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BANANA POWDER AS A NATURAL SUPERDISINTEGRANT IN ORALLY DISINTEGRATING TABLETS OF AMBROXOL HYDROCHLORIDE: FORMULATION AND IN-VITRO EVALUATION

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ABSTRACT

Productive cough and respiratory disorders are commonly managed with ambroxol hydrochloride, but conventional tablets can present a swallowing challenge in paediatric and geriatric patients with dysphagia. Evidence on truly natural superdisintegrants for ambroxol orally disintegrating tablets (ODTs) remains limited. The present study evaluated natural banana powder against the synthetic superdisintegrants croscarmellose sodium and sodium starch glycolate within an ambroxol HCl ODT platform. Nine 200 mg tablets (F1-F9), each loaded with 30 mg of the drug, were produced by two routes (F1-F2 by direct compression; F3-F9 by wet granulation) with graded levels of the three disintegrants. Each batch was characterised by the standard pharmacopoeial physicochemical tests, an in-vitro disintegration assay, and a USP-II dissolution run; full evaluation criteria are shown in Fig. 6. Hardness ranged from 1.57 to 3.88 kg/cm² and friability fell below 1% from F4 onwards. Disintegration was below one minute for F5, F8 and F9. Drug content lay between 97.34% and 99.75%. F8, containing 12 mg banana powder with 6 mg croscarmellose sodium, was the optimum batch, releasing 99.76% of the drug within 18 min. Tablets were held under ICH-Q1A(R2) accelerated conditions for three months and the F8 attributes were preserved throughout. The data indicate that banana powder, particularly in combination with croscarmellose sodium, is a viable natural superdisintegrant for ambroxol HCl orodispersible tablets, with the F8 ratio identified as the most effective composition.

Keywords: ODT, oral, cavity, ambroxol, natural.

INTRODUCTION

Solid oral dosage forms remain the most common route for self-administered medication. Pediatric patients with developing swallowing reflexes and geriatric patients with dysphagia, xerostomia, or limited motor control often struggle with conventional tablets and capsules. Orally disintegrating tablets (ODTs) were developed to address this gap, since they fragment in the buccal cavity in seconds without the need for water.[1,2]

ORO-DISPERSIBLE TABLETS (ODTs):

ODTs incorporate one or more superdisintegrants that swell rapidly on contact with saliva, generate a porous matrix, and break the compressed tablet apart into a soft, swallow-ready dispersion. Effective taste masking is essential because the active ingredient is released directly in the oral cavity. The target disintegration window is typically below three minutes and often below one minute.[3,4]

Mechanism of drug release of ODTs. Rapid fragmentation in the buccal cavity is driven by superdisintegrants, typically crospovidone, croscarmellose sodium, or sodium starch glycolate, that swell on contact with saliva and disrupt the tablet matrix; the released drug then dissolves in the saliva and is partly absorbed across the oral mucosa, with the remainder reaching the gastrointestinal tract.

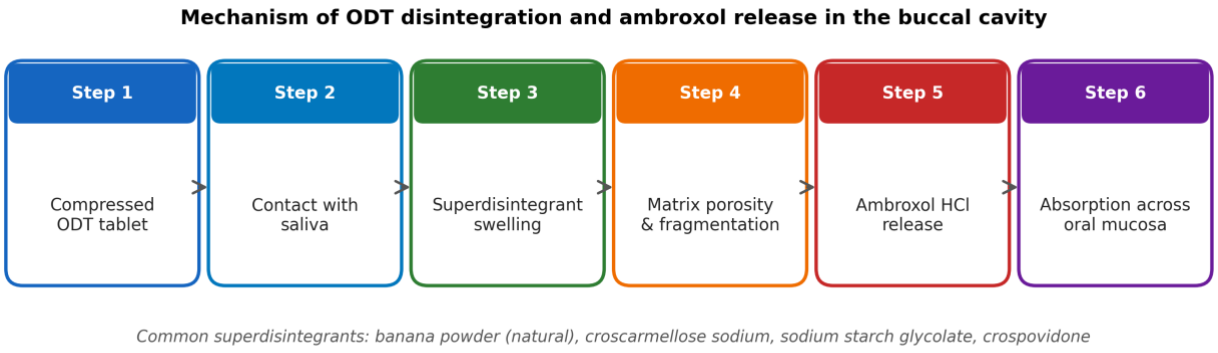

Fig. 1. Schematic of ODT disintegration and ambroxol release in the buccal cavity.

