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Development and Characterization of Taste-Masked Orodispersible Tablets of Domperidone Using Tulsion 339 and Sublimation Technique

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ABSTRACT

Domperidone is a widely used antiemetic and prokinetic drug; however, its intensely bitter taste limits patient acceptance, particularly among pediatric and geriatric patients. The present study aimed to develop taste-masked orodispersible tablets (ODTs) of Domperidone using Tulsion 339 ion-exchange resin and the sublimation technique. Drug-resin complexes (DRCs) were prepared using different drug-to-resin ratios and evaluated for taste masking efficiency and drug content. The optimized DRC (1:3, Drug:Tulsion 339) exhibited effective taste masking with a bitterness score of 1.3 and drug content of $96.12 \pm 0.11\%$. Compatibility studies using FTIR and DSC confirmed the absence of significant drug-excipient interactions. Orodispersible tablets were prepared by direct compression employing crosspovidone as a superdisintegrant and ammonium bicarbonate or camphor as subliming agents. The prepared formulations were evaluated for pre-compression and post-compression parameters, disintegration time, wetting time, water absorption ratio, drug content, in-vitro dissolution, and SEM analysis. All formulations showed acceptable flow properties and complied with pharmacopeial specifications. Among the formulations, batch S4 containing 20% ammonium bicarbonate demonstrated superior performance, exhibiting the shortest disintegration time (15 ± 1.18 s), lowest wetting time (22.71 ± 0.23 s), highest water absorption ratio ($83.79 \pm 1.14\%$), and satisfactory drug content ($99.20 \pm 0.23\%$). The optimized formulation released $96.8 \pm 1.12\%$ of drug within 12 minutes, which was significantly higher than the marketed tablet. SEM analysis confirmed the formation of a highly porous structure following sublimation. The study concluded that taste-masked orodispersible tablets of Domperidone can be successfully developed using Tulsion 339 and ammonium bicarbonate-based sublimation, providing rapid disintegration, enhanced dissolution, improved palatability, and better patient compliance.

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1. INTRODUCTION:

Orodispersible tablets (ODTs) are solid dosage forms designed to disintegrate rapidly in the oral cavity, usually within a few seconds, without the need for water. These formulations offer several advantages over conventional tablets, including ease of administration, rapid onset of action, improved bioavailability, and enhanced patient compliance. Conventional tablets often present swallowing difficulties, particularly among pediatric, geriatric, and bedridden patients suffering from dysphagia. ODTs overcome these limitations by dispersing quickly in saliva, thereby improving convenience and ensuring better adherence to therapy. [1-2] Consequently, ODTs have emerged as an attractive

alternative dosage form for drugs requiring rapid therapeutic action and improved patient acceptability. Domperidone is a dopamine D₂ receptor antagonist widely used as an antiemetic and prokinetic agent in the management of nausea, vomiting, gastroparesis, and gastroesophageal reflux disorders. It exerts its pharmacological action by blocking peripheral dopamine receptors, thereby enhancing gastrointestinal motility and accelerating gastric emptying. Domperidone is considered a suitable candidate for ODT formulation because of its rapid absorption, relatively long half-life, and requirement for prompt therapeutic action during emetic conditions. However, its intensely bitter taste poses a significant challenge in developing patient-friendly oral formulations. Therefore, effective taste masking is essential to enhance palatability and patient acceptance, particularly in pediatric and elderly populations. [3-6]

Taste masking of bitter drugs can be successfully achieved using ion-exchange resin technology, which forms drug-resin complexes capable of preventing drug release in the oral cavity while allowing release in the gastrointestinal tract. Tulsion 339, a weak cation-exchange resin, has been extensively employed for taste masking owing to its high drug-loading capacity, safety, compatibility, and ease of processing. In the present study, the sublimation technique was employed for the development of taste-masked ODTs of domperidone. [7-10] This technique involves the incorporation of volatile materials such as ammonium bicarbonate and camphor into tablet formulations, followed by their removal through sublimation to create a highly porous matrix. The resulting porous structure facilitates rapid water penetration, faster tablet disintegration, and enhanced drug dissolution. Therefore, the study aimed to develop taste-masked orodispersible tablets of domperidone using Tulsion 339 and to evaluate the effectiveness of different subliming agents, namely ammonium bicarbonate and camphor, in improving tablet performance. [11-13]

2. MATERIALS AND METHODS:

2.1 Materials:

Active Drug (Domperidone) was collected from Vama Pharmaceutical Ltd., Nagpur. Binder (Tulsion-339) was collected from Thermax India Pvt. Ltd. and Superdisintegrant (Crosspovidone) was collected from Maple Biotech Pvt. Ltd. Pimpri-Chinchwad, India.

Excipients:

Camphor and Ammonium bicarbonate was collected from Samar Chemicals, India. Aspartame and magnesium stearate were collected from Loba Chemie Pvt. Ltd., Mumbai, India. Moreover,

Microcrystalline Cellulose (Avicel PH-101), Camphor were collected from research laboratory.

Solvents and Reagents:

Hydrochloric acid, Sodium Hydroxide pellets, Potassium Chloride (Ranbaxy Fine Chemicals Ltd. New Delhi), Potassium Bromide (Merck Specialities Pvt. Ltd.), All other reagents employed were of analytical or pharmaceutical grade.

