mg)**	**Amt/Tablet (mg)**
Paracetamol	500.00	500.00	500.00
LT	18.00	42.00	60.00
Gelatin	12.00	12.00	12.00
Mag Stearate	3.00	3.00	3.00
Talc	3.00	3.00	3.00
Lactose	64.00	40.00	22.00
Total tablet weight	**600.00**	**600.00**	**600.00**

Key: Amount per tablet; the amount of ingredients per 600mg weight of Paracetamol tablet.

IG: Intra-granular method of *Lentinus tuber regium* powder (disintegrant) incorporation

2.6.1 Preparation of granules by wet granulation method using intra-granular, and method of disintegrant addition

Three batches of granules each containing paracetamol (83.33 5 w/w), gelatin (2.00 % w/w), magnesium stearate (0.50 % w/w), talc (0.5 % w/w), lactose (10.70 % w/w) and either NLT or BLT or SPLT (at 3.00, 7.00, 10.00 % w/w as disintegrants) were prepared using the wet granulation methods using NLT, BLT and SPLT as disintegrants with sodium starch glycolate as a standard which were all incorporated either intra-granularly (IG) or extra-granularly (EG).

2.6.2 Characterization of formulated granules

2.6.2.1 Bulk density

A 15g of granules from each batch of the samples was loaded into a 50ml glass measuring cylinder and the reading was taking as such and was recorded as the granule bulk volume this was done in triplicate for every batch of the granules.

Bulk density is expressed as:

$$Bulk\ density = mass\ /\ bulk\ volume \quad \ldots\ldots (13)$$

(Hunt N. and Gilkes R., 1992)

2.6.2.2 Tapped density

A 15g of granules from a batch of samples was loaded into a 50ml glass measuring cylinder. The opening of the measuring cylinder was blocked with cotton wool. The measuring cylinder was tapped severally on a padded flat desk and the tapping was progressive until a steady volume was maintained and no further reduction in volume was observed as the tapping progressed and the final volume was read and recorded and the procedure was done in triplicate and subsequently carried out for all the granules samples.

Tap density is expressed as:

$$Tap\ density = mass/tap\ volume \quad \text{..... (14)}$$

(Hunt N. and Gilkes R. 1992)

2.6.2.3 True density

The true density of each batch was determined using n-hexane as a displacement medium. An empty pycnometer of 25ml volume was weighed W the weight was noted and the empty pycnometer was filled with n-hexane, and excess fluid was wiped off. The filled bottle was weighed and the weight was recorded as W1, subsequently a 1.0g quantity of the granules from one batch was weighed and was recorded as W3 and was loaded into the n-hexane filled pycnometer and the excess liquid medium was wipe off and the weight was taken as W4.

Three different readings were taken and granule true density is expressed as:

$$True\ density = W2 \times W3 \div V(W3 - W4 + W2 + W) \quad \text{..... (15)}$$

Where;

V = volume of pycnometer

W=weight of empty pycnometer

W1= weight of pycnometer and n- hexane

W2= the difference between the W and W1

W3= weight of sample powder

W4= weight of sample + n- hexane + pycnometer. (L´opez-Ortiz A. and Rodriguez-Ram´ırez J. 2011)

2.6.2.4 Porosity

The values obtained from the previous bulk density and true density was used to calculate the porosity of the granules as;

$$P = 1 - (bulk\ density/\ true\ density) \times 100 \quad \text{..... (16)}$$

(Berryman J.G and Blair S.C., 1986)

2.6.3 Flow Properties

2.6.3.1 Flow Rate

A funnel used for this experiment was tightly clamped on a retort stand at 7cm from the flat base, the orifice of the funnel was tightly blocked and after a 15g of the granules from a batch was loaded into the funnel the orifice was allowed open to let the powder freely flow. Flow rate was recorded and this procedure was done in triplicate and was repeated for all the granules samples batches.

Flow rate is expressed as:

$$\text{Flow rate} = Mass\ of\ powder \Big/ Time \quad \text{..... (19)}$$

(Kanig J L., 1986)

2.6.3.2 Angle of Repose

A funnel clamped on a retort stand and its stem base fixed at a height of 3cm. The granules was loaded into the funnel while the orifice was tightly closed thereafter the orifice was allowed opened and let the free flow so that the cone apex

of granules heap formed reached the stem. The measurement of the heap diameter was taken the procedure carried out in triplicate and the procedure was repeated for all the granules batches.