Challenges in Formulation of ODTs

- Taste masking. Bitter or unpleasant-tasting drugs require effective taste masking, since the tablet disintegrates directly in the mouth and the drug must not be perceived during the residence time.

➢ Disintegration time and mechanical strength:

The extremely rapid breakdown of orally disintegrating tablets is typically engineered so that disintegration occurs in less than one minute, often within only a few seconds.

The present work develops and evaluates ambroxol HCl ODTs using banana powder as a natural superdisintegrant, alongside croscarmellose sodium and sodium starch glycolate as comparators.[5,6,7]

MATERIALS AND METHODS

Materials

Ambroxol hydrochloride was the active ingredient. Three superdisintegrants were tested: banana powder (the natural candidate) and the synthetic comparators croscarmellose sodium and sodium starch glycolate. Lactose monohydrate and MCC PH-102 were used as fillers, PVPK-30 as binder, magnesium stearate and talc as lubricants, aspartame as sweetener, banana flavour as flavourant, and colloidal silicon dioxide as glidant. All materials were used as supplied[8-10].

Methods

Preformulation

Preformulation testing was performed on ambroxol HCl to confirm identity and gather the physicochemical data needed to guide formulation design.

Drug identity confirmation

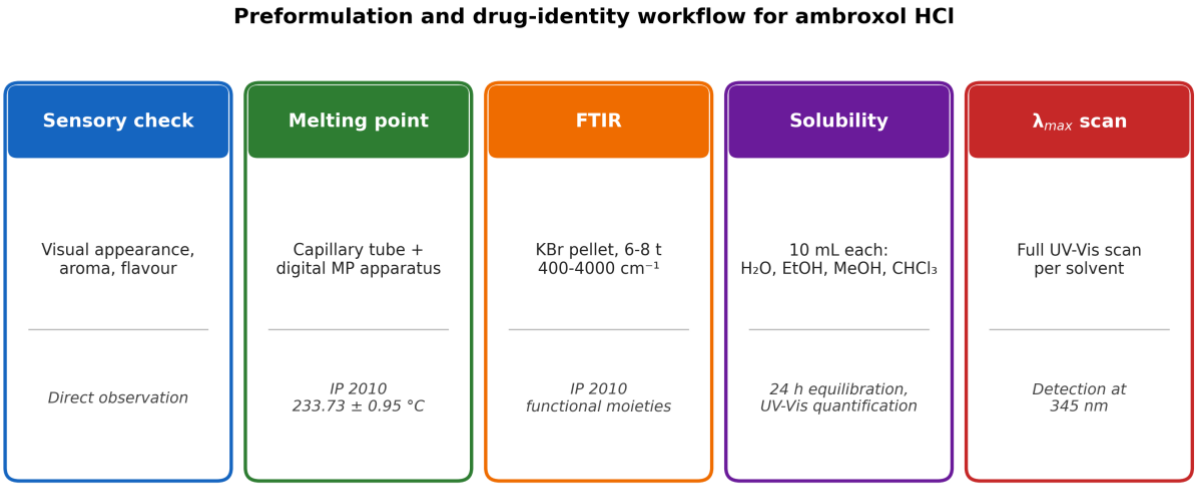

Fig. 2: Preformulation and drug-identity workflow for ambroxol HCl, listing the key parameters used at each step.

Orodispersible tablet production

Nine 200 mg ambroxol HCl ODTs (F1-F9, 30 mg label strength) were prepared with graded levels of banana powder, croscarmellose sodium, and sodium starch glycolate. F1 and F2 were direct-compressed: all components were sieved (#60), blended geometrically, and compressed at 200 mg/fill on a 10-station rotary press. F3-F9 were wet-granulated: actives (#100) and excipients (#60) were blended, granulated with binder, oven-dried at 40 °C, milled (#20), lubricated, and compressed using 7.5 mm tooling on the same press.[11,12]

Composition matrix of the nine ODT formulations (mg per 200 mg tablet)

