VER
Vascular & Endovascular Review

Physicochemical Characterization and In Vivo Evaluation of Taste-Masked Dextromethorphan Hydrobromide Resinates in Orally Disintegrating Tablets for Antitussive Action

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ABSTRACT

Dextromethorphan Hydrobromide (DMH), a widely used centrally acting antitussive, suffers from intense bitterness that limits patient compliance, particularly among paediatric, geriatric, and dysphagic populations. This study aimed to develop taste-masked orally disintegrating tablets (ODTs) of DMH using Carbomer (Carbopol 974P), a non-traditional ion-exchange polymer. Drug–resin complexes (DRCs) were prepared at different drug-to-resin ratios and optimized at 1:1. The complex was characterized by FTIR, DSC, and XRPD to confirm molecular interaction, loss of crystallinity, and structural stability. In vitro taste-masking assessment in simulated salivary conditions (pH 6.8, 5 mL) demonstrated minimal drug release (<0.50% in 120 s), confirming effective masking. The optimized DRC was compressed into ODTs (F1–F7), and formulation F7 exhibited the best physicochemical profile, including rapid disintegration (≤20 s) and 96.0 ± 3.45 % dissolution in 20 minutes. A trained human taste panel reported the DRC and ODTs as tasteless compared to pure drug and marketed tablets. In vivo bioequivalence studies in Wistar rats revealed improved pharmacokinetics for the test formulation, with higher Cmax, AUC, and shorter Tmax relative to the marketed product. The findings confirm Carbopol-based ion-exchange complexation as an effective approach for taste masking and enhanced bioavailability of DMH in ODT formulations.

KEYWORDS: Dextromethorphan Hydrobromide, Taste masking, Carbomer, Carbopol 974P, Orally disintegrating tablets, Drug–resin complex.

How to Cite: Manu Tripathi, Pankaj Kumar Yadav, (2025) Physicochemical Characterization and In Vivo Evaluation of Taste-Masked Dextromethorphan Hydrobromide Resinates in Orally Disintegrating Tablets for Antitussive Action, Vascular and Endovascular Review, Vol.8, No.6s, 359-366.

INTRODUCTION

Taste masking plays a vital role in the development of oral drug formulations, especially for medications with unpleasant or intensely bitter taste profiles. Dextromethorphan Hydrobromide (DMH), a widely used antitussive agent, is particularly known for its strong bitterness and aftertaste, which can negatively influence patient compliance—especially among paediatric, geriatric, and sensitive patient groups. To overcome this problem, several taste-masking approaches have been explored, including microencapsulation, complexation, and polymer coating techniques.[1]

Ion-exchange resins, a class of high molecular weight polyelectrolytes capable of reversible ion binding, offer a promising strategy for masking the bitter taste of DMH. These resins selectively complex with charged drug molecules, reducing their interaction with gustatory receptors in the oral cavity. This method not only provides palatability enhancement but can also modulate drug release for better therapeutic performance.[2]

The present study introduces an innovative formulation approach for developing orally disintegrating tablets of DMH using a non-traditional ion-exchange resin, Carbomer (Carbopol 974P), to achieve effective taste masking. Carbomer is a crosslinkedpolyacrylic acid polymer containing carboxylic functional groups capable of exchanging hydrogen ions with basic drugs like DMH during ion-exchange reactions. Unlike conventional resins, Carbomer does not necessitate acid/base activation or extensive washing steps, offering a significant advantage from a manufacturing and commercial standpoint.[3]

The formulation pathway involved synthesizing a DMH–Carbopol 974P drug-resinate complex, which was subsequently blended with suitable excipients and compressed into orally disintegrating tablets (ODTs). By forming this ionic complex, the concentration of free drug in saliva is minimized, thereby preventing activation of taste receptors and improving palatability.[4] The excipients were selected to ensure rapid tablet disintegration in the oral cavity, enabling swift liberation of the drug from the resinate complex and facilitating systemic absorption following swallowing.

