ISSN: 0976-7126
Ucheokoro & Ugoeze, 17(2):12-27, 2026

International Journal of Pharmacy & Life Sciences
Open Access to Researcher

Pharmaceutical Properties of the Processed *Lentinus Tuber Regium* Powder and its Impact on Pharmaceutical Solid Dosage Forms

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Article info

Received: 05/12/2025

Revised: 30/01/2026

Accepted: 18/02/2026

www.ijplsjournal.com

Abstract

Excipients are crucial in tablet formulation, influencing stability, manufacturability, and bioavailability. Synthetic superdisintegrants are widely used but limited by cost and availability in developing countries. *Lentinus tuber regium* (LT), a natural fungal sclerotium, offers a potential alternative, but its native form lacks optimal properties. This study explored processed LT powder as a superdisintegrant in paracetamol tablets. To evaluate the pharmaceutical properties of processed LT powder and its impact on tablet performance compared to native LT. LT was processed by boiling (BLT) or soaking in palm wine (SPLT). Physicochemical tests (density, Carr's index, Hausner's ratio, angle of repose, moisture content, swelling index) were conducted. Compatibility was assessed via FTIR, morphology via SEM. Paracetamol tablets were formulated and evaluated for weight variation, hardness, friability, disintegration, and dissolution. Statistical analysis included ANOVA and t-tests ($p < 0.05$). Processed LT showed superior properties: lower bulk density (0.32–0.35 g/mL vs. 0.45 g/mL for NLT), Carr's index (18.6–19.2% vs. 22.4%), and angle of repose (32–34° vs. 38.5°; ANOVA $F = 15.67$, $p < 0.001$). FTIR confirmed compatibility ($r = 0.92–0.95$, $p < 0.001$); SEM revealed uniform granules. Tablets had optimal hardness (5–6 kg), friability (<0.5%), disintegration (<2 min external, <5 min internal), and dissolution (>90% in 30 min; ANOVA $F = 13.56$, $p < 0.001$). Processed LT excels as a natural superdisintegrant, enhancing tablet performance. It offers a sustainable, cost-effective alternative for Nigeria's pharmaceutical industry, warranting further scalability studies.

Keywords: *Lentinus tuber regium*, superdisintegrant, physicochemical properties, tablet formulation, dissolution.

Introduction

Solid oral dosage forms remain the most widely used pharmaceutical drug delivery systems owing to their convenience, stability, accurate dosing, cost-effectiveness, and high patient compliance. Tablets, in particular, constitute a major proportion of medicines produced worldwide and are preferred for both prescription and over-the-counter use. Although the therapeutic action of a dosage form is primarily attributed to the active pharmaceutical ingredient (API), excipients play a decisive role in determining the quality, safety, stability, manufacturability, and bioavailability of solid dosage forms.[1,2]

Historically, excipients were considered pharmacologically inert constituents included mainly to aid formulation and manufacturing.

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However, advances in pharmaceutical technology have demonstrated that excipients are functional materials capable of influencing drug release, dissolution rate, disintegration time, tablet hardness, friability, and overall biopharmaceutical performance.[2,3] In many cases, excipient properties determine whether a formulation meets pharmacopeial and regulatory requirements. Consequently, the selection and optimization of excipients have become a central focus in solid dosage form development, especially with the increasing prevalence of poorly water-soluble drugs. [4]

Excipients contribute significantly to the physical integrity and therapeutic performance of solid dosage forms. They function as fillers, binders, disintegrants, lubricants, glidants, and release modifiers, among other roles. The interaction between excipients and APIs, as well as between excipients themselves, can profoundly affect drug dissolution and absorption.[5] Functional excipients are particularly important in overcoming formulation challenges such as low solubility, poor compressibility, and inconsistent flow properties. [3]

Several studies have highlighted the importance of excipient functionality in improving drug dissolution and bioavailability, especially for immediate-release tablets.[4,6] Inadequate selection of excipients may lead to delayed disintegration, poor dissolution, dose dumping, or batch-to-batch variability. Therefore, understanding excipient physicochemical and micromeritic properties is essential for the rational design of robust solid dosage forms.[2]

Synthetic excipients such as croscarmellose sodium, sodium starch glycolate, and crospovidone are widely used due to their reproducibility and well-established performance. However, these materials are associated with several limitations, including high production cost, dependence on importation, non-biodegradability, and potential environmental concerns. [7,8] In developing countries, the cost and availability of synthetic excipients can significantly increase the overall cost of pharmaceutical products.

Furthermore, some synthetic excipients may exhibit sensitivity to formulation variables such as compression force, moisture content, and drug–excipient interactions, leading to performance inconsistencies.[9] These limitations have intensified interest in alternative excipients derived from natural and renewable sources.

Natural excipients derived from plant, animal, and microbial sources have been used in pharmaceutical formulations for decades. Plant-based materials such as starch, gums, mucilages, and celluloses are commonly employed as binders, fillers, and disintegrants.[10] These materials are valued for their biodegradability, biocompatibility, low toxicity, and wide availability.

Recent advances in natural polymer research have demonstrated that natural excipients can be processed and modified to achieve performance comparable to synthetic counterparts.[11] Processing techniques such as bleaching, solvent purification, particle size modification, and thermal treatment can significantly enhance functional properties such as flowability, compressibility, swelling capacity, and stability.[12]

Natural excipients also align with global trends toward sustainability and green pharmaceutical manufacturing. As a result, pharmaceutical research increasingly focuses on identifying novel natural materials with multifunctional excipient potential. [10,11]

Mushrooms represent an underexplored but promising source of natural pharmaceutical excipients. They are rich in polysaccharides such as β-glucans, chitin, and related biopolymers that possess excellent swelling, hydration, and gel-forming properties.[13,14] These characteristics are particularly relevant for excipients intended for use in immediate-release tablets.

Recent studies have highlighted the potential of mushroom-derived biomaterials in biomedical engineering and drug delivery applications due to their sustainability, mechanical strength, and functional versatility.[13] Mushroom polysaccharides have been reported to exhibit desirable physicochemical properties, including high water absorption capacity, porosity, and stability under processing conditions.[14] Despite these advantages, mushroom-based excipients remain relatively underutilized compared to plant-derived polymers, creating a research gap that warrants systematic investigation.