Angle of repose θ is expressed as:

$$\theta = Tan^{-1}\frac{2h}{w} \quad \ldots\ldots (20)$$

Where h = 3cm = distance between stem base and base

W or d = base diameter of cone of heap of powder (Gold G., 1966)

2.6.4 Compression of granules

A 3.00mg of magnesium stearate and talc respectively were added extra-granularly to batch I-VI granules prior to compression into tablets. Compression was done using a carver single punch hydraulic press (Model C, Carver Laboratory Press, Menomonee Falls, W1, USA) fitted with a set of 10.00 mm flat faced punches at a uniform compression pressure of 2.45 Mega pascal (Mpa). The target tablets weights were 600 mg.

2.7 Determination of tablet properties

2.7.1 Weight uniformity: Using the British pharmacopeia method (16) 20 tablets were randomly selected from each batch and were weighed individually and the weight of individual tablet was taken and recorded. (ACCULAB ALC 210.4 Model, Germany).

2.7.2 Tablet hardness and thickness

Ten (10) tablets taken from each batch were randomly taken, hardness was determined using digital hardness tester (Monsanto, India). This same equipment displays the diameter and thickness of each tablet in addition to its hardness. The mean and standard deviation of the values were calculated.

2.7.3 Friability test

Ten (10) tablets from each batch were randomly selected, weighed and placed in the Erweka friabilator (D-63150 Heusenstamm, TAR 220, Germany) which was operated at 25 rpm for 4 minute. The tablets were dusted and reweighed.

Friability of the tablets was calculated using the formula stated as:

B=100(1-W/Wo) …………………………………………………………………… (21)

Where:

B=friability

W=weight of tablet after passing it through the friabilator

Wo= weight of initial tablet (Pifferi G., 1999)

The test is rejected if any tablet caps, laminates or breaks up in the course of the test. Values of B o less than 1% is given as the acceptance limited for uncoated tablet.

2.7.4 Tablet disintegration time

The disintegration time of 6 tablets randomly selected from each batch was determined using 5.8 phosphate buffer solution as the disintegration medium maintained at 37 $\pm 1^{o}$C in a disintegration apparatus (Erweka, Germany).

2.7.5 Standard calibration curve for paracetamol

A 100 mg of pure paracetamol powder was dissolved and made up to 100 ml in a 100 ml volumetric flask using 5.8 phosphate buffer solution to form stock solution. Serial dilution of the stock solution was made to obtain diluted solutions. Subsequently a scan of the solutions was carried out using an UV/vis spectrophotometer (Jen way model 6405), gave the wavelength of maximum absorption of 244nm. The different serially diluted paracetamol solutions were also scanned at 244nm of the spectrophotometer. The absorbance readings were used to calculate the different concentrations of paracetamol which enabled plot the Beer-Lamberts calibration curve.

2.7.6 Dissolution profile

The dissolution profile for each batch of paracetamol tablets was carried out using a six station dissolution apparatus [Erweka® DT600 High Head (DT600HH), Germany]. The rotating paddle method was adopted. The dissolution medium constituted 900 ml of 5.9 phosphate buffer solution maintained at 37 ±1^{o}C with paddle speed maintained at 50 rpm. A 5 ml sample was withdrawn at predetermined intervals of 5, 10, 15, 20, 25, 30 minutes respectively. Replacements with the same volume of 5.9 phosphate buffer solution maintained at the same temperature were done at each sampling time. The absorbance of each sampled solution was read in a UV spectrophotometer (Jenway Spec, model 6405, England) at a wavelength of 244nm.

