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Aminated Tamarind Gum as a Functionalized Natural Carrier for Ketoconazole Solid Dispersion and Fast-Dissolving Tablets

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Abstract: *Background: Ketoconazole (KTZ) is a poorly water-soluble antifungal drug for which dissolution enhancement may improve oral formulation performance. Natural polysaccharides are attractive carriers because of their availability and biocompatibility, while chemical functionalization can modify their physicochemical behavior. This study evaluated aminated tamarind gum (ATG) as a carrier for KTZ solid dispersion. Methods: Tamarind gum was chemically aminated and characterized by microscopy, solubility, pH, swelling, viscosity, ATR-FTIR, 1H NMR, DSC-TGA and PXRD. KTZ-loaded solid dispersions were prepared by kneading at 1:1, 1:2 and 1:3 drug:carrier ratios using TG and ATG. SDs were evaluated for drug content, solubility, dissolution, FTIR, DSC, PXRD, SEM and EDS. Antifungal activity against Candida albicans was assessed, and the optimized SD was incorporated into fast-dissolving tablets. Results: ATG exhibited cold-water solubility of 9.73±1.31 mg/mL, pH 7.18, approximately three-fold swelling and viscosity of 179.76±3.4 cP. KTZ SDs prepared with ATG provided 28.51–33.19-fold aqueous solubility enhancement, compared with 2.55–23.82-fold for TG-based SDs. The optimized SD4 (KTZ:ATG 1:1) was reported to show complete SD drug release within 120 min, while optimized fast-dissolving tablet F5 achieved 100% release within 60 min. The KTZ:ATG SD showed a 27±1.3 mm inhibition zone against C. albicans versus 21±1.1 mm for pure KTZ and 15±1.0 mm for ATG. Conclusion: Amination improved the functional performance of tamarind gum and enabled ATG to act as a promising carrier for KTZ solid dispersion and fast-dissolving tablets.*

Keywords: Ketoconazole; aminated tamarind gum; solid dispersion; natural polymer; fast-dissolving tablet; solubility enhancement; dissolution; Candida albicans

I. INTRODUCTION

Poor aqueous solubility is a major formulation challenge for many orally administered drugs. Solid dispersion technology addresses this limitation by distributing a poorly soluble drug within a hydrophilic carrier, potentially reducing effective particle size, improving wetting and increasing the drug concentration available for dissolution. The uploaded thesis investigates functionalized tamarind gum as a natural carrier for poorly soluble antifungal drugs.

Tamarind gum is a plant-derived xyloglucan with swelling, adhesive and gel-forming properties. Amination introduces amine functionality and can alter hydration, swelling, viscosity and interfacial behavior. The thesis describes ATG as a cationic derivative with improved hydrophilicity and swelling characteristics. These properties provided the rationale for evaluating ATG as a carrier for ketoconazole.

The aim of the present article was to prepare and characterize ATG, develop KTZ-loaded TG and ATG solid dispersions, compare their solubility and dissolution performance, assess antifungal activity, formulate the optimized SD into fast-dissolving tablets and evaluate the resulting dosage forms.

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II. MATERIALS AND METHODS

2.1 Preparation and characterization of ATG

The thesis describes preparation of the amine derivative of tamarind gum using ethylene diamine and sodium borohydride. The synthesized ATG was evaluated for organoleptic characteristics, microscopy, identification tests, cold-water solubility, pH, swelling index, viscosity and micrometric properties. ATR-FTIR, solid-state 1H NMR, DSC-TGA and PXRD were used to examine chemical and solid-state characteristics.

2.2 Preparation of KTZ solid dispersions

KTZ was dissolved in methanol and the required amount of carrier was added. The mixture was continuously kneaded in a mortar for 30 min. The solvent was removed, producing a hardened mass that was crushed, dried and passed through sieve No. 80. Six batches were prepared: SD1–SD3 using TG at KTZ:TG ratios of 1:1, 1:2 and 1:3, and SD4–SD6 using ATG at KTZ:ATG ratios of 1:1, 1:2 and 1:3. The products were stored in sealed containers at 30±1°C.

Batch	Composition	Ratio
SD1	KTZ:TG	1:1
SD2	KTZ:TG	1:2
SD3	KTZ:TG	1:3
SD4	KTZ:ATG	1:1
SD5	KTZ:ATG	1:2
SD6	KTZ:ATG	1:3

Table 1. Composition of KTZ solid dispersion batches.

2.3 Solid-dispersion evaluation

Drug content and percentage yield were determined by UV spectrophotometry. Saturation solubility was measured using the shake-flask method in distilled water, with 24 h equilibration at 37°C and 100 rpm and measurement at 238 nm. For dissolution of KTZ and its SDs, USP Apparatus II was used with 900 mL of pH 6.8 phosphate buffer at 37±0.5°C and 50 rpm; aliquots were removed at predetermined intervals and analyzed spectrophotometrically. FTIR, DSC and PXRD were used to assess drug–carrier interaction and solid-state transformation. SEM and EDS were used for morphology and elemental confirmation.