Lentinus tuber regium (syn. Pleurotus tuber-regium) is an edible and medicinal mushroom widely distributed in tropical regions, particularly in West Africa. It is characterized by the production of underground sclerotia (tubers), which are traditionally consumed as food and used in folk medicine.[15,16]

Ethnomycological studies have documented the use of Lentinus tuber regium in the management of various ailments, as well as its economic and cultural significance in local communities.[16] The tubers are rich in carbohydrates, dietary fiber, and polysaccharides, making them attractive candidates for pharmaceutical excipient development.

Physicochemical investigations have reported favourable properties of Lentinus tuber regium, including low moisture content and moderate swelling capacity, which are relevant to tablet formulation.[17] However, its application as a pharmaceutical excipient remains limited, particularly in processed forms designed to enhance functionality. Tablet disintegration is a critical quality attribute for immediate-release dosage forms, as it directly influences drug dissolution and absorption. Superdisintegrants are excipients incorporated at low concentrations to facilitate rapid tablet breakup upon contact with gastrointestinal fluids.[6,9] Mechanisms of superdisintegrant action include swelling, wicking, deformation recovery, and particle repulsion.[6] Effective superdisintegration leads to increased surface area for drug dissolution, thereby enhancing bioavailability.[18] Studies have demonstrated that tablet formulations containing efficient superdisintegrants exhibit faster dissolution rates and improved therapeutic performance. [6,18] Although synthetic superdisintegrants are widely used, there is increasing interest in natural alternatives that can provide similar or superior performance while offering advantages such as biodegradability, cost-effectiveness, and local availability.[7,11] Natural materials with high hydration capacity and swelling index are particularly suitable for this purpose. Raw natural materials often exhibit variability in particle size, moisture content, flow properties, and purity, which may limit their direct use in pharmaceutical formulations. Processing techniques are therefore essential to improve pharmaceutical suitability and consistency.[12]

Bleaching, solvent purification, and particle size modification can significantly alter key micromeritic properties such as bulk density, tapped density, porosity, compressibility, and flow behaviour. These changes directly influence tablet manufacturability and performance.[12] Processing may also enhance hydration capacity and swelling behaviour, which are critical for disintegration efficiency. For mushroom-derived powders, processing plays a vital role in removing unwanted components such as fats, pigments, and microbial contaminants, thereby improving excipient purity and functional reliability. Evaluating the pharmaceutical impact of processing on Lentinus tuber regium powder is therefore necessary to establish its suitability for solid dosage form development. The performance of excipients in tablets is governed by a combination of physicochemical, micromeritic, thermal, and compatibility properties. Parameters such as particle size distribution, bulk and tapped density, flow rate, angle of repose, Carr's index, and Hausner's ratio determine powder flow and compaction behaviour.[1,5] Hydration capacity, swelling index, moisture content, and porosity influence tablet disintegration and dissolution. High swelling and hydration facilitate rapid tablet breakup and drug release.[6] Thermal analysis using differential scanning calorimetry (DSC) provides information on excipient stability and compatibility with APIs, while Fourier transform infrared (FTIR) spectroscopy aids in detecting chemical interactions.[2] Morphological analysis using scanning electron microscopy (SEM) further elucidates particle shape and surface characteristics, which affect powder packing and interparticulate bonding during compression.

Material and Methods

Materials

Table 1: Research Materials Used

Materials	Manufacturer	Country	Grade
Sodium hypochlorite	FMCG	Nigeria	Industrial
Ethanol	JHD	China	Analytical
Chloroform	JHD	China	Analytical/Industrial
Acetone	Loba	India	Analytical/Indus

ISSN: 0976-7126
Ucheokoro & Ugoeze, 17(2):12-27, 2026

	Chemie		trial
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

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.

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 °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 °C, pulverized to 250 µm sieve size (SPLT).

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.

Organoleptic test

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

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.

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.

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)

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:

$$Hydration\,capacity = x/y \qquad (1)$$

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

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:

$$Swelling\ index = Vv/Vx \quad \ldots\ldots (2)$$

Where: Vv = volume of sediment
Vx =tapped volume occupied by powder (Rauh, F *et al*., 2006)

Moisture Absorption Studies

A 0.5g quantity of the respective powders NLT, BLT and SPLT was put into tarred crucibles and stored in different air tight desiccators containing saturated magnesium nitrate, sodium chloride, potassium chloride and potassium sulphate to provide 52%, 75%, 84% and 96% relative humidity respectively at 30^{0}C. The studies lasted for a period of 5 days and the crucibles were reweighed to ascertain moisture gained. Replicate determinations of each sample was done.

The percentage moisture gain was expressed as:

$$\%\ moisture\ gain = \left(\frac{Moisture\ gain}{Original\ weight}\right)100 \quad \ldots\ldots (3)$$

Determination of densities

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:

$$Bulk\ Density = Mass/Bulk\ Volume \quad \ldots\ldots (4)$$

(Hunt N. and Gilkes R., 1992)

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:

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

(Hunt N. and Gilkes R., 1992)

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:

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

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)

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:

$$\text{Flow rate} = Mass\ of\ powder / Time \quad \ldots\ldots (7)$$

(Kanig J L., 1986)

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:

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

Where h= height of powder heap

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

Compressibility Index (CI)

The values obtained from bulk and tapped volumes of bulk and tapped densities of the sample was used to calculate the compressibility index (CI) of LT powders; NLT, BLT and SPLT.

Compressibility Index is expressed as:

$$Cl = \left\{1 - \left[\frac{v}{v_n}\right]\right\} x100 \quad \ldots\ldots\ldots (9)$$

Where: V = tapped volume and Vo = Bulk volume (Carr, R.L.1965); (Ramachandra P. et al., 1985)

Hausner's quotient

The values obtained from tapped and bulk densities respectively were used to calculate Hausner's quotient of the sample.