Comprehensive physicochemical characterization of the DMH–resin complex was conducted to assess parameters such as drug loading efficiency and release behaviour. These attributes are critical for achieving optimal taste masking without compromising bioavailability. In vitro studies were also performed to evaluate the disintegration performance, dissolution profile, and simulated salivary release to confirm the extent of taste masking achieved.[5]

The findings of this study demonstrate that ion-exchange resins like Carbomer can effectively suppress the bitterness of DMH while retaining the rapid release characteristics needed for ODT formulations. This approach holds substantial potential for improving patient adherence, particularly for individuals with swallowing difficulties, young children, and older adults. By enhancing palatability and ensuring prompt onset of action, this strategy contributes meaningfully to improved treatment outcomes and quality of life.[6]

Dextromethorphan Hydrobromide is a centrally acting antitussive that suppresses the cough reflex by acting on the cough center in the medulla oblongata. It is commonly used to manage nonproductive (dry) cough and is valued for its efficacy and low risk of dependence. Its mechanism involves modulation of sigma-1 receptors and NMDA receptor antagonism without the narcotic effects associated with opioid derivatives.[7]

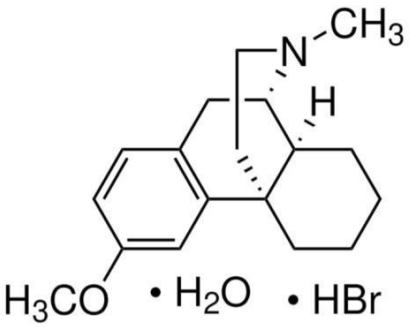

Fig. 1 - DMH Structure

MATERIALS AND METHODS

Materials

DMH was acquired from Jubilant Life Sciences in Noida, while Taste Masker Carbopol 974P was received as a gift from Lubrizol Life Science in Mumbai samples, Microcrystalline cellulose Lactose, Crospovidone, Magnesium stearate, Aspartame and chemicals of ultrapure grade were purchased from research lab Mumbai.

Methods

The analytical technique of Liquid chromatography with high performance (HPLC)) for DMH An established high-performance liquid chromatography (HPLC) methodology was employed for the examination of dextromethorphan hydrobromide (DMH) in rat plasma, The analytical HPLC method (Agilent 1200) utilized a Phenyl column (ZORBAX Eclipse XDB-Phenyl, 4.6 x 150 mm, 5 µm) maintained at ambient temperature. The mobile phase consisted of 50% KH_2PO4 buffer (10mM, with adding 0.02% of triethylamine; adjusted with phosphoric acid to pH 3.5), 20% methanol and 30% acetonitrile. A volume of 100 micro litre treated sample was injected into an YMC-Pack phenyl column (5micro m, 150mm×4.6 mm). The flow rate was 1.0 ml/min. The eluent was detected with fluorescence excitation at 230 nm and emission at 330 nm.[8]

2.1 Synthesis of Pharmaceutical–Resin Complex (DRC)

Batch processing was employed to produce the drug-resin combination. Three drug-resin complexes were produced utilizing Carbomer (Carbopol 974P polymer). The ratios of drug to resin, specifically 3:1, 2:1, and 1:1, were quantified and added to 50 ml of deionized water in a glass beaker.The resulting suspension was agitated for 30 minutes using a magnetic stirrer and then let to whirl at a temperature of 37 ± 0.5 °C for an additional five hours. The complexes were removed using vacuum filtering, thereafter rinsed with deionized water to eradicate residual pharmaceuticals and ions, and the material was dried until a stable weight was achieved. The true loading capacity was evaluated via spectrophotometric measurement of the filtrate at a wavelength of 278 nm. The disparity between the initial and residual quantities of medication in the filtrate was utilized to compute the amount of drug incorporated into the complexes.[9, 10]

2.2 Characterization drug–resin complex (DRC)

2.2.1 FTIR spectroscopy

FTIR spectroscopy was used to investigate the DMH and Carbopol 974P polymer chemical interaction. An infrared spectrometer with fourier transform (Bruker Alpha II) was used to get the samples' IR spectra. The scanning range for The KBr disk method readings ranged from 4000 to 400 cm^{-1}. The outcome is illustrated in Fig. 2.