3. RESULTS AND DISCUSSION

3.1 Dissolution Profile of Paracetamol Tablets

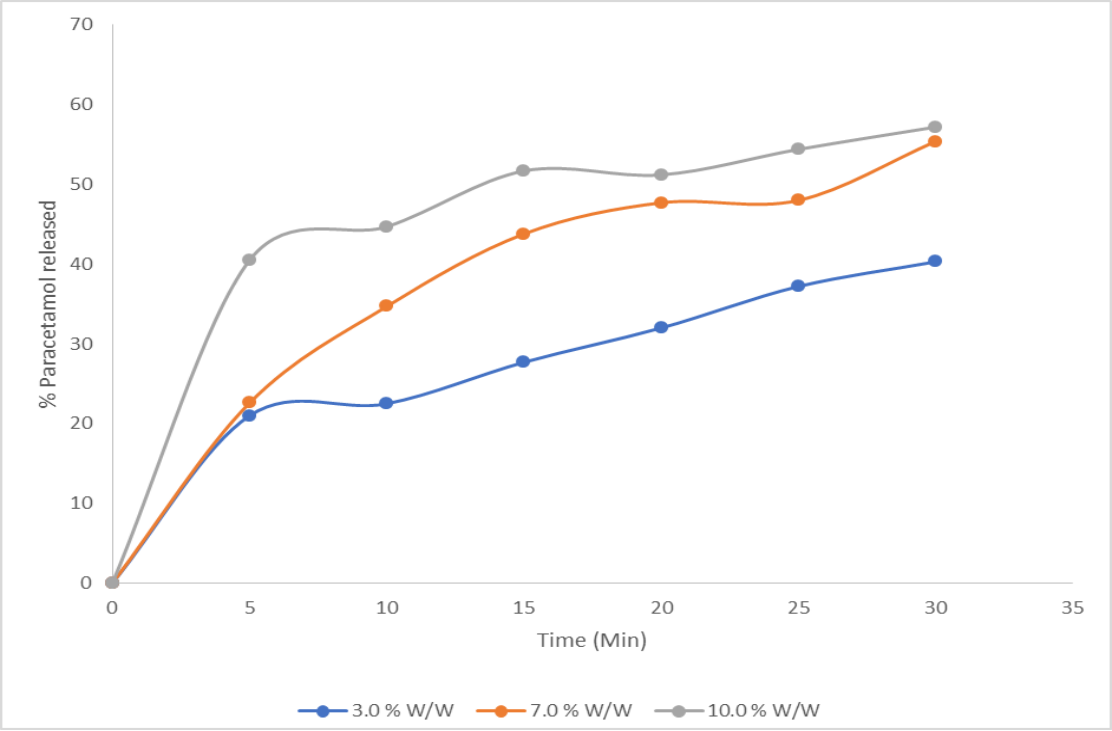

Fig. 3.1: Dissolution of Paracetamol from tablets containing intra-granular NLT.

At 10.0 % w/w 57.0 % of the paracetamol was released into the dissolution medium and was the peak release. At 7.0 % w/w 53.0 % of the paracetamol was released into the dissolution medium and the minimum paracetamol released at 3.0 % given 47.0 % drug release.