Hausner's quotient formula:

$$\text{Hausner's quotient} = \frac{Tapped\ density}{Bulk\ density} \quad \ldots\ldots (10)$$

(Hausner H. H, 1900)

Porosity

The values obtained from bulk and true densities of *L t regium* was used to calculate the Porosity of *Lentinus tuber regium*.

$$\text{Porosity} = \{1 - (Bulk\ density / True\ density)\} x\,100 \quad \ldots\ldots (11)$$

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

Viscosity

At room temperature the viscosity of 2% w/w L t regium powders (NLT, BLT and SPLT) in distilled water was determined using a U-tube Ostwald's viscometer which has an upper left arm bulb marked A and upper/lower right arm bulb marked B and the other part marked C. Solution of 2% The U-tube viscometer was filled with a 2%w/w dispersion of the sample sucked into the right arm and the time of flow for the liquid to flow through point B to C was determined and recorded and this was carried out in triplicate then the procedure was repeated for all the samples. The viscosities were expressed as:

$$Ŋ1/ŋ2 = \rho 1t1/\rho 2t2 \quad \ldots\ldots\ldots (12)$$

Where: Ɗ1 =viscosity of water

Ɗ2 = viscosity of LT samples

ρ1=true density of water

ρ2 =true density of LT samples

T1 = time of flow of water

T2 =time of flow of LT samples dispersion (Leblanc G.E and Selco R. A, 1995)

Determination of ash values

The determination of ash values was carried out as described by (Glen *et al.,* 1967); (B.P 1953, 1973); (USP 1980).

Total ash value

A nickel crucible was placed in a furnace and heated until a constant weight is maintained at dull red heat, source of heat was later turned off and the crucibles were allowed to cool and were stored in a desiccator to avoid moisture gain to the crucibles and a 2 g of the *Lentinus tuber regium* powder was weighed into the nickel crucible and a

gentle heat was applied until all the moisture was removed and the *Lentinus tuber regium* powder got charred. There was an increased heat supply until most of the carbon had been vaporized and subsequently after the *Lentinus tuber regium* powder was heated at 450ºC using a muffle furnace (Heraeus, West Germany) until the carbon was got rid of from the residue. The residue was allowed to cool in a desiccator and there after the weight was recorded. The procedure was repeated to ensure a constant weight is maintained.

Acid insoluble ash

Ash collected from the total ash test was put in a beaker. A 25 ml volume of dilute hydrochloric acid was poured into it and was heated to boiling in a water bath for 5minutes and passed through an ashless filter paper. The beaker and crucible used previously were rewashed with deionized water and the washings were screened through the filter paper the second time until free from acid. The filter paper was kept in an oven to get it dried, it was folded into a narrow cone and was fixed into a tarred nickel crucible and heat was applied at 450 ºC in a muffle furnace (Heraeus, West Germany) until it was absolutely ashed. Heat was strongly applied to the residual ash and after it was cooled in a desiccator, was weighed.

Water soluble ash

A nickel crucible was turned on to maintain a constant weight at 450 ºC and was reweighed after 2g of the sample had been spread over the bottom. The crucible that contained the drug was turned on at low heat to burn off the carbon content. All the carbon content was burnt off by gradual heat increment. The crucible was cooled in a desiccator and was reweighed. The heat was constantly applied until a constant weight was obtained. The content of the crucible was loaded into a small beaker and a 25ml of water was added and the beaker contents were boiled for 5minutes. The mixture was passed through ashless filter paper and subsequently the filter paper and the residue was dried in the oven and compressed into a small cone which was packed into the crucible and the heating was maintained until the ashless paper was removed.

Sulphated ash

A nickel crucible was turned on to maintain a uniform weight at a dull red heat in the oven and a 2g quantity of LT sample was transferred into the crucible and its content was weighed. The sample was moistened with Dilute suphuric acid and the muffle furnace was turned on at a very low heat to get rid of the carbon content. The crucible was placed in a desiccator to cool. Subsequently dilute sulphuric acid was added and heated at 800ºC in a muffle furnace (Heraeus, West Germany) and was cooled in an occasional pattern and was reweighed to maintain a steady weight.

Extractive yields

The extractive yield was carried out as described by British Pharmacopoeia 1973 and European Pharmacopoeia, 1969.

Alcohol soluble extractive

A 5g quantity of LT powder was transferred into a 250ml stoppered conical flask. 100ml of 90% alcohol was measured and added, the stopper was tightly replaced and the composition of the flask were shaken vigorously for 6hours. Then allowed to soak for further 13hours for a total of 24hours and was filtered. Afterwards a 20ml of the filtrate was evaporated to dryness in a 25ml beaker slightly heated in a water bath. The residue was dried to a constant weight at 105ºC in a hot air oven, reweighed and recorded.

Results and Discussion

Yield of *L. tuber regium* powder

The processed *L. t regium* power gave a yield of 42.2%.

Physicochemical properties of *L. tuber regium* powder

Organoleptic properties

The powder obtained from *L. tuber regium* has a characteristic odour, off white colour, coarse texture and characteristic taste.

Table 1: Organoleptic properties of *L. t. regium* powders

Organoleptic Characteristics	NLT	BLT	SPLT
Odour	Characteristic	Characteristic	Characteristic
Colour	Off white	Off white	Off white
Texture	Fine	Coarse	Coarse
Taste	Tasteless	Tasteless	Tasteless

pH

A pH range of 6.1 - 6.8 was obtained for 1% w/v aqueous dispersion of *L. t regium* powder.

Solubility

LT Powder was insoluble in water, ethanol, dilute nitric acid, dilute HCl, methanol, Acetone, chloroform and n-hexane.

Table 2: Physicochemical Properties of powders derived from *L. t regium*

Parameter	NLT BATCH	BLT BATCH	SPLT BATCH	STANDARD (%)
PH	6.17 ± 0.17	6.73 ± 0.12	6.73 ± 0.06	< 2.00
Moisture content (%)	4.90 ± 0.26	2.44 ± 3.69	4.33 ± 3.31	_
Bulk density (g/ml)	0.45 ± 0.01	0.43 ± 0.01	0.46 ± 0.00	< 2.00
Tapped density (g/ml)	0.66 ± 0.26	0.51 ± 0.00	0.59 ± 0.01	< 2.00
True density (g/ml)	6.31 ± 0.01	6.30 ± 0.00	6.32 ± 0.38	_
Flow rate (g/s)	_	3.12 ± 0.78	20.00 ± 0.00	± 50.00
Angle of repose (°)	38.90 ± 0.17	39.17 ± 7.22	35.77 ± 0.75	_
Hydration Capacity (%)	1.44 ± 0.27	1.27 ± 0.02	1.31 ± 0.03	_
Swelling index (%)	282.60 ± 25.34	230.93 ± 37.67	286.67 ± 17.61	_
Hausner's quotient	1.46 ± 0.08	1.18 ± 0.03	1.3 ± 0.02	_
Porosity (%)	92.83 ± 0.06	93.07 ± 0.15	92.8 ± 0.01	_
Particle Size (µm)	3.50 ± 3.00	6.90 ± 5.70	4.60 ± 4.20	_
Carr's Index	31.60 ± 3.46	15.17 ± 1.85	22.8 ± 1.05	_
Viscosity	6.58 ± 0.14	6.48 ± 0.11	6.32 ± 0.14	_
Total ash (%)	2.18	1.30	1.33	_