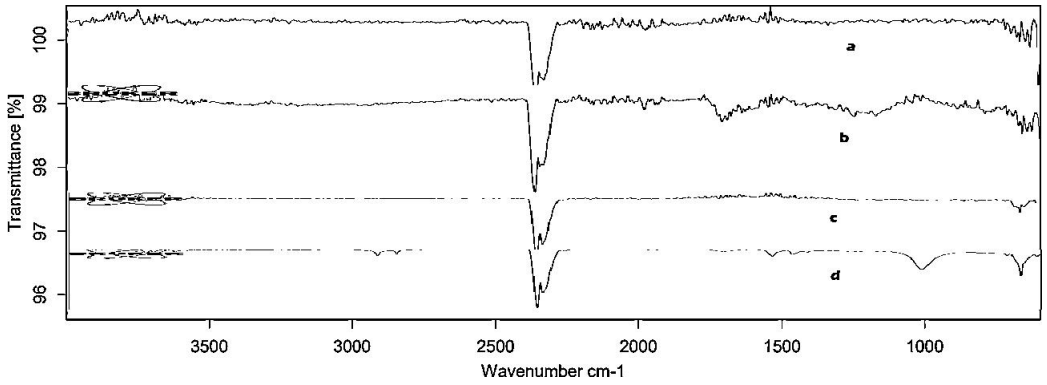

Fig. 2 – FT-IR spectra of Pure DMH (a), Pure Carbopol974P (b), DMH Carbopol974P complex (c), DMH Carbopol 974P physical mixture (d)

2.2.2 Differential Scanning Calorimetry (DSC)

Differential Scanning Calorimetry (DSC) analyses were conducted on both the pure drug and the resinate to evaluate the molecular condition of the drug within the drug-resin complex. The samples' DSC curves were acquired using a differential scanning calorimeter (TA Instrument HTLP 071). After each sample was put inside an aluminium pan, the aluminium cover was crimped on. The pace of heating was 10 °C per minute. All measurements were performed within The temperature range spans from 0 to 500 °C, utilizing a nitrogen purge at a flow rate of 50 mL/min. The results are depicted in Fig. 3.

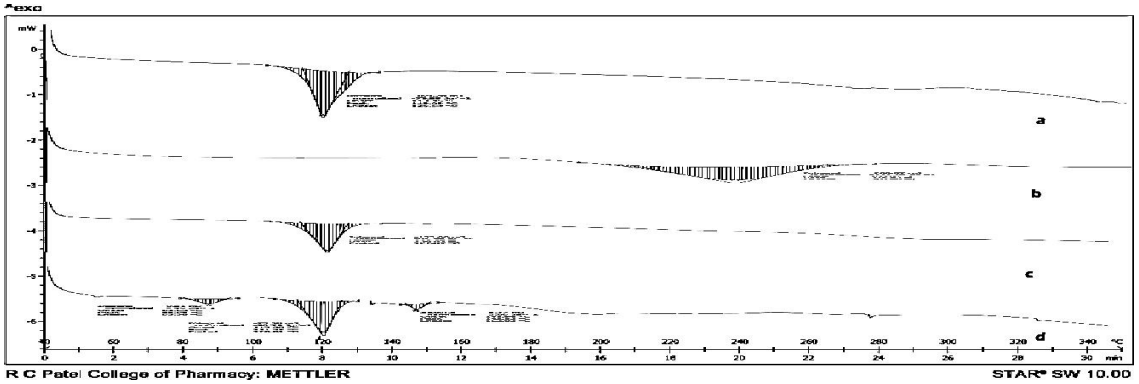

Fig. 3 – DSC spectra of DMH API (a), Carbopol 974P polymer (b), DMH Carbopol 974P complex (c), DMH and Carbopol 974P physical mixture (d)

2.2.3 X-ray Powder Diffraction (XRPD)

An automated X-ray diffractometer (Bruker D2 PHASER) utilizes a Cu K filter and SC70 radiation detector, operating at 40 kV and 30 mA, with a scanning speed of 10 mm/secto conduct X-ray diffraction investigations on materials. Figure 4 presents the findings.