	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9
Ambroxol HCl	30	30	30	30	30	30	30	30	30
Banana Powder	2	3	2	4	8	8	10	12	14
Di Calcium Phosphate (DCP)	70	79	80	—	—	—	—	—	—
Croscarmellose Sodium	—	2	4	2	4	5	6	6	4
Sodium Starch Glycolate	—	—	1	2	—	1	—	—	—
Lactose Monohydrate	—	—	—	80	78	71	76	70	60
MCC PH-102	—	—	—	—	—	20	22	15	20
PVPK-30	—	0.5	1	1	2	1	2	2	2
IPA	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Banana Flavor	5	5	5	5.5	5.5	6	5.5	6	6
Colloidal Silicon Dioxide	1	1.5	1.5	1.5	2	2	2	2	2
Magnesium Stearate	1	1.5	1.5	2	2	2	2.5	2	2
Mannitol (Plain)	88.5	74	66.5	64.5	60	43.5	34.5	45	50
Citric Acid anhydrous	—	—	4	3.5	4	5	4.5	4	4
Aspartame	2	2.5	2.5	3	3.5	4	3	4	4
Talcum	0.5	1	1	1	1	1.5	2	2	2
TOTAL (mg)	200	200	200	200	200	200	200	200	200

Low mg High mg q.s. (sufficient) Not used

Fig. 3: Composition matrix of the nine ODT formulations (mg per 200 mg tablet).

Evaluation parameters

Fig. 4 summarises the five evaluations performed on each compressed batch (F1-F9); the friability formula is included within the figure for reference.

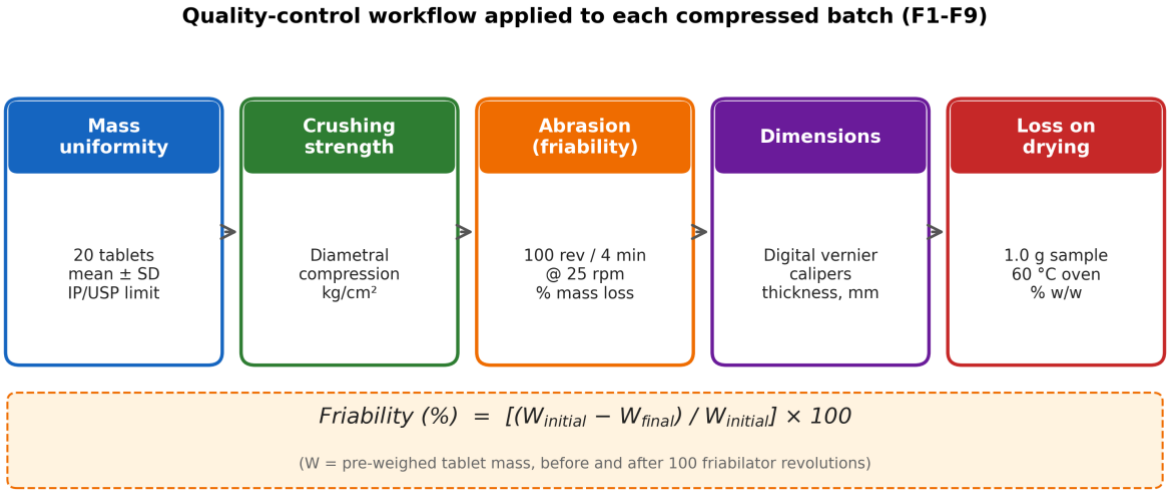

Fig. 4: Quality-control workflow applied to each compressed batch.

Results

Drug characterisation

Melting point

The capillary fusion method gave a melting point of 233.73 ± 0.95 °C (n = 3; individual readings 233.4, 233.0 and 234.8 °C), within the IP 2010 specification.

Wavelength of maximum absorbance (λmax)

The calibration curve was linear from 2 to 10 µg/mL (y = 0.0624x − 0.0651, R^2 = 0.9785; absorbance at 345 nm; see Fig. 5).