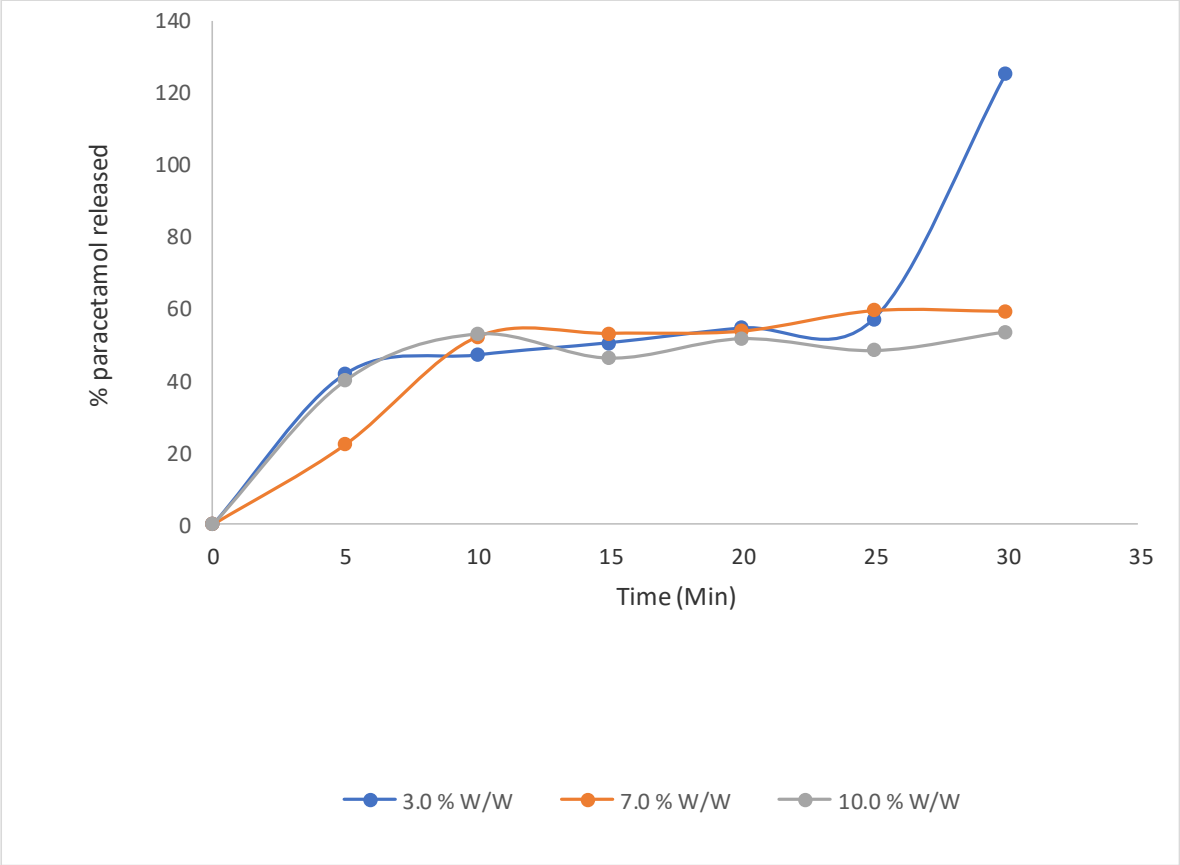

Fig. 3.2: Dissolution of Paracetamol from tablets containing intra-granular BLT.

At 3.0 % w/w about 128.0 % of the paracetamol was released into the dissolution medium and was the peak release. At 7.0 % w/w 58.0 % of the paracetamol was released into the dissolution medium and the minimum paracetamol released at 10.0 % given 50.0 % drug release.

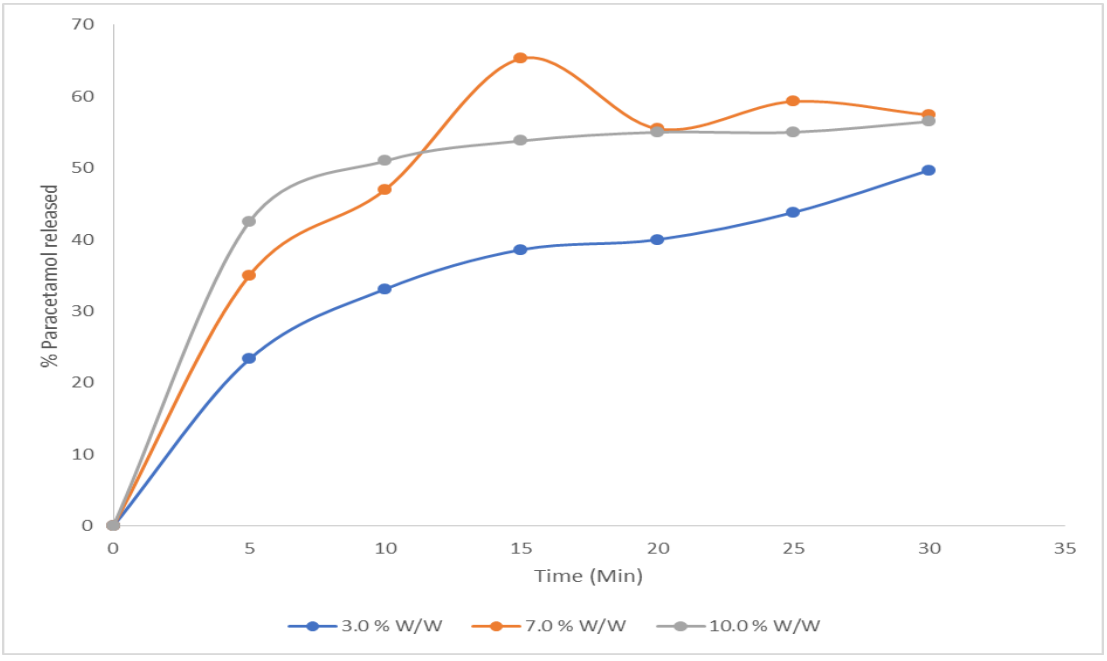

Fig. 3.3: Dissolution of Paracetamol from tablets containing intra-granular SPLT.

At 7.0 % w/w 65.0 % of the paracetamol was released into the dissolution medium and was the peak release. At 10.0 % w/w 54.0 % of the paracetamol was released into the dissolution medium and the minimum paracetamol released at 3.0 % given 47.0 % drug release.