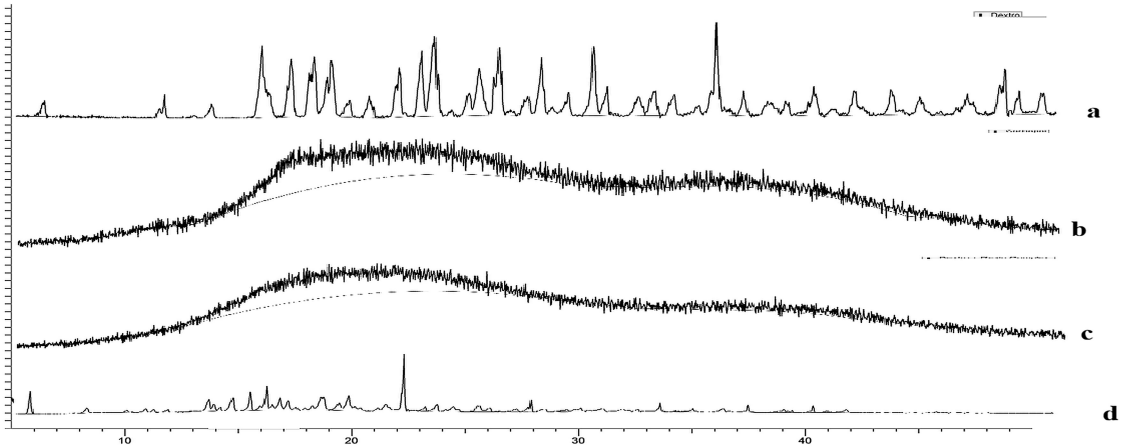

Fig. 4 - XRD spectra of Pure DMH (a), Pure Carbopol 974P (b), DMHCarbopol 974P complex (c), DMH Carbopol 974P physical mixture (d).

2.3 In Vitro Assessment of Drug Release from Drug–Resin Complex under Simulated Oral Cavity Conditions

An in vitro study was conducted to evaluate the drug release from the DMH-Carbopol complex (Drug-Resin Complex) in the oral cavity following aDMHinistration. A USP A phosphate buffer with a pH of 6.8 was prepared to evaluate the release of the drug from the compound. Twenty milligrams of the drug-resin combination was allocated into two 25 mL glass bottles, subsequently augmented with 5 mL of the buffer solution. The bottles were permitted to stay still for 60 seconds and 120 seconds, respectively. FollowingDuring the designated timeframe, the suspensions underwent filtration utilizing a 0.45 µm nylon filters were utilized, and the filtrates obtained were subsequently analyzed for drug concentration.[11]

Table 1: In-Vitro Evaluation of Drug Release from Drug–Resin Complex in Simulated Oral Cavity Conditions

Sample	Time (s)	Amount of Free drug in 5 ml pH 6.8 Phosphate buffer (mg)	% drug release
DMHCarbopol 974P Resin Complex	60	0.08 ± 0.006	0.40 ± 0.15
	120	0.10 ± 0.013	0.50 ± 0.33

2.4 Formulation of taste masked DMH orally disintegrating tablets (ODT)

To get suitable formula for preparation of the DMH orally disintegrating tablets (ODT).40 mg drug resin complex of DMH and Carbopol 974P was utilized along with suitable excipients for each formulation (F1 through F7). The composition of each formulation is presented below in Table 2. To guarantee a homogenous composition, every ingredient was well combined. A tablet press machine was used to compress the lubricated blend of drug resin complex along with other excipients into tablets, adjusting the compression parameters to obtain the required level of hardness and consistent weight. To make sure that compressed tablets met the necessary standards, tests were conducted on the finished product to assess its quality.[12,13,14]

Table 2:Formulation of taste masked DMH orally disintegrating tablets (ODT)

S. No.	Table Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7
1	Drug Resin Complex (DMH + 974P) equivalent to 20 mg of DMH	40.0	40.0	40.0	40.0	40.0	40.0	40.0
2	Microcrystalline cellulose (Avicel PH 102)	242.0	–	120.0	160.0	180.0	83.0	63.0
3	Lactose Monohydrate (Pharmatose 200M)	–	242.0	120.0	83.0	63.0	160.0	181.0
4	Crospovidone (Polyplasdone XL-10)	9.2	9.2	9.2	9.2	9.2	9.2	9.2
5	Magnesium stearate	2.9	2.9	2.9	2.9	2.9	2.9	2.9
6	Aspartame	3.9	3.9	3.9	3.9	3.9	3.9	3.9
	Tablet Weight (mg)	**300**	**300**	**300**	**300**	**300**	**300**	**300**

2.5 Evaluation of taste-masked orally disintegrating tablets (ODT)

2.5.1 Physicochemical Assessment of DMH Orally Disintegrating Tablets (ODT)

The physicochemical parameters of DMH ODT of prepared batches were assessed, and the findings are presented in Table 3.