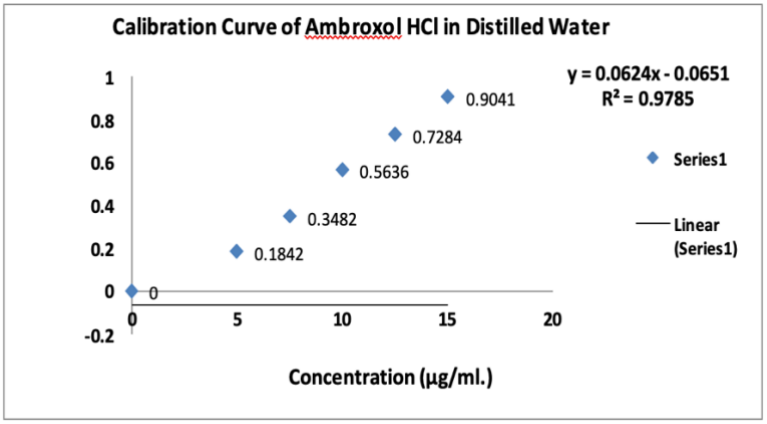

Fig 5: UV spectra of Ambroxol in distilled water

FTIR Spectra of Ambroxol HCl:-

The recorded FTIR spectrum of ambroxol HCl, with the principal absorption bands assigned to its functional groups, is shown below.

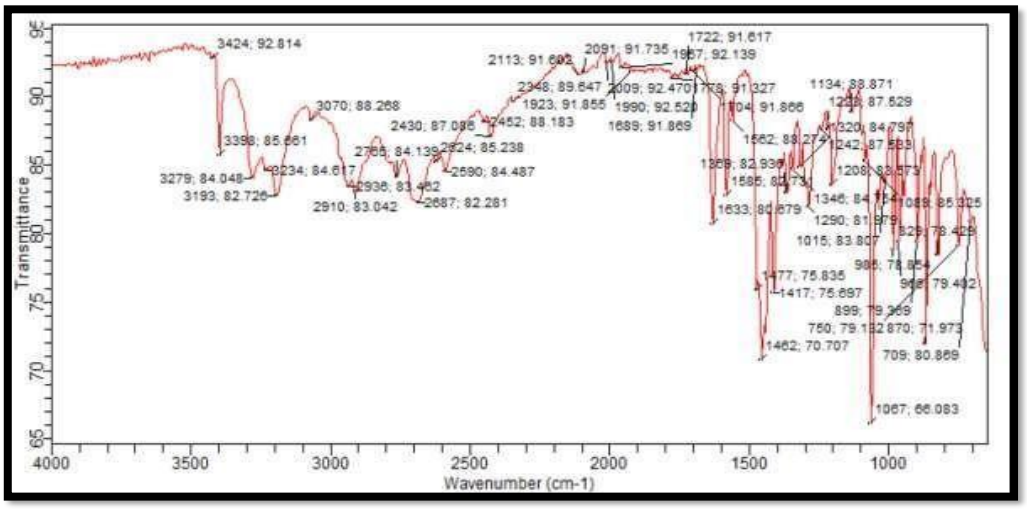

Fig 6: Ambroxol HCl FTIR Spectrum (Sample)

Post-compression characterisation results for all nine formulations are summarised in Fig. 7; the F8 batch consistently met the target ranges across mass uniformity, hardness, friability, disintegration, wetting, and drug content. The friability and disintegration datasets are visualised in Fig. 8 and Fig. 9 below, drug content in Fig. 10, the full release curves in Fig. 11, and the release-kinetics R^2 values in Fig. 12.