Equipments:

Rotary Press Tablet Compression Machine (RIMEK Minipress-I, Karnavati Engineering Ltd., Mehsana, Gujarat), Dhona Balance (Dhona Instruments Pvt. Ltd., Kolkata), Digital pH meter (Model No. NIG 333, Naina Solaris Ltd. India), Monsanto Hardness tester (Cadmach Machinery Pvt. Ltd., Ahmedabad), Roche Friabilator USP XVIII (Model No. EF-1W, Electrolab Pvt. Ltd., Goregaon (E), Mumbai), Sieves (Sethi Standard Test Sieves), Double Beam UV-Spectrophotometer (Techcomp UV 2300), Dissolution Apparatus USP XVIII (Model No. TDT – 06P, Electrolab Pvt. Ltd., Goregaon (E), Mumbai), FTIR Spectrophotometer (Model No. 8400 S, Shimadzu Asia Pacific Pvt. Ltd., Singapore), Digital Vernier Caliper (ASAHI, India), Ultrasonicator (PCI, Mumbai).

2.2 Preformulation Studies:

2.2.1 Identification of Drug [15-18]

a) Melting Point Determination

The melting point of domperidone was determined by the capillary method using a digital melting point apparatus. The observed melting point was compared with the reported value to confirm the identity and purity of the drug.

b) Fourier Transform Infrared (FTIR) Spectroscopy

FTIR analysis was performed to identify domperidone and assess drug-excipient compatibility. The drug sample was mixed with potassium bromide (KBr), compressed into a pellet, and scanned in the range of 4000–400 cm⁻¹. The obtained spectra were compared with standard characteristic peaks of domperidone.

c) Differential Scanning Calorimetry (DSC) Analysis

DSC analysis was carried out to study the thermal behavior of domperidone and evaluate compatibility with excipients. Approximately 5 mg of sample was heated from 40°C to 300°C at a rate of 10°C/min under a nitrogen atmosphere, and thermograms were recorded.

d) UV-Visible Spectroscopy

Preparation of 0.1 N HCl: 0.1 N hydrochloric acid was prepared by dissolving 3.65 g of HCl in distilled

water and making up the volume to 1000 mL.

Determination of λ_{max} : A solution containing 10 mg of domperidone in 100 mL of 0.1 N HCl was scanned in the range of 200–400 nm using a UV–Visible spectrophotometer, and the λ_{max} was determined.

Preparation of Standard Calibration Curve: A stock solution of domperidone (1000 $\mu\text{g/mL}$) was prepared by dissolving 100 mg of drug in 100 mL of 0.1 N HCl. This solution was further diluted to obtain a secondary stock solution of 100 $\mu\text{g/mL}$. Aliquots of 5, 10, 15, 20, 25, 30, 35, and 40 mL were withdrawn and diluted to 100 mL with 0.1 N HCl to obtain concentrations of 5–40 $\mu\text{g/mL}$. The absorbance of each solution was measured at 284 nm, and a calibration curve of absorbance versus concentration was plotted.

Table No.1: Absorbance values for standard calibration curve of domperidone in 0.1M HCl

Sr. No.	Concentration ($\mu\text{g/mL}$)	Absorbance
1	0	0
2	5	0.046
3	10	0.101
4	15	0.130
5	20	0.169
6	25	0.225
7	30	0.259
8	35	0.297
9	40	0.368

2.2.3 Drug-Excipient Compatibility Studies [19-21]

a) Fourier Transform Infrared (FTIR) Spectroscopy

FTIR spectroscopy was performed to evaluate the compatibility between domperidone and formulation excipients. Samples of pure drug and drug–excipient mixtures were prepared using the KBr pellet method and scanned over the range of 4000–400 cm^{-1} . The obtained spectra were compared for any significant changes in characteristic peaks indicating possible interactions.

b) Differential Scanning Calorimetry (DSC)

DSC analysis was carried out to assess the thermal compatibility of domperidone with selected excipients. Samples were heated from 40°C to 300°C at a rate of 10°C/min under a nitrogen atmosphere. Thermograms of the pure drug and drug–excipient mixtures were compared, and the absence of significant changes in the characteristic endothermic peak confirmed compatibility between the drug and excipients.

2.3 Taste Masking by Ion Exchange Resin [25-27]

2.3.1 Pretreatment of Tulsion 339

Tulsion 339 resin was washed with distilled water to remove impurities and then soaked in distilled water

for 30 minutes for complete swelling. The swollen resin was filtered and used for further studies.

2.3.2 Preparation of Drug–Resin Complex (DRC)

The pretreated resin was dispersed in distilled water and allowed to swell. Domperidone was added to the resin dispersion under continuous stirring and stirred for 4 hours to form the drug–resin complex. The complex was then filtered, washed with distilled water, dried at 50°C, passed through sieve No. 60, and stored in a desiccator for further use.

2.3.3 Optimization Studies [22-24]

a) Effect of Drug:Resin Ratio

To optimize drug loading, drug–resin complexes were prepared using different drug-to-resin ratios of 1:1, 1:2, and 1:3. The prepared complexes were evaluated for percent drug complexation. The ratio showing maximum drug loading and satisfactory taste masking was selected for further studies.

b) Effect of Resin Swelling Time

The effect of resin swelling time on drug complexation was studied by swelling the resin for different time intervals (15, 30, 45, and 60 minutes) before the complexation process. The prepared complexes were analyzed for percent drug loading. The swelling time producing maximum drug complexation was selected as the optimized condition for further formulation development.