Table 3: Physico-chemical evaluation of DMH orally disintegrating tablets (ODT)

Tablet Parameters	F1	F2	F3	F4	F5	F6	F7
Weight Variation (%)	300 ± 1.4	300 ± 1.5	300 ± 1.3	300 ± 1.6	300 ± 1.7	300 ± 1.5	300 ± 1.4
Thickness (mm)	4.0 ± 0.18	4.1 ± 0.16	4.0 ± 0.13	4.0 ± 0.17	4.2 ± 0.15	4.1 ± 0.14	4.1 ± 0.12
Hardness (kg/cm²)	3.9 ± 1.1	3.8 ± 1.0	3.6 ± 0.8	3.7 ± 1.2	4.0 ± 1.1	3.9 ± 0.9	3.8 ± 0.8
Friability (%)	0.79	0.72	0.88	0.81	0.74	0.82	0.80
Disintegration Time (Sec)	26 ± 3	29 ± 3	23 ± 3	21 ± 2	31 ± 3	34 ± 5	19 ± 3
Drug Content (%)	100.10 ± 0.05	98.6 ± 0.38	99.3 ± 0.30	99.0 ± 0.36	99.1 ± 0.32	97.80 ± 0.03	99.0 ± 0.29
Time (min)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**
	% Drug Release of Label claim						
5	30.0 ± 1.30	27.5 ± 1.20	33.5 ± 1.15	36.0 ± 1.40	25.0 ± 1.18	23.0 ± 1.10	40.0 ± 1.35
10	57.0 ± 2.30	54.0 ± 2.15	62.5 ± 2.20	65.0 ± 2.40	52.0 ± 2.25	49.0 ± 2.10	70.0 ± 2.30
15	75.5 ± 2.85	72.0 ± 2.80	80.0 ± 2.90	83.0 ± 3.25	72.5 ± 2.85	69.5 ± 2.55	90.0 ± 3.05
20	89.5 ± 3.15	86.5 ± 3.30	91.0 ± 3.35	94.0 ± 3.55	84.5 ± 3.20	81.5 ± 3.05	96.0 ± 3.45

25	98.0 ± 3.45	95.0 ± 3.20	99.0 ± 3.60	100.0 ± 3.70	93.5 ± 3.30	91.0 ± 3.35	100.0 ± 3.55
30	99.5 ± 3.25	98.0 ± 3.17	99.0 ± 3.15	100.0 ± 3.40	97.0 ± 3.05	95.5 ± 2.95	100.0 ± 3.30

2.5.2 Drug content uniformity of DMH orally disintegrating tablets (ODT)

The tablets from the prepared batches were subjected to a content uniformity test. Initially, the tablet was weighed and subsequently ground into a powder. The powdered tablet was subsequently placed into a 100 ml volumetric flask, and 0.1N HCl was added until the designated spot was attained. The solution that resulted was filtered, and the initial milliliters of the filtrate were eliminated. Using this method, 10 ml of the filtrate was transferred into a 50 ml volumetric flask, and 0.1 N HCl was added to reach the calibration point. The solution underwent spectrophotometric analysis at a wavelength of 278 nm. The drug concentration (µg/ml) remained ascertained utilizing the standard calibration curve pertinent to the specific medication.[15,16]

2.5.3 Dissolution study of DMH orally disintegrating tablets (ODT) in 0.1N HCl

The assessment of orally disintegrating tablets from the prepared batches was conducted for dissolution study. Dissolution study of tablets were conducted using a USP-type II dissolution apparatus. Each flask in the closured device contained 900 cc of buffer (pH 1.2), kept maintained at a temperature of 37 ± 0.5°C and rotated at a speed of 50 rpm. Tablets stood placed hooked on each flask. At specified intervals, 5 ml of the substance was obtained and purified using a 0.45 µm filter membrane sieve. Thereafter, the sample was enhanced by means of a dissolving agent to get a consistent volume. The filtrate was examined at 278 nm using a UV-visible spectrophotometer. The dissolution data is presented in the table3.[17,18]

2.6 In Vivo Evaluation of Taste for Pharmaceutical Resin Complex and DMH Orally Disintegrating Tablets (ODTs)

A trained taste panel of six healthy volunteers aged 20 to 30 years undertook an evaluation of the flavor character of the pharmaceutical resin complex and its tablets.