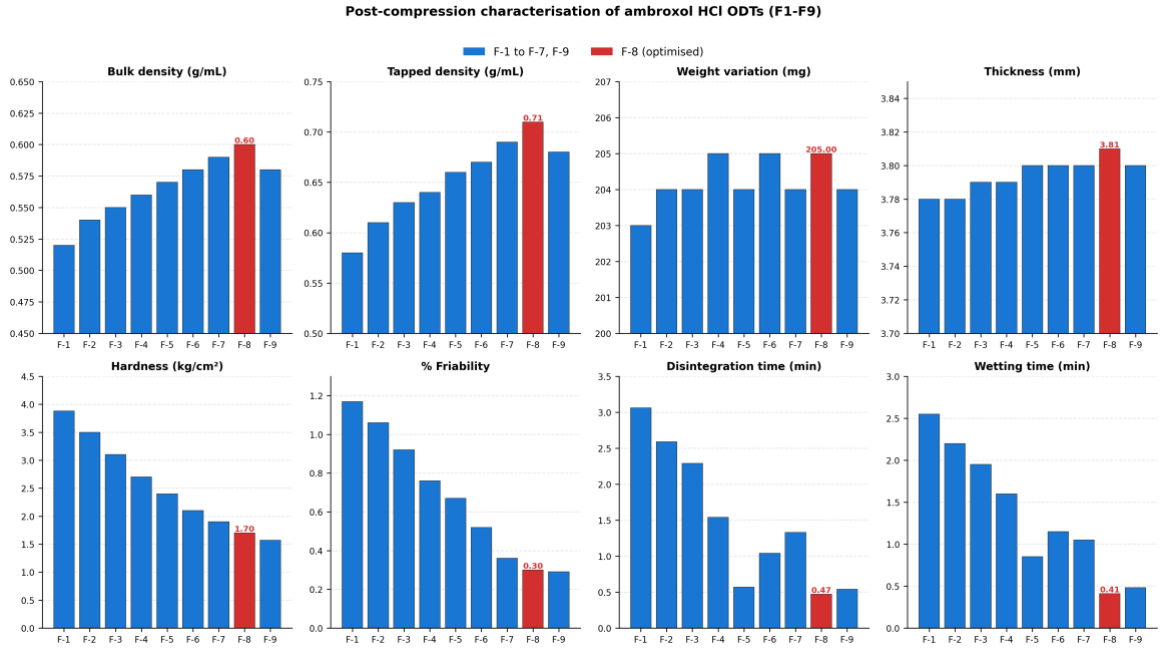

Fig. 7: Post-compression characterisation of ambroxol HCl ODTs (F1-F9); F8

% Friability:

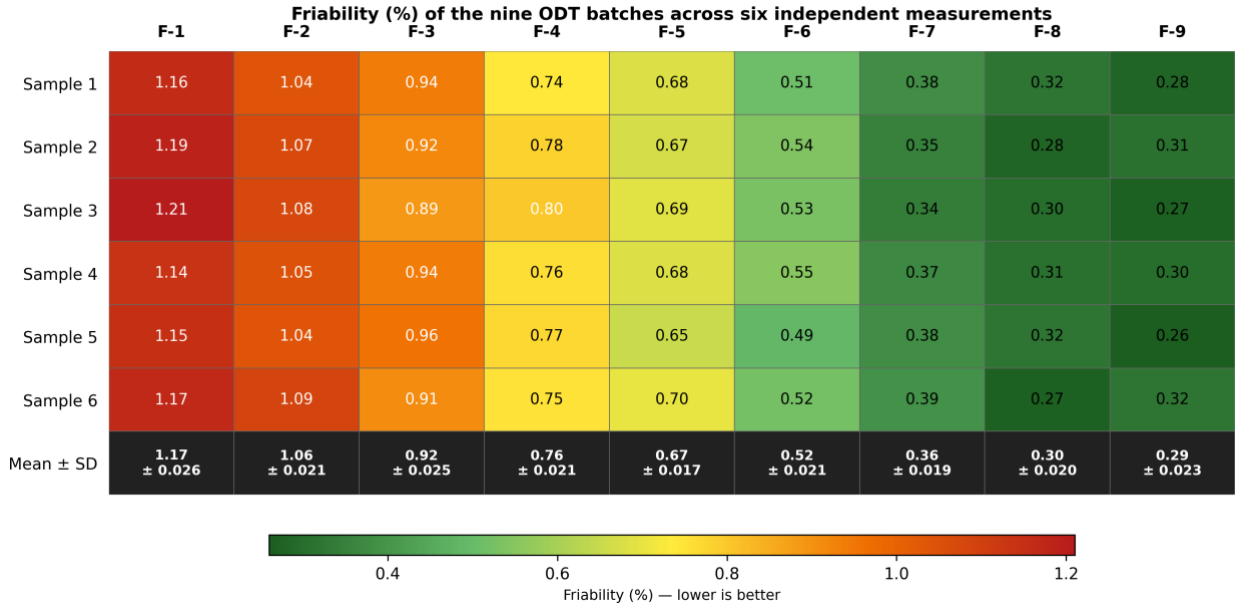

Fig. 8: Friability (%) of the nine ODT batches across six independent measurements.