2.3.4 Evaluation of Drug–Resin Complex (DRC)[28-29]

a) Percent Drug Complexation

An accurately weighed quantity of drug–resin complex equivalent to 10 mg of domperidone was dissolved in 0.1 N HCl, filtered, and analyzed at 284 nm using a UV spectrophotometer. The percentage drug complexation was calculated using the formula:

$$\% \text{ Drug Complexation} = \frac{[(\text{Total Drug Added} - \text{Free Drug}) / \text{Total Drug Added}] \times 100}{}$$

b) Taste Evaluation

Taste masking efficiency was evaluated by a panel of healthy volunteers. The drug–resin complex was placed on the tongue for 30 seconds, and bitterness was scored on a scale of 0–4, where 0 indicated no bitterness and 4 indicated strong bitterness.

c) Drug Content

Drug–resin complex equivalent to 10 mg of domperidone was dissolved in 0.1 N HCl, filtered, and analyzed at 284 nm using a UV spectrophotometer. Drug content was determined from the standard calibration curve and expressed as percentage drug content.

2.4 Formulation of Orodispersible Tablets [30-31] Selection of Superdisintegrant

Superdisintegrants are incorporated into tablet formulations to promote rapid disintegration upon contact with saliva or aqueous fluids, thereby enhancing drug dissolution and absorption. They facilitate water penetration into the tablet matrix and promote its breakup into smaller particles, increasing the effective surface area available for dissolution. The efficiency of tablet disintegration depends on factors such as the type and concentration of superdisintegrant, tablet hardness, and dosage form size. Crosspovidone was selected as the superdisintegrant in the present study due to its excellent swelling and wicking properties, which contribute to rapid tablet disintegration.

2.4.1 Composition of Formulations (S1–S8)

Table No.2: Formulation Table Drug: Tulsion-339 (1:3)

Tablet Composition (mg)	S1	S2	S3	S4	S5	S6	S7	S8
DRC*	40	40	40	40	40	40	40	40
Ammonium Bicarbonate	5	10	15	20	-	-	-	-
Camphor	-	-	-	-	5	10	15	20
Crosspovidone	5	5	5	5	5	5	5	5
Avicel PH102	15	15	15	15	15	15	15	15
Mannitol	29	24	19	14	29	24	19	14
Aspartame	4	4	4	4	4	4	4	4
Mag. stearate	2	2	2	2	2	2	2	2
Tablet weight	100	100	100	100	100	100	100	100

2.4.2 Preparation Method

Orodispersible tablets of domperidone were prepared by the direct compression method using the optimized drug–resin complex (Drug:Tulsion 339, 1:3). Crosspovidone was used as a superdisintegrant, Avicel PH 102 and mannitol as diluents, aspartame as a sweetener, and ammonium bicarbonate or camphor as subliming agents. Formulations S1–S4 contained ammonium bicarbonate at concentrations of 5%, 10%, 15%, and 20%, respectively, while formulations S5–S8 contained camphor at the same concentrations. All ingredients were accurately weighed, passed through sieve No. 40, and blended uniformly. The powder blend was lubricated with magnesium stearate and compressed into tablets using 6 mm punches. Prior to compression, pre-compression parameters such as angle of repose, bulk density, tapped density, compressibility index, and Hausner's ratio were evaluated. The compressed tablets were subjected to sublimation at 65°C for 8 hours to obtain porous orodispersible tablets. The prepared tablets were then evaluated for hardness, friability, weight variation, wetting time, water absorption ratio, disintegration time, and in-vitro drug release. The optimized formulation was further

compared with a marketed domperidone tablet.

2.5 Evaluation of Powder Blend[32-34]

Precompression assessment of physical parameter of mixture blend ²⁵

For a research paper, you can write the evaluation parameters in a concise form as follows:

2.6 Evaluation of Powder Blend and Tablets

a) Angle of Repose

The flow property of the powder blend was determined by the fixed funnel method. The angle of repose (θ) was calculated using the equation:

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

b) Bulk Density

Bulk density was determined by measuring the volume occupied by a known weight of powder before tapping.

$$LBD = W/V_0$$

c) Compressibility Index

Compressibility of the powder blend was evaluated using Carr's Index.

$$\text{Carr's Index (\%)} = [(TBD - LBD)/TBD] \times 100$$

d) Hausner's Ratio

Hausner's ratio was calculated to assess powder flowability.

$$\text{Hausner's Ratio} = TBD/LBD$$

e) Hardness

Tablet hardness was measured using a Monsanto hardness tester and expressed in kg/cm².

f) Friability

Friability was determined using a friabilator operated for 100 revolutions and calculated as:

$$\% \text{ Friability} = [1 - (W/W_0)] \times 100$$

g) Thickness

Tablet thickness was measured using a digital vernier caliper and expressed as mean $\pm$ SD.

h) Wetting Time and Water Absorption Ratio

Wetting time was determined by placing a tablet on tissue paper soaked with water. Water absorption ratio was calculated using:

$$R = 100 (W_b - W_a)/W_a$$

i) Disintegration Time

In-vitro disintegration time was measured using a digital disintegration test apparatus containing distilled water maintained at $37 \pm 2^\circ\text{C}$.

j) In-vitro Dissolution Studies

Dissolution studies were performed using USP Apparatus Type II (Paddle Method) at 50 rpm in 900 mL of 0.1 N HCl (pH 1.2) maintained at $37 \pm$

0.5°C. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically at 284 nm.

k) Drug Content

Twenty tablets were powdered, and an amount equivalent to 10 mg of domperidone was dissolved in 0.1 N HCl, filtered, suitably diluted, and analyzed at 284 nm using a UV-visible spectrophotometer. Drug content was calculated from the standard calibration curve.