The medication, a resin complex equivalent to 20 mg of DMH, DMH ODT, and DMH marketed tablets (DEX-20), was held in the mouth for 60 seconds by each volunteer, and the bitterness level was evaluated against the pure drug using a numerical scale. After a duration of 60 seconds, the broken tablet was taken out, and the oral cavity was meticulously rinsed with distilled water.A numerical scale was employed with the subsequent values: 0 = tasteless, 0.5 = aftertaste, 1.0 = slight, 1.5 = slight to moderate, 2.0 = moderate, 2.5 = moderate to strong, 3 = powerful, and 3+ = very strong.[19, 20]

Table 4. Bitterness Evaluation by Taste Panel

Samples	Volunteer 1	Volunteer 2	Volunteer 3	Volunteer 4	Volunteer 5	Volunteer 6
DMH (Pure Drug)	5	6	4	5	3	6
DMH Resinate	0	1	1	0	0	0
DMH ODT	0	0	0	0	0	1
Marketed Product (DEX-20)	3	2	2	3	4	3

Bitterness level: 0 = tasteless, 0.5 = aftertaste, 1.0 = slight, 1.5 = slight to moderate, 2.0 = moderate, 2.5 = moderate to strong, 3 = strong and 3+ =very strong.

2.7 *In vivo studies*

The animal experiments received approval from the Institutional Animal Ethics Committee (IAEC) at Pinnacle Biomedical Research Institute, Bhopal, which is recognized by the Government of India to oversee and regulate animal research (Protocol approval reference number- PBRI/IAEC/03-06-24/004). The research adhered to the protocols set forth by the Committee for the Purpose of Control and Supervision of Experiments on Animals.

The animals were provided with unlimited access to water but were withheld from food for a duration of 6 hours prior to the experiment. The study involved Wistar pests of both genders, each weighing between 300 and 350 grams. The improved formulation, suspended in 1 ml of 0.5% Carboxymethyl Cellulose (CMC) for oral delivery, was delivered to the rats via an oral cannula.

Bioequivalence Study in Wistar Rats

To assess the influence of complexation on the bioavailability of DMH, a bioequivalence study was performed, comparing orally disintegrating tablets (ODTs) of DMH containing the drug resin complex (DRC) with a commercially available preparation (DMH 20) utilizing a parallel study design. The research included two cohorts of Wistar rats, designated as follows:

Group 1 (Test Group): Rats in this group were given orally disintegrating tablets (ODTs) that contained the drug-resin complex in an aqueous suspension at a dose of 50 mg/kg.[21]

Group 2 (Control Group): Rats in this group were given the marketed form of DMH (DEX-20) at a dose of 50 mg/kg, which is the same as the other groups.

Each group consisted of six Wistar rats to guarantee sufficient statistical power.

Blood samples (0.5 ml) were composed from the retro-orbital plexus of each rat at specified time intervals (30 minutes, 1, 2, 4, 6, 8, 12, 16, 20, and 24 hours) following drug treatment. Blood samples were collected immediately. The sample was centrifuged at 5000 rpm for a duration of 15 minutes, after which the plasma was preserved at -20ºC until it was analyzed.

Pharmacokinetic parameters, including the maximum plasma concentration of the medication (C_{max}), the duration required to attain this peak concentration (T_{max}), and the area beneath the plasma concentration-time curve. (AUC), were assessed to ascertain bioavailability of the test formulation in comparison to the commercial product.

The mean plasma drug concentrations at each time interval were used to construct pharmacokinetic profiles for both formulations, allowing a comprehensive assessment of bioequivalence. The pharmacokinetic parameters observed in the study are summarized as follows:[22, 23]

Table 5. Pharmacokinetic Parameters of Test and Marketed Formulations.

Parameter	DMH Resin Complex ODT (Test)	DMH Marketed Preparation (Reference)	Statistical Significance
C_{max} (ng/mL)	1057.50 ± 52.45	1050.50 ± 52.73	0.7029 (Not significant)
T_{max} (h)	1.0 ± 0.0	2.0 ± 0.0	0.0041 (significant)
AUC_{0-t} (ng·h/mL)	12549.19 ± 652.50	12443.75 ± 624.67	0.1103 (significant)
$AUC_{0-\infty}$ (ng·h/mL)	12981.59 ± 673.74	12724.60 ± 651.67	0.0048 (significant)