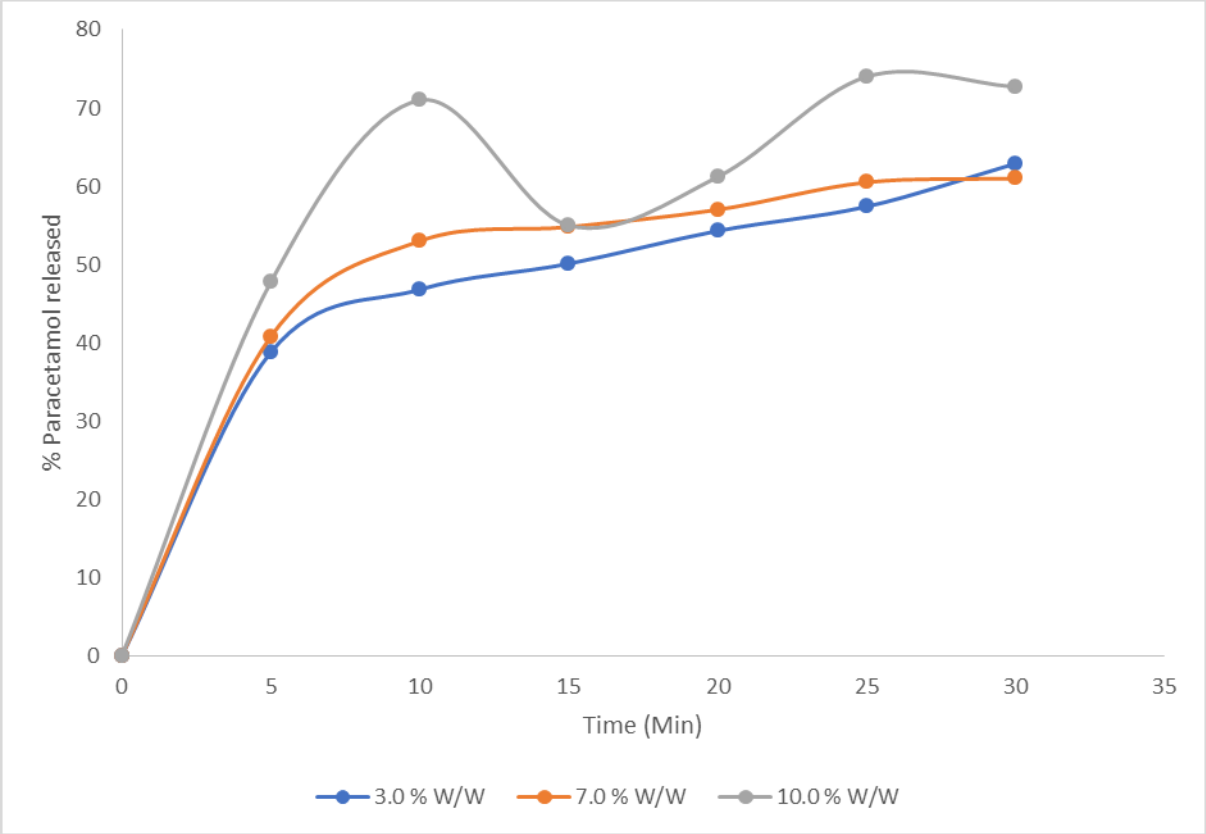

Fig. 3.4: Dissolution of Paracetamol from tablets containing intra-granular SSG.

At 10.0 % w/w 72.0 % of the paracetamol was released into the dissolution medium and was the peak release. At 3.0 % w/w 60.0 % of the paracetamol was released into the dissolution medium and the minimum paracetamol released at 7.0 % given 58.0 % drug release.

4. DISCUSSION

This chapter critically discusses the results obtained from the evaluation of the tablet performance of paracetamol formulations prepared using different processing methods of *Lentinus tuber-regium* (LT) powder as a natural disintegrant. The study compared the three concentration levels (3.0%, 7.0%, and 10.0% w/w) against sodium starch glycolate (SSG) as the synthetic standard. All determinations were performed in triplicate, and data are presented as Mean ± Standard Error of the Mean (SEM). Statistical significance was assessed using one-way ANOVA followed by post-hoc tests ($p < 0.05$ considered significant).

Dissolution Profiles of Paracetamol Tablets

Figures 3.1–3.4 illustrate the dissolution profiles of paracetamol tablets formulated using *Lentinus tuber regium* (LT) powders processed by different methods, natural (NLT), bleached (BLT), and solvent-purified (SPLT) incorporated intra-granularly at concentrations of 3.0%, 7.0%, and 10.0% w/w, with sodium starch glycolate (SSG) serving as the reference superdisintegrant.