2.6.7 Water Absorption Ratio

Water absorption ratio was determined by placing a tablet on a wetted tissue paper in a Petri dish containing 6 mL of distilled water. The tablet was weighed before (W_a) and after wetting (W_β), and the water absorption ratio was calculated using:

$$R = [(W_\beta - W_a)/W_a] \times 100$$

2.6.8 In-vitro Disintegration Time

The disintegration time of tablets was determined using a USP disintegration test apparatus containing distilled water maintained at $37 \pm 0.5^\circ\text{C}$. The time required for complete disintegration of the tablets was recorded and expressed in seconds.

2.6.9 In-vitro Dissolution Study

In-vitro dissolution studies were carried out using USP Dissolution Apparatus Type II (Paddle Method) at 50 rpm in 900 mL of 0.1 N HCl maintained at $37 \pm 0.5^\circ\text{C}$. Samples were withdrawn at predetermined intervals, analyzed at 284 nm, and cumulative drug release was calculated.

2.6.10 SEM Analysis[35-37]

Scanning Electron Microscopy (SEM) was performed to study the surface morphology and porosity of the optimized formulation. The samples were gold-coated and examined under a scanning electron microscope at suitable magnifications.

2.6.11 Comparison with Marketed Tablet

The optimized formulation was compared with a marketed domperidone tablet for disintegration time, wetting time, water absorption ratio, and drug release profile. Both formulations were evaluated under identical conditions, and their dissolution profiles were compared.

3. RESULTS AND DISCUSSION:

3.1 Preformulation Studies

3.1.1 Melting Point

Melting point:⁶² The melting point of the Domperidone was found to be 252 to 253°C, which complies with melting point reported ones.

3.1.2 FTIR Analysis

All the prominent and primary peaks were observed

in FTIR spectrum of Domperidone (Fig.no.1) and match with the reference spectrum of pure domperidone. (Journal of chemical & pharmaceutical research 2011,3(6):655-664.

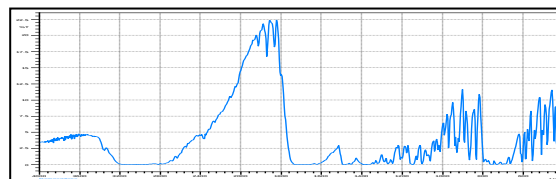


Figure: 1 FTIR Spectrum of drug sample

3.1.3 DSC Analysis

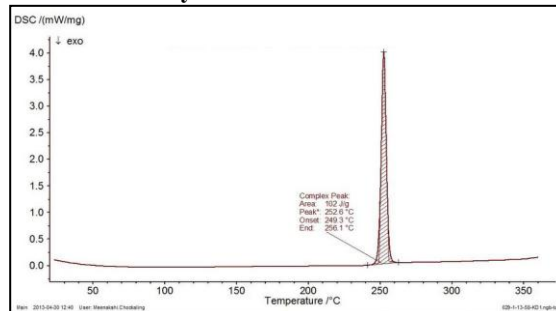


Fig.No.2 DSC studies of domperidone

The melting point of domperidone is 244 to 248°C according to reference given in European Pharmacopoeia 5 (pg.no.1473). The melting of domperidone was found to be 252.6°C shown in fig.no.13. By Comparing the melting point of drug, no significant changes were observed in peak of drug. Hence it confirms that given sample is domperidone.

3.1.4 UV Spectroscopy and Calibration Curve

The λ_{max} of Domperidone was found to be 284.0 nm which complies with the specification of USP NF 2000 (Figure No. 3)

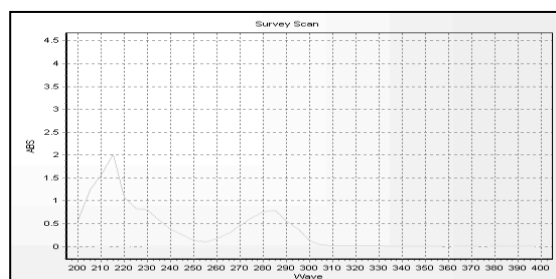


Figure 3: Scanning of domperidone in 0.1N HCl

Table No.3: Absorbance values for standard calibration curve of domperidone in 0.1M HCl

Sr. No.	Concentration (µg/ml)	Absorbance
1	0	0
2	5	0.046
3	10	0.101
4	15	0.130
5	20	0.169
6	25	0.225
7	30	0.259
8	35	0.297
9	40	0.368

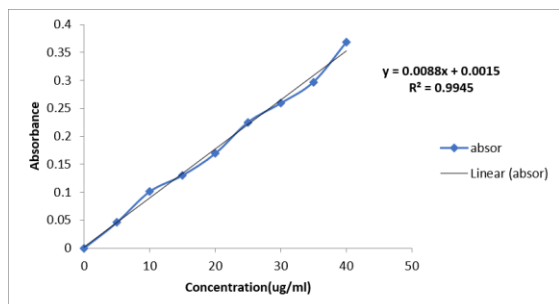


Fig. No. 4: Standard calibration curve of drug in 0.1N HCl

The calibration curve for domperidone in 0.1N HCl in the concentration range of 5 µg/ml to 40 µg/ml was a straight line. The absorbance increased with the increase in concentration. Thus the standard curve followed the Beer-Lambert's Law.