2.4 Antifungal activity

The agar cup method was used against Candida albicans. The inhibition zone of KTZ:ATG SD was compared with pure KTZ, ATG and negative control.

2.5 Fast-dissolving tablet formulation

The optimized KTZ SD was formulated as 50 mg KTZ-equivalent fast-dissolving tablets by direct compression. The thesis formulation contained the optimized SD, Neusilin, crosscarmellose cellulose, anhydrous lactose, microcrystalline cellulose, magnesium stearate and talc. Eight formulations (F1–F8) were prepared by varying excipient proportions, particularly the superdisintegrant and filler components.

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8
Optimized SD (KTZ eq. 50 mg)	150	150	150	150	150	150	150	150
Neusilin	34.5	39	44.5	49	49.5	59	59.5	64.5
Crosscarmellose cellulose	30	27.5	25	25	25	20	20	19.5
Anhydrous lactose	50	50	50	50	50	50	50	50
Microcrystalline cellulose	30	28	25	20.5	20	15.5	15	10.5
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Talc	4	4	4	4	4	4	4	4

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Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8
Total weight (mg)	300	300	300	300	300	300	300	300

Table 2. KTZ fast-dissolving tablet formulation design reported in the thesis.

2.6 Tablet evaluation and stability

Tablets were assessed for thickness, diameter, weight variation, hardness, friability, content uniformity, disintegration time and dissolution. In vitro dissolution used USP Apparatus II with 900 mL pH 6.8 phosphate buffer at 37±0.5°C and 50 rpm, with samples collected up to 60 min. The optimized F5 formulation was stored at 40°C/75% RH for three months and evaluated at monthly intervals.

III. RESULTS AND DISCUSSION

3.1 Characterization of ATG

ATG was described as a light pale-yellow, irregular, rough and brittle powder. Cold-water solubility was 9.73±1.31 mg/mL, and the 1% dispersion had a pH of 7.18. The swelling index was approximately three times the dry volume and viscosity was 179.76±3.4 cP. Micrometric properties included bulk density 0.79±0.09 g/mL, tapped density 0.85±0.07 g/mL, angle of repose 24.94±1.00°, Carr's index 7.05±1.2% and Hausner ratio 1.07±0.08.

ATG property	Reported value
Cold-water solubility	9.73±1.31 mg/mL
pH (1% dispersion)	7.18
Swelling index	≈3× dry volume
Viscosity (1%)	179.76±3.4 cP
Bulk density	0.79±0.09 g/mL
Tapped density	0.85±0.07 g/mL
Angle of repose	24.94±1.00°
Carr's index	7.05±1.2%
Hausner ratio	1.07±0.08

Table 3. Physicochemical and micrometric properties of ATG.

3.2 Spectroscopic and solid-state characterization

ATR-FTIR of ATG showed changes in the broad hydroxyl region and alterations in the carbonyl and C–O–C regions after amination, together with bands attributed to C–N stretching. Solid-state 1H NMR showed resonance features consistent with the modified polymer. DSC-TGA indicated substantial mass loss between approximately 25 and 350°C, with greater loss at higher temperatures. PXRD displayed a broad diffuse halo rather than sharp crystalline reflections, supporting predominantly amorphous ATG.

For the optimized KTZ SD, the thesis reports disappearance/attenuation of characteristic crystalline drug features in FTIR/PXRD and SEM evidence of KTZ particles dispersed within a continuous ATG matrix. The PXRD peaks of crystalline KTZ at approximately 10.00°, 15.75°, 20.00°, 25.50°, 28.30°, 30.64°, 35.40°, 39.57°, 40.00°, 45.90° and 50.11° were markedly attenuated in SD5, supporting a predominantly amorphous dispersion.

3.3 Solubility enhancement

The thesis reports that TG-based KTZ SDs provided 2.55–23.82-fold enhancement in water, whereas ATG-based SDs provided 28.51–33.19-fold enhancement. Thus, chemical amination produced a carrier that performed better than native TG over the tested ratios. The optimized ATG formulation was selected for further dosage-form development.

Carrier	Range of fold enhancement in water
Tamarind gum (TG)	2.55–23.82

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Carrier	Range of fold enhancement in water
Aminated tamarind gum (ATG)	28.51–33.19

Table 4. Reported range of KTZ solubility enhancement.

The source thesis reports SD4 (KTZ:ATG 1:1) as the optimized SD for subsequent tablet formulation, while the experimental series also included SD5 and SD6. The manuscript therefore preserves the thesis designation and does not reinterpret the optimization criterion.