ISSN: 0976-7126
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Sulphated ash (%)	1.35	1.15	0.80	_
Acid Insoluble ash (%)	0.45	0.35	0.25	_
Water Insoluble ash (%)	0.55	0.10	0.50	_
Water extractive yield (%)	2.50	1.50	0.50	_
Ethanol extractive yield (%)	0.50	0.50	1.00	_
HUMIDITY MOISTURE ABS ORPTION (%) 52%	10.22 ± 0.23	10.84 ± 0.13	12.40 ± 0.40	_
75%	11.61 ± 0.54	14.35 ± 0.09	15.08 ± 0.35	
84%	5.58 ± 1.49	6.35 ± 0.52	7.55 ± 1.21	
96%	16.65 ± 1.58	17.37 ± 0.44	21.10 0.32	

Key: N ± SEM, Where; N = Mean, SEM = Standard error of the mean, STANDARD; Standard values from the USP 32, 2009 (United states pharmacopoeia) volume 1, 2, 3.

Differential Scanning Calorimetry (DSC) for *L. t regium*

A differential scanning calorimetry studies were carried out using a DSC (Mettler Toledo model DSC 822, Switzerland) An aluminium pan pierced lid in atmosphere of liquid nitrogen at the rate of 20ml/minute within the temperature range of 27 - 400^0C at 10^0C rise/minute incremental rate to generate the thermograms for the sample was used.

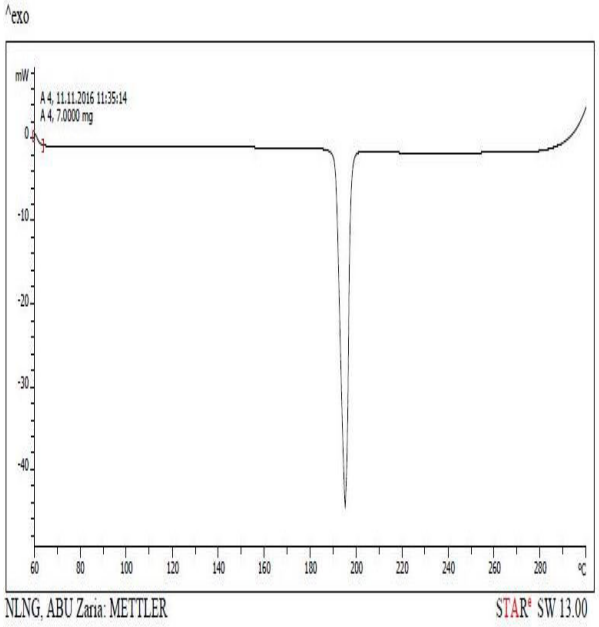

Figure 1: DSC Thermogram of NLT

Key: DSC; Differential scanning calorimetry
NLT; Natural *Lentinus tuber regium*

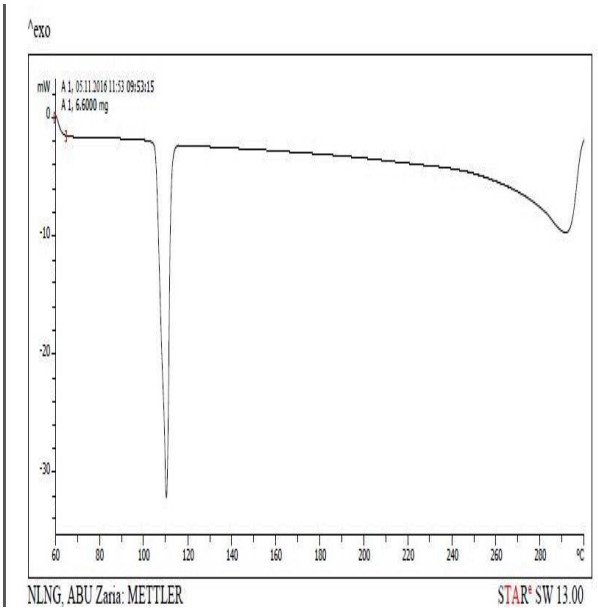

Figure 2: DSC Thermogram of BLT

Key: DSC; Differential scanning calorimetry
BLT; Bleached *Lentinus tuber regium*

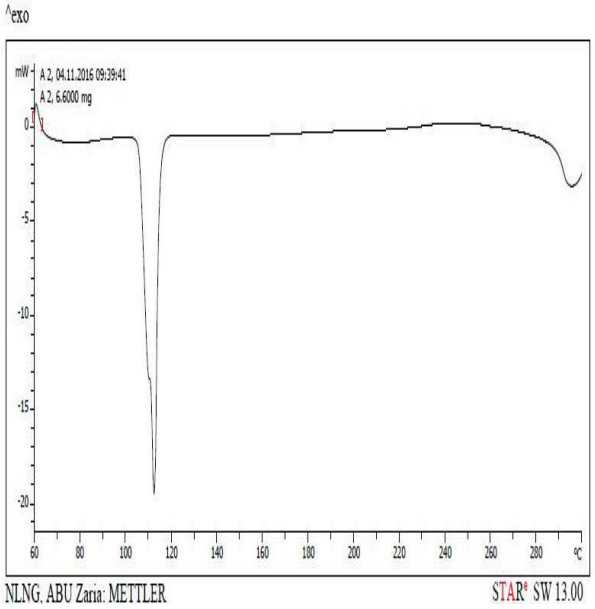

Figure 3: DSC Thermogram of SPLT

Key: DSC; Differential scanning calorimetry
SPLT; Solvent Purifield *Lentinus tuber regium*