3.2 Drug-Resin Complex Evaluation Compatibility

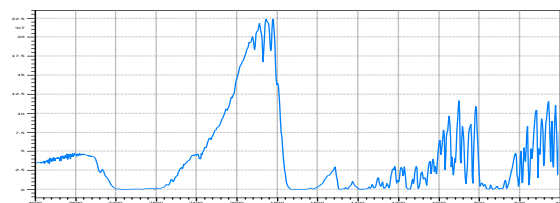


Fig. No. 5: FTIR spectrum of domperidone

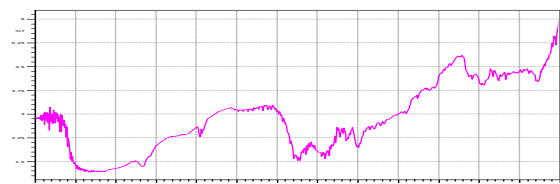


Fig. No.6: FTIR spectrum of tulsion 339

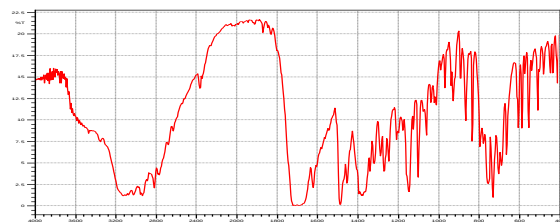


Fig. No. 7: FTIR spectrum of tulsion 339 and drug

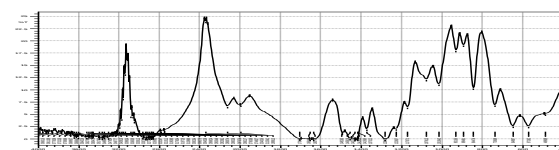


Fig. No.8: FTIR spectrum of crosspovidone

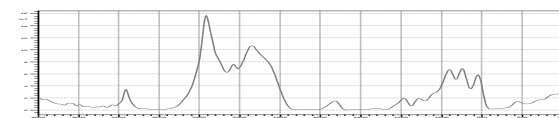


Fig. No.9: FTIR spectrum of Crosspovidone and domperidone

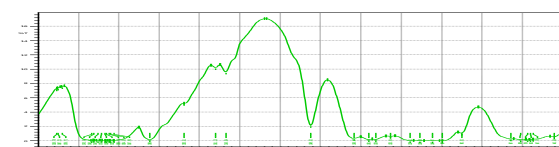


Fig. No.10: FTIR Spectrum of Avicel-PH 102

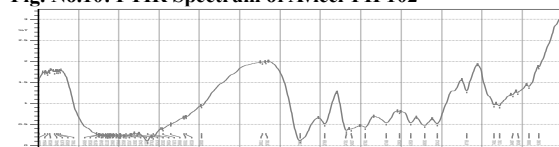


Fig. No. 11: FTIR spectrum of physical blend (drug : tulsion 339)

The infrared spectra of domperidone, tulsion 339 and drug: resin complex shown in figure 16 to 25 respectively. Drug spectrum shows prominent peaks at 3355.91 cm⁻¹, 1724.24 cm⁻¹, 2819.73 cm⁻¹, corresponding to the -NH stretching, C=O and C-H stretching respectively. Tulsion 339(D:R) shows a characteristic peak at 3353.98 cm⁻¹, corresponding to the -NH stretching, at 1712.67 cm⁻¹ corresponding to -C=O stretching of aryl acids, and at 2819.52 cm⁻¹ corresponding to -C-H stretching. By comparing the peaks of drug observed in drug spectrum, it was observed that no significant changes occur in peak of drug and resin. Hence it was concluded that domperidone was found to be compatible with tulsion 339.

4.2.2. DSC THERMOGRAM ANALYSIS

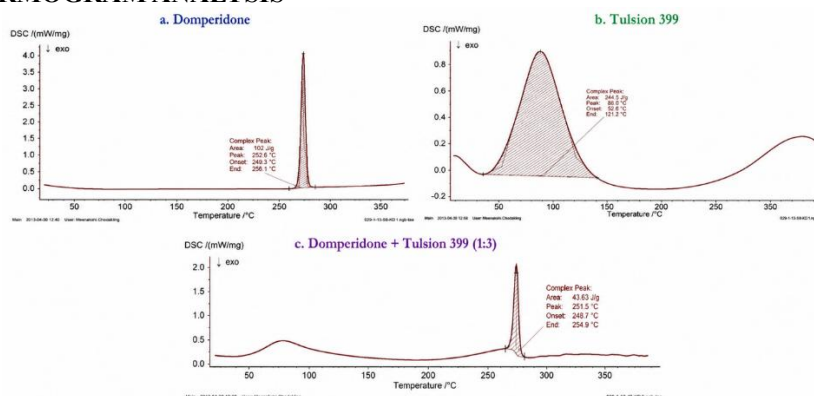


Figure no. 12: Interpretation of DSC thermogram of drug T-339

The Differential Scanning Calorimetry (DSC) thermograms of pure Domperidone, Tulsion 339 resin, and the Domperidone–Tulsion 339 complex (1:3) were recorded to investigate the thermal behavior and compatibility of the drug with the ion-exchange resin. Pure Domperidone exhibited a sharp endothermic peak at **252.6°C** (onset 249.3°C, endset 256.1°C) with an enthalpy of **102 J/g**, corresponding to its characteristic melting point and confirming its crystalline nature. Tulsion 339 showed a broad endothermic peak at **88.3°C** (onset 52.6°C, endset 121.2°C) with an area of **244.5 J/g**, which may be attributed to the loss of absorbed moisture and the thermal characteristics of the resin. The DSC thermogram of the Domperidone–Tulsion 339 complex displayed an endothermic peak at **251.5°C** (onset 248.7°C, endset 254.9°C) with a reduced enthalpy value of **43.63 J/g**. The slight shift in peak temperature and reduction in peak area indicate partial interaction of the drug with the resin and a decrease in crystallinity due to complex formation. However, the characteristic melting peak of Domperidone remained present without any significant change or appearance of new peaks, suggesting the absence of chemical incompatibility between the drug and Tulsion 339. Therefore, the DSC study confirms the successful formation of the drug–resin complex while demonstrating the thermal compatibility and stability of Domperidone with Tulsion 339.