3.4 Dissolution of KTZ solid dispersions

Pure KTZ showed approximately 32% dissolution in the source experiment, whereas the optimized SD was reported to achieve complete release within 120 min. The enhanced dissolution was attributed to improved wetting and dispersion, increased accessible surface area and reduction in crystalline drug content within the polymeric matrix.

3.5 Antifungal activity

Sample	Zone of inhibition against C. albicans (mm)
KTZ:ATG SD	27±1.3
Pure KTZ	21±1.1
ATG	15±1.0
Negative control	NA

The KTZ:ATG SD produced the largest inhibition zone among the tested samples. The thesis suggests that improved antifungal activity may be associated with enhanced dissolution and the contribution of ATG; however, the assay alone does not establish the mechanism.

3.6 Fast-dissolving tablets

Parameter	Range across F1–F8	F5
Thickness (mm)	1.69±0.15 to 3.01±0.057	—
Diameter (mm)	≈10.01–10.02	—
Hardness (kg/cm²)	4.20±0.25 to 5.25±0.15	—
Friability (%)	<1	—
Weight (mg)	300.25±0.07 to 302.02±1.65	—
Content uniformity (%)	94.86±1.72 to 100.25±0.89	—
Disintegration time (s)	58.47±1.0 to 90.32±1.62	—

The powder blends showed generally acceptable flow characteristics, with bulk density of 0.37–0.77 g/cm³, tapped density of 0.61–0.83 g/cm³, Carr's index of 16.57–24.57% and Hausner ratio of 1.06–1.20. F5 was identified as the most promising formulation.

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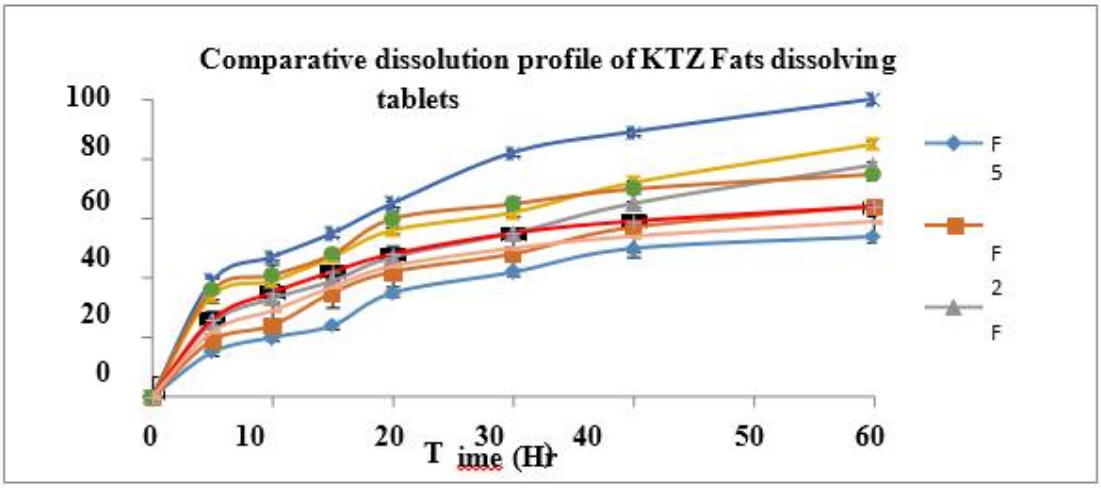

Figure 1. Dissolution profile of KTZ fast-dissolving tablet F5,

F5 released 39% at 5 min, 47% at 10 min, 55% at 15 min, 65% at 20 min, 82% at 30 min, 89% at 40 min and 100% at 60 min. Increasing CCS concentration beyond the optimum was associated with slower release in the source data, consistent with the possibility of increased matrix resistance, gel formation and reduced water penetration.

3.7 Stability

The optimized F5 formulation was stored at 40°C/75% RH for three months. The thesis reports that the physicochemical characteristics showed no major change during the study and that the formulation remained strong and consistent over the three-month period.

IV. CONCLUSION

Amination transformed tamarind gum into a functionalized natural carrier with favorable hydration, swelling and powder properties. KTZ solid dispersions prepared with ATG showed greater aqueous solubility enhancement than those prepared with native TG. Solid-state characterization supported successful dispersion of KTZ within the polymer matrix with reduced crystallinity. The KTZ:ATG SD showed enhanced antifungal activity in the C. albicans assay and was successfully incorporated into fast-dissolving tablets. Among the tablet batches, F5 showed the most rapid release, reaching 100% dissolution within 60 min. These findings indicate that ATG is a promising natural carrier for improving the dissolution performance of poorly water-soluble KTZ.

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