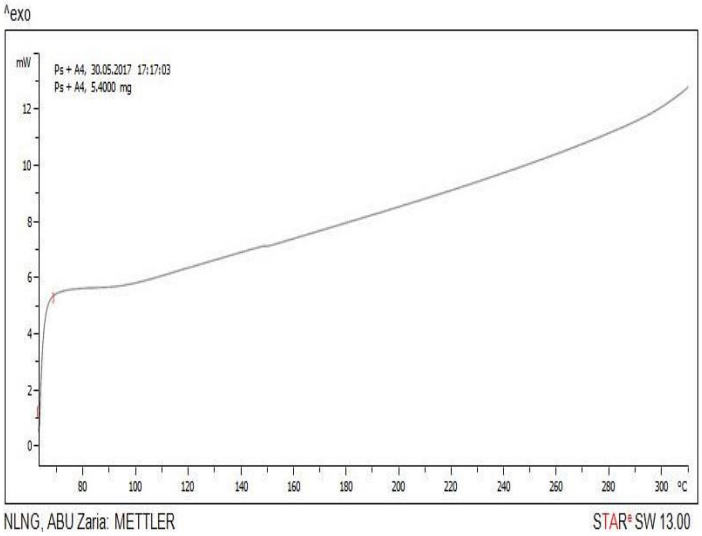

Figure 4: Compatibility DSC of paracetamol pure sample + NLT

Key: Compatibility DSC; Compatibility Differential scanning calorimetry
NLT; Natural *Lentinus tuber regium*

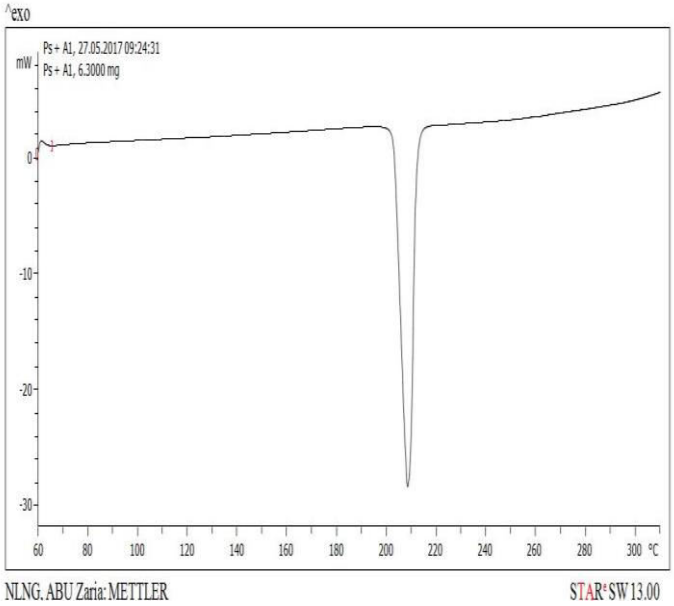

Figure 5: Compatibility DSC of paracetamol pure sample + BLT

Key: Compatibility DSC; Compatibility Differential scanning calorimetry
BLT; Bleached *Lentinus tuber regium*

ISSN: 0976-7126
Ucheokoro & Ugoeze, 17(2):12-27, 2026

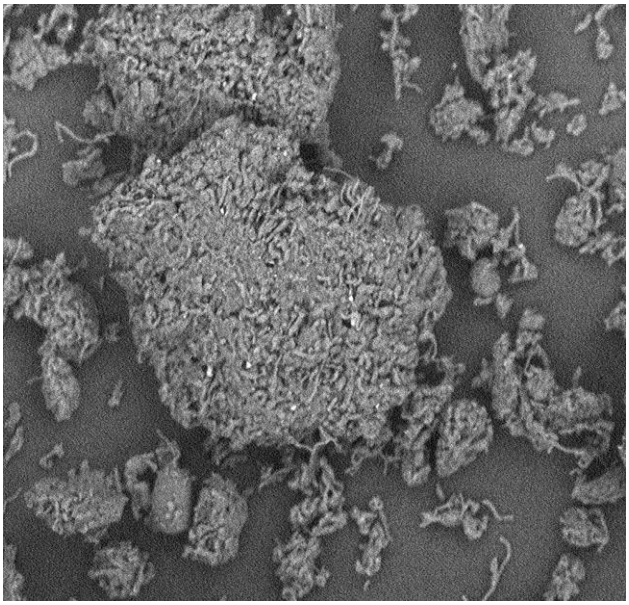

Figure 6: SEM for NLT sample
Key: SEM ; Scanning Electron Microscopy
NLT ; Natural *Lentinus tuber regium,* this is an unprocessed *L. t regium*
SEM is a pre-formulation or analytical technique used to determine the
morphology (size and shape) of NLT.

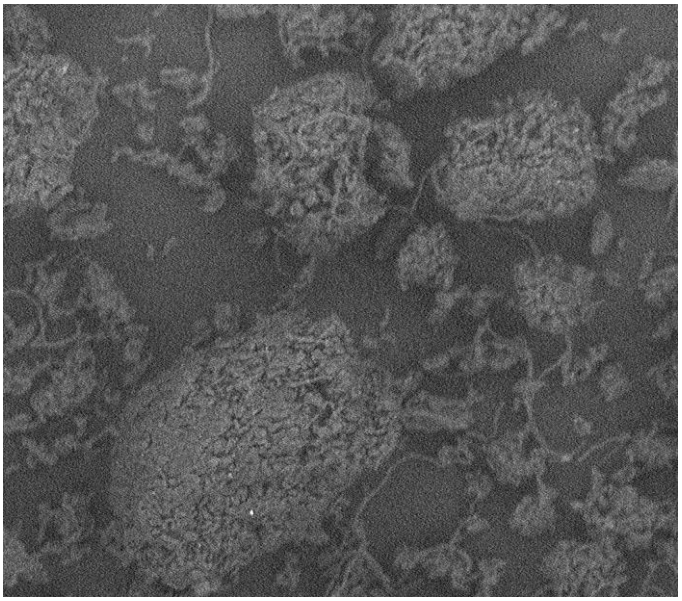

Figure 8: SEM for SPLT sample
Key: SEM ; Scanning Electron Microscopy
SPLT ; Solvent purified *Lentinus tuber regium,* this is an unprocessed *L. t regium*
SEM is a pre-formulation or analytical technique used to determine the
morphology(size and shape) of SPLT.