3.2 Drug-Resin Complex Evaluation

4.5.1 Taste evaluation of solid drug resin complex:

Results of taste evaluation by panel method are shown in table no.13

Table No. 4: Sensory evaluation data of DRC (tulsion-339)

Sensory Evaluation Data of DRC (Tulsion-339)									
Ratio of DRC	Scores given by different group about taste of drug: Tulsion-339 complex								
	Group I			Group II			Group III		
	1	2	3	1	2	3	1	2	3
Pure drug	5	5	5	5	5	5	5	5	5
1:1	3	2	2	3	2	3	3	3	3
1:2	3	1	2	3	2	1	3	2	1
1:3	1	2	1	1	1	1	1	2	1
	Average Bitterness value								
	5								
	2.66								
	2.0								
	1.3								

Scoring scale: 1 = No bitterness 2 = Slight bitterness 3 = Moderate bitterness 4 = Very bitter 5 = Extremely bitter

Results of taste evaluation by panel method revealed that Tulsion-339 mask the bitter taste of drug completely at 1:3 ratio, which shows satisfactory masking of taste.

4.5.2 Assay of drug resin complex::

Table no.5: Percent drug content of drug: resin complexes

Ratio of drug: resin	% Drug content
1:3 (Tulsion 339)	96.12 ± 0.11

3.3 Evaluation of Powder Blend

The pre-compression evaluation of all batches (S1–S8) demonstrated acceptable flow and packing characteristics. Bulk density ranged from **0.43–0.54 g/cm³** and tapped density from **0.48–0.62 g/cm³**, indicating good powder packing ability. The angle of repose values (**20.30°–28.14°**) suggested good to excellent flow properties. Carr's Index ranged from **7.40% to 14.54%**, while Hausner's ratio varied between **1.08 and 1.15**, confirming satisfactory compressibility and flowability of the powder blends. Among all batches, **S4 and S6 exhibited the best flow properties**, as evidenced by their lower angle of repose, Carr's Index, and Hausner's ratio values. Overall, all formulations were found suitable for direct compression into tablets.

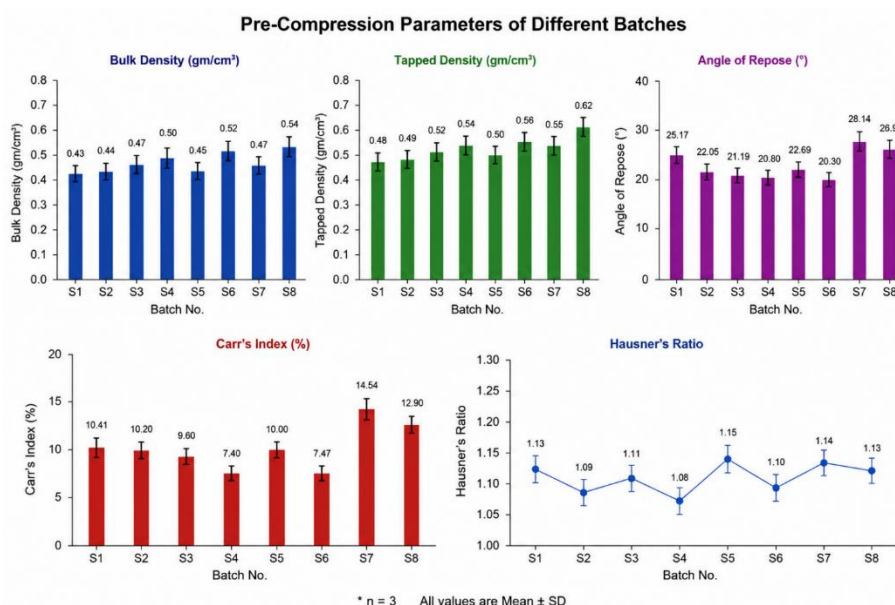


Figure 13: Pre-compression Parameter of different batches

3.4. Evaluation of Orodispersible Tablets: Hardness, Thickness, Friability, Weight Variation, Disintegration Time, Wetting Time, Water Absorption Ratio, and Drug Content Uniformity

Orodispersible tablets were prepared by direct compression and evaluated for tablet properties like weight variation, hardness, thickness, friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution. The post-compression evaluation of all tablet batches

(S1–S8) demonstrated acceptable physicochemical characteristics and compliance with pharmacopeial limits. Friability values ranged from **0.64% to 0.78%**, which were below 1%, indicating adequate mechanical strength of the tablets. Hardness values varied between **2.33 and 3.53 kg/cm²**, confirming sufficient tablet integrity while maintaining rapid disintegration properties. Tablet thickness was found to be uniform (**4.10–4.37 mm**), and weight variation results (**97.23–101.00%**) indicated consistent die filling and uniform tablet weight.