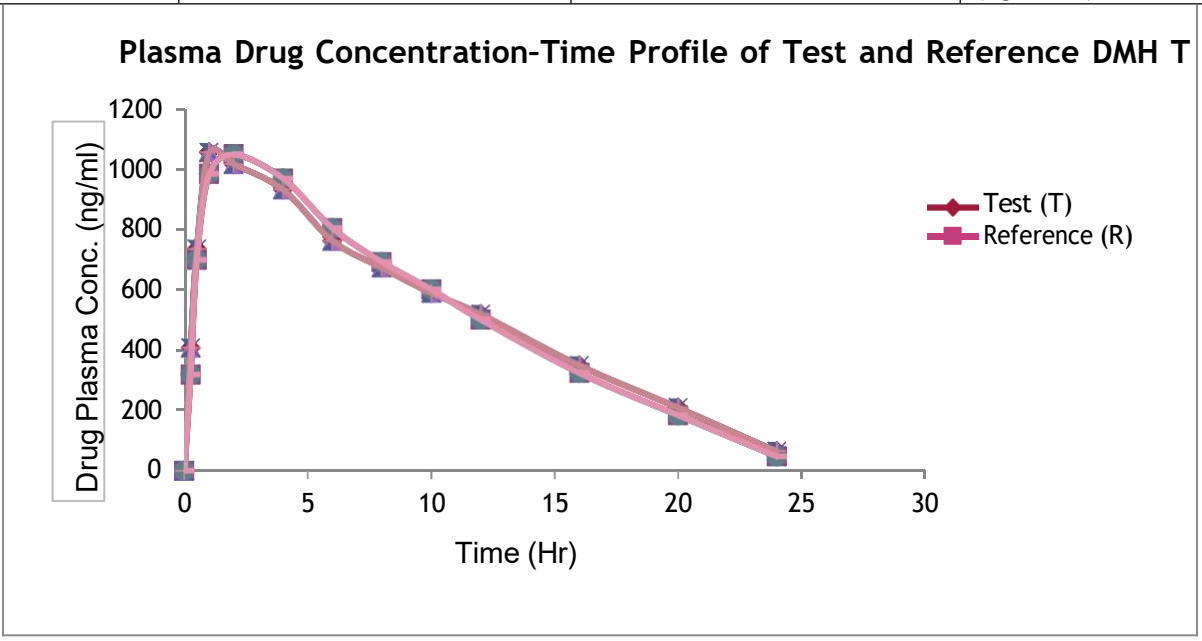

Fig 5-Comparative Plasma Drug Concentration-Time Profile of DMH Resin Complex ODT and DMH Marketed Preparation (DEX-20)

Statistical analysis

Data were expressed as mean ± standard error (n = 6). Statistical techniques were assessed through one-way analyses of variance, followed by Tukey's multiple comparisons, conducted with GraphPad Prism (version 6.0.1, Graph Pad Software Inc., La Jolla, CA) to evaluate variances across all biochemical parameters.A difference was deemed significant if $p < 0.05$. GraphPad Prism (version 6.0.1, GraphPad Software Inc., La Jolla, CA)

RESULTS AND DISCUSSION

3.1 Impact of DMH Resin Proportion on Drug Incorporation

Assemblies The products were produced with varying ratios of drug to resin (w/w), ranging from 1:1 to 1:3 in an aqueous environment. No substantial improvement in drug loading was seen. When comparing the ratios from 1:1 to 1:3. Hence, 1:1 ratio was found to be the most suitable for drug-resin complex (DRC) formation.

3.2 Evaluation using Fourier-Transform Infrared Spectrophotometry:

Carbonyl stretching band of DMH is around 1702 cm^{-1}. This band disappeared in the resinate complex and new bands appeared

around 1685 cm^{-1}. These changes show how ionic interactions and hydrogen bonds function with the resin matrix. The FT-IR ranges of both drug-resin developments and the bodilycombination of the drug had identical peaks, signifying that the drug's structure remained unchanged during the complexation of DMH with Carbopol 974. This finding validates the suitability of the chosen resins and excipients. Moreover, novel maxima were detected in the drug-resin complexes. But the drug peak remained constant, so confirming that the complexes were formed without compromising the drug's characteristics.