In-vitro Disintegration

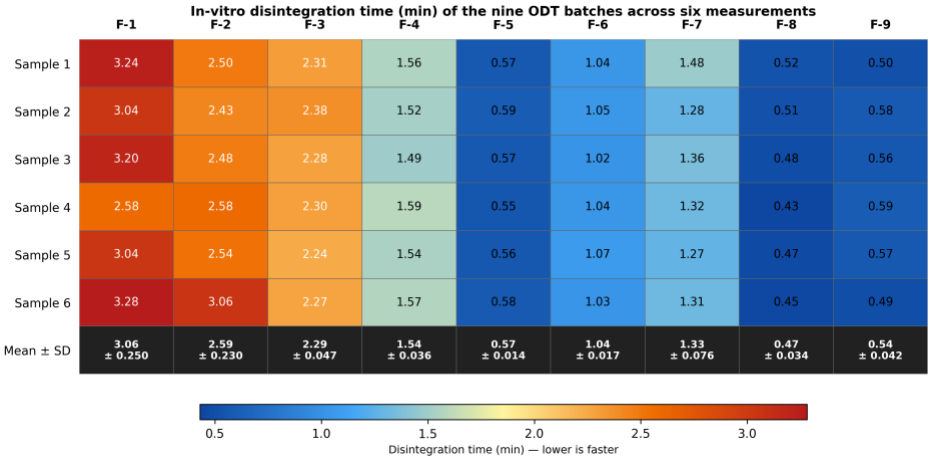

Fig. 9: In-vitro disintegration time (min) of the nine ODT batches across six measurements.

% Drug content

Drug content of each batch was assayed by UV-Vis absorbance at 345 nm; results across F1-F9 are shown in Fig. 10.

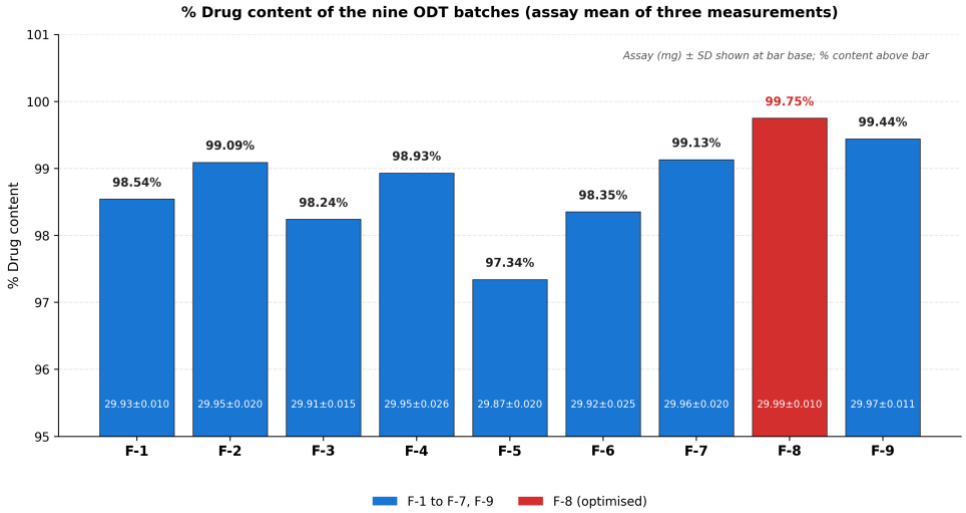

Fig. 10: % Drug content of the nine ODT batches (assay mean of three measurements).

In-vitro drug release. Dissolution profiles were generated in a USP-II apparatus. Across the nine batches, F8 delivered the highest output, releasing 99.76% of ambroxol HCl by 18 min. The complete time-course is shown in Fig. 11, and the corresponding release-kinetics fits are shown in Fig. 12.

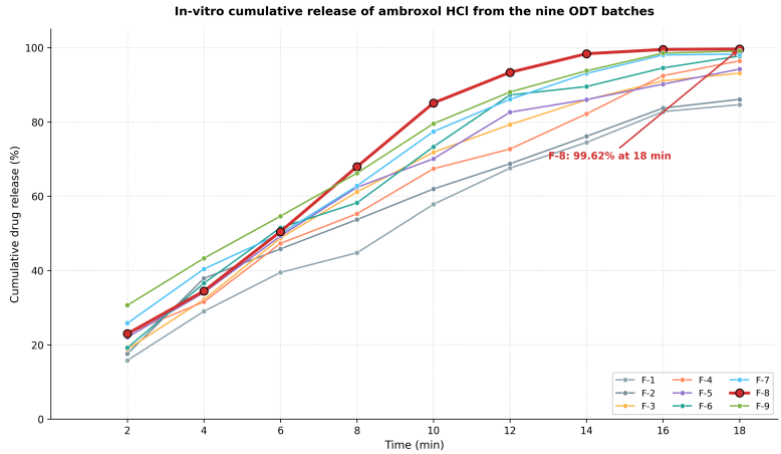

Fig. 11: In-vitro cumulative release of ambroxol HCl from the nine ODT batches; F8 in red.