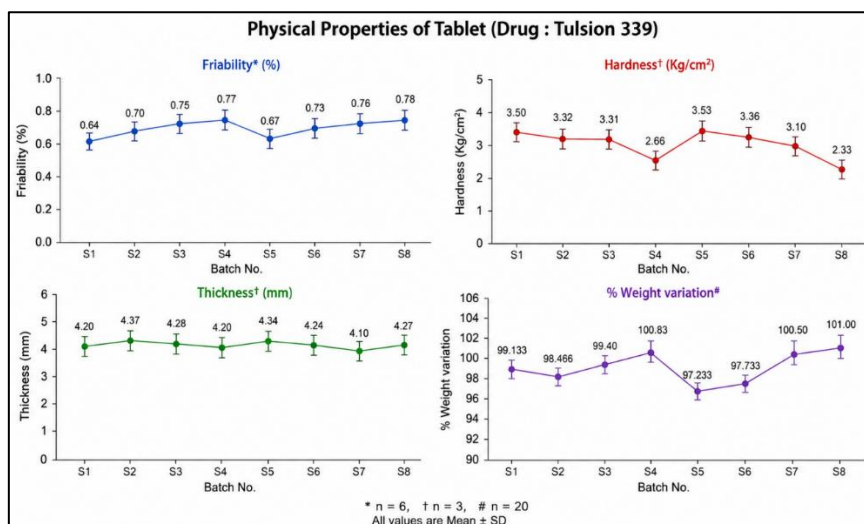


Figure 14: Evaluation of Orodispersible Tablets: Hardness, Thickness, Friability, Weight Variation

The disintegration time of the formulations ranged from **15 to 25 seconds**, demonstrating the suitability of the tablets for rapid oral disintegration. Batch **S4** exhibited the shortest disintegration time (**15 ± 1.18 sec**), indicating superior tablet performance. Wetting time varied between **22.71 and 34.66 seconds**, with

S4 showing the lowest wetting time (**22.71 ± 0.23 sec**), suggesting rapid water penetration into the tablet matrix. The water absorption ratio ranged from **74.78% to 83.79%**, with the highest value observed for **S4 (83.79 ± 1.14%)**, which contributed to its faster disintegration behavior.

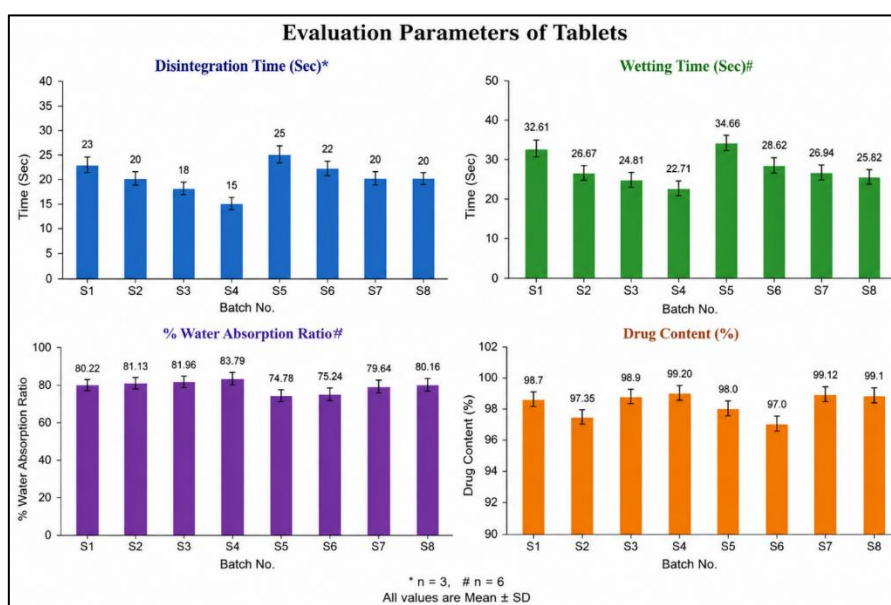


Figure 15: Evaluation of Orodispersible Tablets: Disintegration Time, Wetting Time, Water Absorption Ratio, and Drug Content Uniformity

Drug content was found to be within the acceptable range (97.0–99.20%) for all formulations, indicating uniform drug distribution. Among all batches, **S4 demonstrated the most desirable characteristics**, including the fastest disintegration time, shortest wetting time, highest water absorption ratio, and satisfactory drug content, suggesting that it was the optimized formulation for orodispersible tablet development.