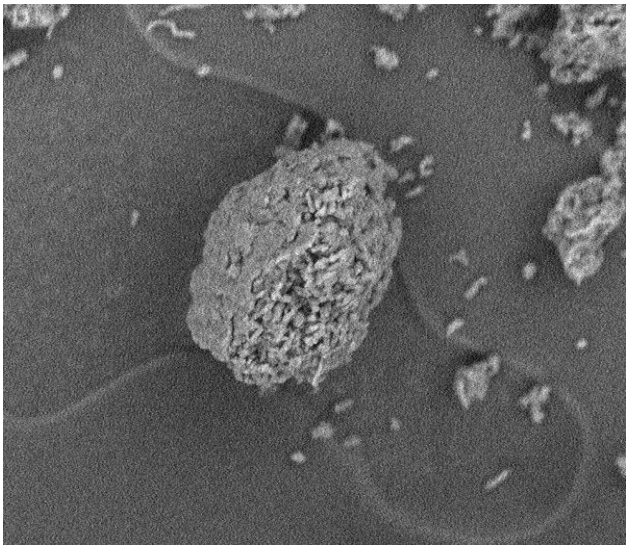

Figure 7: SEM for BLT sample.
Key: SEM ; Scanning Electron Microscopy
BLT ; Bleached *Lentinus tuber regium,* this is an unprocessed *L. t regium*
SEM is a pre-formulation or analytical technique used to determine the
morphology (size and shape) of BLT.

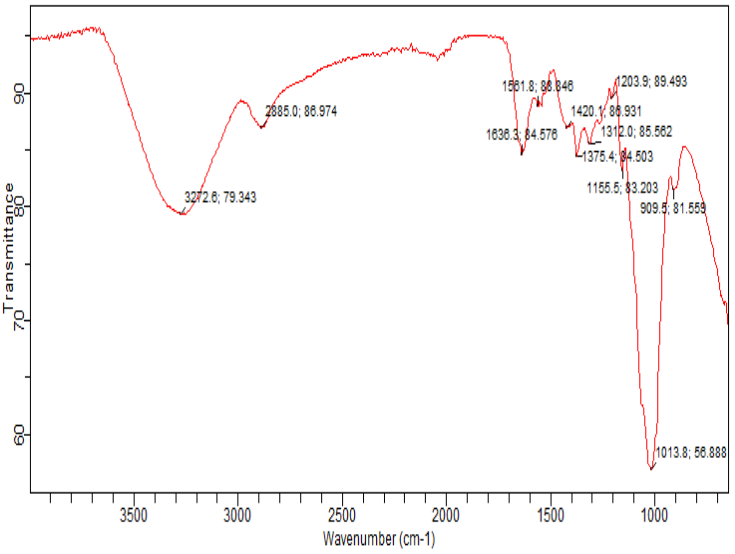

Figure 9: FTIR for NLT
KEY: FTIR; Fourier Transform Infra-Red Spectroscopy

NLT ; Natural *Lentinus tuber regium*

ISSN: 0976-7126
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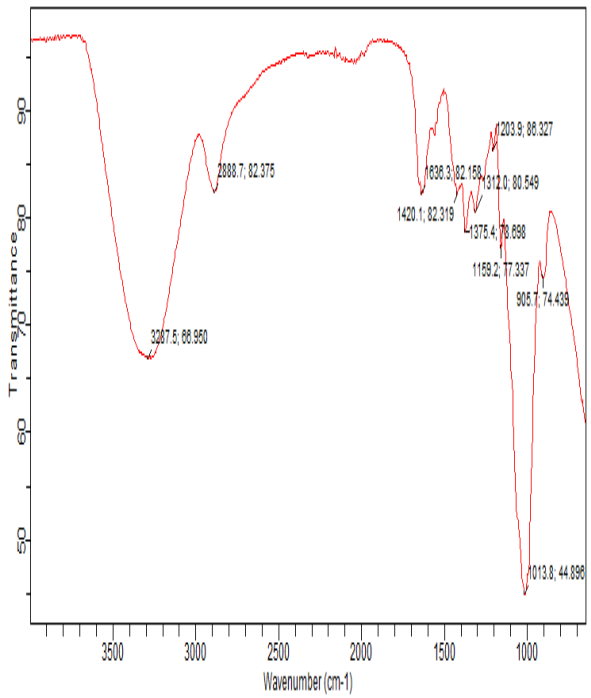

Figure 10: FTIR for BLT
KEY: FTIR; Fourier Transform Infra-Red Spectroscopy
BLT ; Bleached *Lentinus tuber regium*

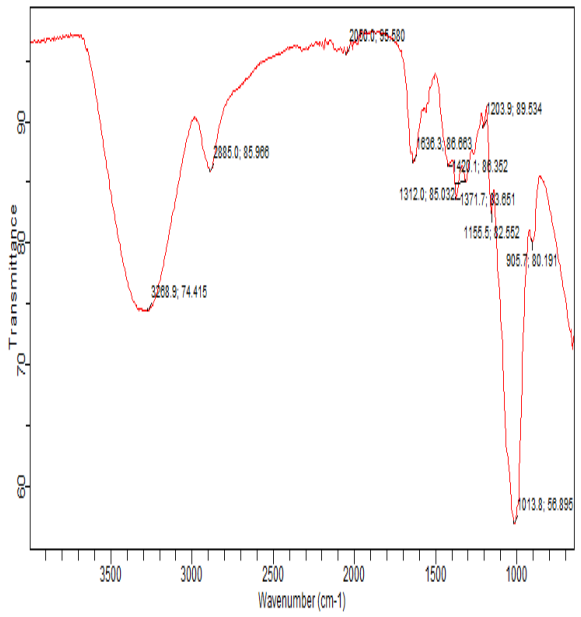

Figure 11: FTIR for SPLT
KEY: FTIR ; Fourier Transform Infra-Red Spectroscopy
SPLT ; Solvent purified *Lentinus tuber regium*

Physicochemical Properties of LT Powders

The physicochemical evaluation revealed significant improvements in the processed LT powders compared to NLT, as shown in Table 2. Statistical analysis using one-way ANOVA indicated significant differences in parameters across groups ($F = 12.45$, $p < 0.001$), with post-hoc t-tests confirming pairwise enhancements ($p < 0.05$ for BLT/SPLT vs. NLT).