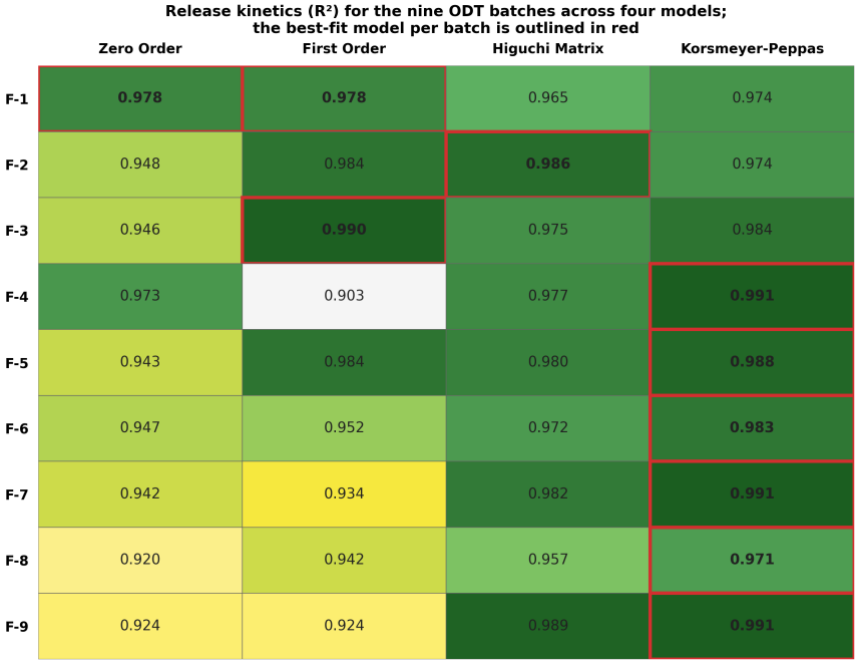

Fig. 12: Release kinetics R^2 values for the nine ODT batches across four kinetic models; the best-fit model per batch is outlined in red.

DISCUSSION

Pre-compression behaviour. The bulk and tapped densities of the nine powder blends fell within the typical pharmaceutical range and reflected reasonable packing characteristics. Flow indices derived from these values were acceptable for direct compression of F1-F2 and for the

dried granules of F3-F9, with F8 showing the most uniform fill.

Post-compression behaviour. Hardness ranged from 1.57 to 3.88 kg/cm² across the series and decreased as the banana-powder loading increased, consistent with a softer matrix once the disintegrant level rose. Friability tracked the same trend and dropped below 1% from F4 onwards. Tablet thickness lay between 3.78 and 3.81 mm and individual weights were within 203-205 mg, so every batch satisfied pharmacopoeial mass-uniformity and dimensional limits. F8 met all four post-compression criteria simultaneously.

Disintegration and release. Disintegration time fell with rising banana-powder content; F5, F8 and F9 disintegrated in under one minute, and F8 cleared its dose within 0.47 min. Wetting time followed the same trend, and F8 released 99.76% of ambroxol HCl by 18 min. The data are consistent with banana powder acting as a swelling natural superdisintegrant whose effect is amplified when paired with croscarmellose sodium, as in F7-F9. Stability. Under ICH accelerated storage, every formulation retained its appearance, assay, and release behaviour over the three-month window, supporting the chemical stability of ambroxol HCl in this matrix.

CONCLUSION

Among the nine prepared formulations, F8 was the optimised ambroxol HCl ODT, releasing 99.76% of the active ingredient within 18 min. The faster disintegration and wetting observed at higher banana-powder loadings, combined with croscarmellose sodium, support banana powder as an effective natural superdisintegrant for ambroxol ODTs. F8 also retained its quality attributes through a 3-month accelerated stability programme at 40 °C and 75% RH, suggesting that banana powder is a viable natural alternative or co-disintegrant in this dosage form.

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