3.5 In-vitro Dissolution Studies:

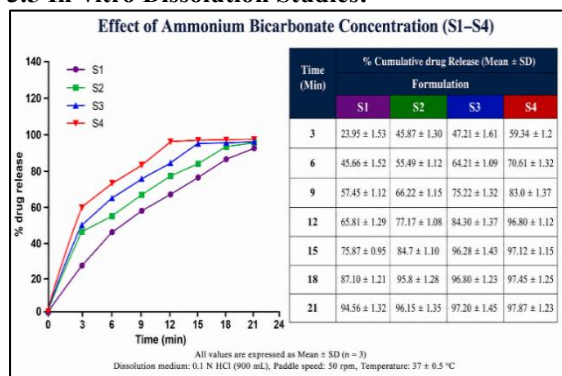


Table No. 16: In-vitro drug release of formulation S1 to S4

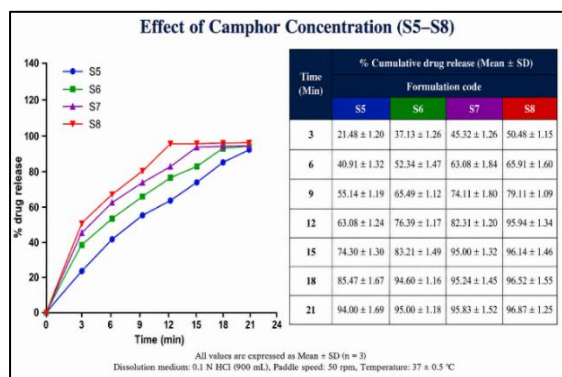


Fig.No.17: In vitro drug release of formulation S5-S8

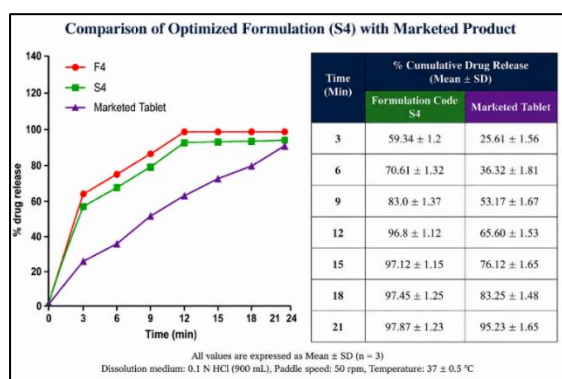


Fig.No.18: In vitro drug release of formulation S4 and Marketed Tablet (VOMISTOP)

Among the ammonium bicarbonate formulations (S1–S4), formulation S4 containing 20% ammonium bicarbonate exhibited the highest cumulative drug release (97.87 ± 1.23% at 21 min) and the fastest dissolution profile, indicating superior tablet porosity and disintegration.

Similarly, among the camphor formulations (S5–S8), S8 containing 20% camphor showed the highest drug release (96.87 ± 1.25% at 21 min), although its performance was slightly lower than that of S4. When the optimized formulation S4 was compared with the marketed tablet, S4 exhibited significantly faster and higher drug release, releasing 96.8 ± 1.12% drug within 12 min compared to 65.60 ± 1.53% from the marketed formulation. These results indicate that ammonium bicarbonate was a more effective subliming agent than camphor and that the optimized formulation S4 provided superior dissolution characteristics, suggesting a faster onset of therapeutic action than the marketed product. In-vitro Drug release data of S4 and Marketed Tablet

3.6 SEM Analysis: The SEM studies showed that the tablet produced is porous in nature, which can be easily identified as seen in figures which shows the difference between tablets before and after sublimation (fig.18).

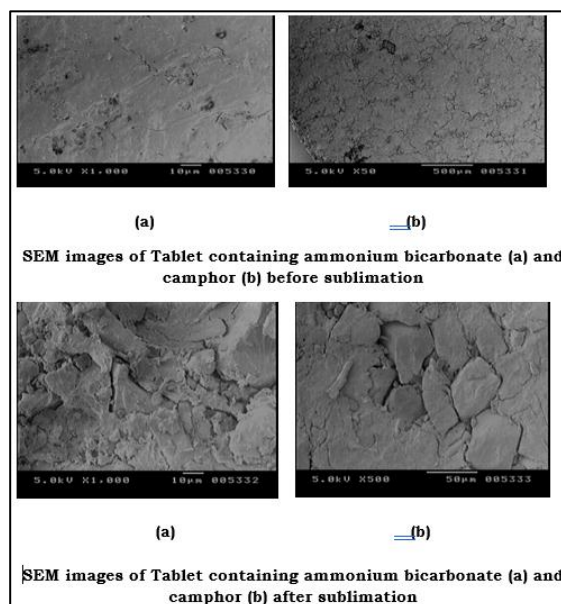


Figure 19: SEM analysis

4. CONCLUSION:

The present study successfully developed taste-masked orodispersible tablets of Domperidone using Tulsion 339 ion-exchange resin and the sublimation technique. Effective taste masking was achieved with the optimized drug–resin complex at a drug-to-resin ratio of 1:3, which exhibited satisfactory drug loading and palatability. Compatibility studies confirmed the absence of significant interactions between Domperidone and Tulsion 339. The sublimation technique proved effective in producing highly porous tablets with rapid disintegration characteristics. Among all formulations, batch S4 containing 20% ammonium bicarbonate demonstrated the most desirable performance, exhibiting the shortest disintegration time (15 s), lowest wetting time, highest water absorption ratio,

and maximum drug release (96.8% within 12 min). Furthermore, the optimized formulation showed superior dissolution behavior compared to the marketed Domperidone tablet. The results also indicated that ammonium bicarbonate was a more effective subliming agent than camphor in enhancing tablet porosity, disintegration, and drug release. Overall, the study demonstrates that the combination of ion-exchange resin taste masking and sublimation technology is a promising approach for the development of patient-friendly orodispersible tablets with improved palatability and rapid therapeutic action.

5. FUTURE SCOPE:

Further studies can be conducted to evaluate the long-term stability of the optimized formulation under ICH-recommended storage conditions. In-vivo bioavailability and pharmacokinetic studies are required to establish the correlation between the enhanced in-vitro performance and therapeutic efficacy. Scale-up and industrial feasibility studies may be undertaken to assess the commercial applicability of the developed formulation. The taste-masking approach using ion-exchange resins can also be extended to other bitter drugs to improve patient compliance. Additionally, clinical evaluation of the optimized formulation may provide further evidence of its effectiveness and patient acceptability.[37-40]

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