3.3 Differential Scanning Colorimetric Evaluation: The thermogram of he DMH active pharmaceutical ingredient (API) had a clear endothermic peak at 120°C, which showed that it was melting. The DMH Carbopol 974P complex, on the other hand, had a wider peak at 120°C. The DSC thermogram of the resin complexes had peaks similar to those of the pure drug; however, it lacked a notable endothermic peak. This discovery indicates that the medication is consistently discrete and exists in an formless form within the drug-resin amalgamation.

3.4 X-Ray Diffractometry Evaluation: X-ray diffraction (XRD) analysis confirms that the complexation of DMH with Carbopol 974P effectively conceals its bitter taste by diminishing its crystallinity and modifying its molecular structure, thereby obstructing direct interaction with taste receptors. The DMH-Carbopol 974P complex showed that the sharp and intense peaks of crystalline DMH API, like those at 16.153° and 21.247° 2θ, were greatly reduced. This means that some of the DMH API was turned into an amorphous state. This structural change enhances the solubility of DMH, which can lead to improved dissolution and bioavailability. In contrast, the physical mixture retained most of the crystalline peaks, suggesting that simple blending does not achieve the same level of interaction. These findings support the use of Carbopol 974P as an effective carrier for the enhancement of solubility as well as the masking of taste, ultimately improving the therapeutic potential of DMH.

3.5 Evaluation of Taste Masking in Vitro for Drug Resinate

The traditional approach to in vitro dissolving research is constrained in its capacity to accurately emulate the actions of an orally disintegrating tablet (ODT) within the buccal cavity, mostly because of the use of an excessively high volume of dissolution media. To resolve this issue, our team created a more physiologically correct dissolution model, in which drug release was assessed using 5 mL of phosphate buffer at pH 6.8, accurately replicating the pH and volume of saliva. This method was utilized to evaluate the taste-masking efficacy of the drug-resonatecombination. The results indicated that less than 0.50% of the medicine was released after 120 seconds (see Table 1). Furthermore, given that the disintegration time of the ODT was under 20 seconds, the actual drug release upon in vivo administration would be even lower, rendering it insufficient to elicit a bitter taste. The in vivo taste-masking study results further validated these findings.

3.6. Dissolution Studies Evaluation: The dissolving profiles of seven tablet formulations (F1 to F7) were analysed examined, evaluated, and revealing significant differences in drug release over time. Formulation F7 demonstrated the highest release across all time points, reaching 96.0 ± 3.45 % at 20 minutes, indicating superior dissolution properties. In contrast, F6 consistently had the lowest release, with 81.5 ± 3.05 % at 20 minutes, suggesting slower dissolution. These results suggest that F7 is the most promising formulation for rapid and complete drug release.

3.7. In Vivo Evaluation of Taste Masking for DMH Resinate ODT: An assessment of taste-masking was performed utilizing the time-intensity method with a group of healthy human volunteers.to assess the palatability of DMH formulations. Pure DMH API and marketed tablets (DEX-20) were perceived as bitter, whereas the drug-resin complex of DMH and its orally disintegrating tablets (ODTs) were reported to be tasteless. These findings indicate that complexation of DMH API with Carbopol 974P effectively masks the unpleasant flavor of the medication, showcasing adequate taste-masking characteristics.

3.8. Animal Study Evaluation: The Test formulation of DMH demonstrates superior pharmacokinetic performance compared to the DMH marketed formulation in this animal study. The higher AUC_{0}–t (12549.19 ± 652.50 ng·h/ml vs. 12443.75 ± 624.67 ng·h/ml) and C_{max} (1057.50 ± 52.45 ng/ml vs. 1050.50 ± 52.73 ng/ml) indicate that the Test formulation provides greater systemic drug exposure and achieves higher peak plasma concentrations, suggesting better bioavailability. Additionally, the shorter T_{max} (1 hours vs. 2 hours) for the Test formulation reflects faster absorption, which may lead to a quicker onset of action. Overall, the Test formulation appears to be more efficient in terms of bioavailability and absorption characteristics than the DMH marketed formulation.

CONCLUSION

The study's findings demonstrate that drug-resin complexes not only successfully conceal the unpleasant flavor of DMH but also improve bioavailability as evidenced by higher plasma concentrations up to 24 hours compared to the marketed preparation. The procedure for complexation using Ion-exchange resin constitutes straightforward economical method, resulting in a tablet formulation that improves patient compliance and simplifies medication administration.

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