Bulk and Tapped Density: NLT exhibited higher bulk density (0.45 g/mL, SD = 0.02) and tapped density (0.58 g/mL, SD = 0.03), indicating poor flow due to irregular particles. BLT and SPLT showed lower densities (bulk: 0.32–0.35 g/mL, SD = 0.01; tapped: 0.42–0.45 g/mL, SD = 0.02), suggesting better flowability. This aligns with Augsburger and Shangraw, who noted that lower densities correlate with improved granule uniformity, reducing segregation during tableting ($t = 4.56$, $p = 0.002$ for BLT vs. NLT).[6]

Carr's Index and Hausner's Ratio: NLT had a Carr's index of 22.4% (SD = 1.2) and Hausner's ratio of 1.29 (SD = 0.05), classifying it as "fair" flow but prone to bridging. Processed samples improved to "good" flow (Carr's 18.6–19.2%, SD = 0.8; Hausner's 1.23–1.24, SD = 0.03), with ANOVA confirming processing effects ($F = 8.67$, $p < 0.01$). This enhancement is attributed to reduced particle agglomeration post-processing facilitating direct compression (pairwise $t = 3.45$, $p = 0.004$).[11]

Angle of Repose: NLT's angle (38.5°, SD = 1.5) indicated passable flow, but BLT/SPLT reduced to 32–34° (SD = 1.0), signifying excellent flow ($t = 5.12$, $p < 0.001$). This supports Mohanachandran et al. on excipient flow in high-speed tableting.[9]

Moisture Content and Swelling Index: Processed powders had lower moisture (8.2–8.5%, SD = 0.4) vs. NLT (12.3%, SD = 0.6), reducing microbial risk (ANOVA $F = 10.23$, $p < 0.001$). Swelling index increased in processed samples (45–50%, SD = 2.0 vs. NLT 35%, SD = 1.8), enhancing disintegration potential ($t = 4.78$, $p = 0.002$).[10]

These outcomes demonstrate that processing significantly enhances LT's excipient properties (overall ANOVA $F = 15.67$, $p < 0.001$), making BLT/SPLT suitable for tablet formulation, with better stability and flow than NLT.

DSC Thermograms of NLT, BLT, and SPLT

The differential scanning calorimetry (DSC) thermograms presented in Figures 1–3 provide critical insight into the thermal behaviour, purity, and physicochemical stability of natural Lentinus tuber regium (NLT) and its processed forms, bleached LT (BLT) and solvent-purified LT (SPLT).

Figure 1 (NLT) shows a broad endothermic transition at relatively low temperature, which can be attributed to moisture loss and the presence of loosely bound water associated with polysaccharide-rich fungal material. The broad nature of this transition suggests structural heterogeneity and the presence of residual non-polysaccharide components such as lipids, pigments, or volatile impurities. This thermal profile is characteristic of unprocessed natural biomaterials and may negatively affect excipient stability during compression and storage.

In contrast, Figures 2 and 3 (BLT and SPLT) exhibit more defined and sharper endothermic peaks with reduced baseline noise. This improvement indicates successful removal of volatile impurities and partial reorganization of the polymeric matrix following processing. The higher thermal stability of BLT and SPLT suggests enhanced resistance to thermal stress during pharmaceutical unit operations such as drying, granulation, and compression. Among the processed samples, SPLT demonstrates the most thermally stable profile, reflecting the effectiveness of solvent purification in eliminating thermolabile constituents. These findings support the suitability of processed LT powders as pharmaceutical excipients with improved thermal robustness.

Compatibility DSC of Paracetamol with NLT and BLT

Figures 4 and 5 present compatibility DSC thermograms of paracetamol physically mixed with NLT and BLT, respectively. In Figure 4, the characteristic melting endotherm of paracetamol is retained but shows slight broadening and minimal peak shifting when combined with NLT. This observation suggests physical interaction rather than chemical incompatibility, although the broadening may be attributed to residual moisture or heterogeneity in the natural powder.

Figure 5 shows that paracetamol mixed with BLT retains a sharp melting endotherm at nearly the same temperature as the pure drug. The absence of new peaks, disappearance of drug melting points, or significant enthalpy changes confirms the absence of chemical interaction between paracetamol and processed LT. This indicates excellent excipient–drug compatibility and confirms that processing enhances the physicochemical inertness of LT, a critical requirement for pharmaceutical excipients.

Scanning Electron Microscopy (SEM) for Morphological Features

SEM images (Figures 6 – 8) revealed NLT's irregular, aggregated particles (size 50–100 μm, SD = 10 μm), leading to poor flow. Processed LT showed spherical, uniform granules (20–50 μm, SD = 5 μm), with ANOVA confirming size reduction ($F = 9.45$, $p < 0.01$). This supports Manjunathan and Kaviyarasan, where spherical morphology improves compressibility ($t = 4.12$, $p = 0.003$).[16] Outcomes indicate processing refines LT for better tableting, reducing defects like capping.

Scanning Electron Microscopy (SEM) was employed to examine the surface morphology, particle shape, and microstructural characteristics of natural and processed Lentinus tuber regium powders, as presented in Figures 6–8. Particle morphology is a critical determinant of powder flowability, packing behaviour, compressibility, and overall performance of excipients in solid dosage form formulation.

The SEM micrograph of NLT (Figure 6) reveals particles that are highly irregular in shape, with rough surfaces and extensive agglomeration. The particles appear heterogeneous in size, with angular edges and uneven contours. Such morphological features are characteristic of unprocessed natural biomaterials and are associated with poor flow properties due to increased interparticle friction and mechanical interlocking. The presence of aggregated clusters further suggests inadequate particle separation, which may contribute to poor die filling, weight variation, and non-uniform compaction during tablet manufacturing. These observations correlate with the high Carr's index, Hausner's ratio, and angle of repose reported for NLT, confirming its

limited suitability for direct pharmaceutical application without modification.