Figure 3.1: Intra-granular NLT: The dissolution profile of tablets containing intra-granular NLT showed a concentration-dependent but generally modest drug release. Maximum paracetamol release (57.0%) occurred at 10.0% w/w, while the lowest release (47.0%) was observed at 3.0% w/w. The relatively slow and incomplete dissolution is attributable to the unprocessed nature of NLT, which retains a dense matrix with limited porosity and lower hydration capacity. These characteristics restrict rapid water penetration and tablet disintegration, thereby delaying drug liberation. The results indicate that unmodified LT possesses limited efficiency as a disintegrant when used intra-granularly.

Figure 3.2: Intra-granular BLT: Figure 3.2 demonstrates a marked improvement in dissolution behaviour following bleaching treatment. At 3.0% w/w, BLT tablets exhibited an exceptionally rapid and high drug release (128.0%), indicating enhanced tablet disintegration and efficient drug dispersion. The superior performance at lower concentration suggests that bleaching disrupts the fibrous structure of LT, increases surface area, and enhances swelling and wicking mechanisms. However, increasing the concentration to 7.0% and 10.0% w/w resulted in reduced drug release (58.0% and 50.0%, respectively), possibly due to excessive gel formation or increased tablet cohesiveness, which may impede dissolution at higher disintegrant loadings.

Figure 3.3: Intra-granular SPLT: The dissolution profile of SPLT-containing tablets (Figure 3.3) revealed optimal drug release at 7.0% w/w (65.0%), while lower release was observed at both 3.0% and 10.0% w/w. Solvent purification likely removed lipophilic and non-functional components, yielding a more porous and hydrophilic powder capable of efficient water uptake. The decline in dissolution at 10.0% w/w may again be associated with particle crowding or excessive swelling, which can reduce effective drug diffusion pathways within the tablet matrix.

Figure 3.4: Intra-granular SSG: SSG-based tablets (Figure 3.4) showed consistently good dissolution performance, with peak drug release (72.0%) at 10.0% w/w. This behaviour reflects the well-established swelling and strain recovery mechanisms of SSG. However, the comparable and, in some cases, superior dissolution observed with BLT and SPLT confirms that processed LT powders can rival conventional synthetic superdisintegrants.

Generally, figures 3.1–3.4 demonstrate that processing significantly enhances the disintegrant efficiency of Lentinus tuber regium. Bleaching and solvent purification improve dissolution performance by modifying particle structure, increasing porosity, and enhancing hydration behaviour. The results confirm that processed LT, particularly BLT at low concentration and SPLT at moderate concentration, is a viable natural alternative to SSG for immediate-release paracetamol tablet formulations.

5. CONCLUSION

This study systematically investigated the influence of intra-granular method of disintegrant incorporation in paracetamol tablets formulation.

Figures 3.1–3.4 collectively demonstrate the impact of intra-granular incorporation of *Lentinus tuber regium* (LT) powders, natural (NLT), bleached (BLT), and solvent-purified (SPLT) on the dissolution behaviour of paracetamol tablets, with sodium starch glycolate (SSG) serving as the reference superdisintegrant. The results clearly establish that both the processing and incorporation methods, and disintegrant concentration critically influence drug release performance. Tablets containing intra-granular NLT (Figure 3.1) exhibited comparatively low and incomplete

dissolution across all concentrations, with a maximum drug release of 57% at 10.0% w/w. This limited performance is attributable to the unprocessed powder's dense structure, reduced porosity, and poor hydration capacity, which hinder rapid water penetration and tablet disintegration. In contrast, bleaching significantly enhanced dissolution efficiency (Figure 3.2). BLT tablets showed exceptionally rapid and high drug release at 3.0% w/w, indicating improved swelling, wicking, and matrix disruption. However, increasing BLT concentration resulted in reduced dissolution, likely due to excessive gel formation or increased matrix cohesiveness at higher levels. SPLT-containing tablets (Figure 3.3) demonstrated optimal dissolution at 7.0% w/w, reflecting effective structural modification and removal of hydrophobic constituents through solvent purification. Reduced performance at 10.0% w/w suggests particle crowding and restricted diffusion pathways at higher loadings. SSG-based tablets (Figure 3.4) displayed predictable concentration-dependent dissolution, with peak release at 10.0% w/w. Importantly, BLT and SPLT performed comparably to, and in some cases better than, SSG. Overall, Figures 3.1–3.4 confirm that processed *Lentinus tuber regium,* when appropriately incorporated intra-granularly, is a viable natural superdisintegrant for immediate-release paracetamol tablets.

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