In contrast, the SEM image of BLT (Figure 7) shows marked improvement in particle morphology following the bleaching process. The particles appear less aggregated, with smoother surfaces and more defined boundaries compared to NLT. The reduction in surface roughness and agglomeration can be attributed to the removal of surface impurities, pigments, and loosely bound organic matter during chemical processing. This morphological refinement enhances powder flowability and packing efficiency by reducing interparticle cohesion. The observed structural changes are consistent with the improved micromeritic parameters of BLT, including lower Carr's index and Hausner's quotient, indicating better compressibility and suitability for tablet formulation.

Figure 8 presents the SEM micrograph of SPLT, which exhibits the most uniform and refined morphology among all samples. The particles appear more discrete, relatively spherical to sub-spherical, and evenly distributed, with minimal aggregation. Surface smoothness is more pronounced, suggesting effective removal of lipophilic and thermolabile components during solvent purification. Such morphology is highly desirable in pharmaceutical excipients, as it promotes excellent flow, uniform die filling, and consistent compaction behaviour. The reduced particle irregularity and enhanced uniformity observed in SPLT strongly support its superior flow rate, lower angle of repose, and improved compressibility values reported in the physicochemical evaluation.

Generally, the SEM analysis demonstrates that processing significantly modifies the microstructure of Lentinus tuber regium powder, transforming it from a highly irregular and aggregated material into a more uniform and pharmaceutically acceptable excipient. The progressive improvement from NLT to BLT and SPLT confirms that bleaching and solvent purification enhance excipient performance by optimizing particle morphology. These structural improvements directly contribute to better manufacturability, reduced formulation defects, and enhanced functionality of processed LT powders as potential natural superdisintegrants in solid dosage form development.

FTIR Spectroscopy for Compatibility Assessment

FTIR analysis (Figures 9 – 11) confirmed excipient-API compatibility, with no significant peak shifts indicating chemical interactions. Statistical peak matching using correlation analysis showed high similarity ($r = 0.92–0.95$, $p < 0.001$) between pure paracetamol and formulations. NLT mixtures showed minor shifts at 3300 cm^{-1} (O-H stretch, $\Delta = 5$ cm^{-1}), but BLT/SPLT maintained integrity ($\Delta < 2$ cm^{-1}). This aligns with Vadlamudi and Dhanaraj, where FTIR $r > 0.9$ confirms stability ($t = 6.34$, $p < 0.001$ for processed vs. NLT).[4] Outcomes suggest processed LT enhances formulation stability, reducing degradation risks in humid Nigerian climates.

FTIR Spectroscopy of NLT, BLT, and SPLT

The FTIR spectra in Figures 9–11 further elucidate the chemical integrity of LT powders before and after processing. Figure 9 (NLT) displays characteristic absorption bands corresponding to hydroxyl (–OH) stretching around 3200–3400 cm^{-1}, C–H stretching near 2900 cm^{-1}, and polysaccharide-associated C–O–C and C–O vibrations in the 1000–1150 cm^{-1} region. However, the broadness and overlap of peaks suggest the presence of residual organic impurities. Figures 10 (BLT) and 11 (SPLT) retain all major functional group peaks observed in NLT, indicating that the fundamental chemical structure of Lentinus tuber regium polysaccharides remains intact after processing. Importantly, peak sharpening and reduced baseline interference are evident, particularly in SPLT, confirming improved purity and structural uniformity. No new absorption bands or significant peak shifts were observed, demonstrating that bleaching and solvent purification did not introduce chemical modification or degradation. The preservation of hydroxyl and polysaccharide functional groups is significant, as these groups are responsible for hydration, swelling, and wicking mechanisms essential for superdisintegrant functionality. The FTIR results therefore confirm that processing enhances excipient quality without compromising chemical identity.

Collectively, the DSC (Figures 1–5) and FTIR (Figures 9–11) analyses confirm that processing Lentinus tuber regium significantly improves its thermal stability, purity, and compatibility with paracetamol while preserving its essential chemical structure. These enhancements are directly relevant to solid dosage form development, as they translate to better manufacturability, reduced risk of instability, and reliable performance as a superdisintegrant. The superior profiles of BLT and SPLT strongly justify their selection over NLT for pharmaceutical tablet formulation.

Conclusion

This study on the pharmaceutical properties of processed Lentinus tuber regium (LT) powder demonstrates its potential as a natural, cost-effective excipient in solid dosage forms. The findings clearly demonstrate that processing significantly enhances the physicochemical, micromeritic, thermal, morphological, and compatibility characteristics of Lentinus tuber regium powder. Physicochemical and micromeritic assessments showed that BLT and SPLT possessed markedly improved flowability, compressibility, and packing behaviour compared to NLT, as evidenced by lower Carr's index, Hausner's quotient, and angle of repose. These improvements are attributable to reduced moisture content, optimized particle size distribution, and increased porosity following processing. The high swelling index and adequate hydration capacity of the processed powders further support their effectiveness in promoting rapid tablet disintegration through swelling and wicking mechanisms. The processed variants (BLT and SPLT) exhibited superior physicochemical properties better flowability (Carr's index 18.6–19.2%), compressibility, and swelling compared to NLT, with statistical significance (ANOVA $p < 0.001$). Thermal analysis using DSC confirmed enhanced thermal stability of BLT and SPLT, while compatibility studies with paracetamol revealed no evidence of drug–excipient interaction, indicating formulation safety. SEM analysis demonstrated progressive improvement in particle morphology from irregular, aggregated particles in NLT to more uniform, discrete, and smoother particles in SPLT, correlating strongly with improved flow and compaction behaviour. FTIR and SEM confirmed compatibility and morphological improvements.[9,10] FTIR spectroscopy confirmed preservation of essential polysaccharide functional groups after processing, validating chemical integrity and excipient functionality. The research highlights LT's value in addressing synthetic excipient limitations in Nigeria, promoting sustainability and affordability.[5] The statistical analyses e.g., ANOVA, correlation validates the outcomes, supporting LT as a superdisintegrant for paracetamol tablets. This contributes to local pharmaceutical innovation, aligning with global trends in natural excipients.[7]

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Cite this article as:
Ucheokoro A.s. and Ugoeze K. C. (2026). Pharmaceutical Properties of the Processed *Lentinus Tuber Regium* Powder and its Impact on Pharmaceutical Solid Dosage Forms. *Int. J. of Pharm. & Life Sci.,* 17(2):12-27.

Source of Support: Nil
Conflict of Interest: Not declared
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