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Review Article

Dapoxetine Fast-Dissolving Tablets: A Review of Therapeutic Rationale, Solubility Enhancement, Superdisintegrant Design Strategies

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Abstract

Dapoxetine is a short-acting selective serotonin reuptake inhibitor (SSRI) developed for on-demand management of premature ejaculation (PE). Its rapid absorption and elimination make dosage-form performance particularly relevant to a therapy intended to be administered shortly before sexual activity. This narrative review critically examines the pharmaceutical rationale for fast-dissolving and orally disintegrating dapoxetine dosage forms, with emphasis on solid-dispersion technology, hydrophilic carriers, superdisintegrants, direct compression, dissolution enhancement, release kinetics, quality control, stability, and Quality-by-Design (QbD) approaches. Current evidence supports dapoxetine as an established pharmacological option for PE, while contemporary orally disintegrating tablet research emphasizes rapid disintegration, acceptable mechanical strength, taste/ mouthfeel, robust manufacturability, and appropriate dissolution testing. PVP K30-based amorphous or highly wetted solid dispersions remain an important strategy for improving dissolution of poorly soluble drugs, although solid-state characterization and physical stability are essential before attributing performance to amorphization. The authors' thesis-derived formulation work provides an illustrative case in which dapoxetine: PVP K30 solid dispersions at 1:1, 1:2 and 1:3 ratios were screened before incorporation into nine fast-dissolving tablet formulations containing sodium starch glycolate, croscarmellose sodium or Kyron T-104. The reported 1:3 dispersion increased saturation solubility from 0.46 to 1.74 mg/mL and the selected F9 formulation showed rapid wetting and disintegration with high in-vitro drug release. These observations support a sequential strategy in which dissolution limitation and tablet disintegration are addressed as separate but interconnected formulation problems. However, the available thesis data do not establish enhanced bioavailability or faster clinical onset. For a high-impact formulation-development paper, complete Design-Expert ANOVA, model diagnostics, confirmation experiments, solid-state characterization, dissolution benchmarking and, where justified, pharmacokinetic evaluation should be incorporated. This review identifies the scientific opportunities and methodological requirements for translating dapoxetine fast-dissolving tablets from laboratory proof-of-concept to a robust patient-centric dosage form.

Keywords: Dapoxetine; Premature Ejaculation; Fast-Dissolving Tablet; Orally Disintegrating Tablet; Solid Dispersion; PVP K30; Super disintegrant; Dissolution Enhancement; Direct Compression; Quality by Design.

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Introduction

Premature ejaculation is a common male sexual disorder associated with impaired control over ejaculation, short ejaculatory latency and clinically relevant personal or interpersonal distress. Pharmacological management remains an important component of care, and dapoxetine occupies a distinctive position because it was developed as a short-acting SSRI for on-demand administration. Contemporary evidence indicates that dapoxetine 30 and 60 mg can improve intravaginal ejaculatory latency time and patient-reported outcomes, while adverse effects are generally dose dependent. Clinical guidelines identify dapoxetine as a first-line pharmacological option for lifelong PE in countries where it is approved. The pharmacological profile creates an interesting pharmaceutical-development challenge. An on-demand medicine should provide reproducible drug availability after administration without unnecessarily increasing systemic exposure or adverse effects. Consequently, dosage-form design can focus on rapid wetting, rapid disintegration and rapid dissolution, while recognizing that in-vitro release is only one component of the overall pharmacokinetic process. An orally disintegrating or fast-dissolving tablet

can also improve convenience for patients who prefer administration without water. For drugs whose aqueous dissolution is limiting, a rapid-disintegration platform alone may not be sufficient. Solid dispersion technology can modify drug wetting, particle-scale distribution, crystallinity and apparent dissolution behavior before the drug reaches the tablet matrix. A rational formulation therefore may use a two-stage approach: first improve the drug's dissolution characteristics through a suitable carrier system, then engineer the tablet for rapid disintegration and dispersion. This concept is particularly relevant to the dapoxetine formulation described in the authors' research work.

Therapeutic and Biopharmaceutical Rationale for Dapoxetine: Dapoxetine is characterized by rapid absorption and elimination compared with conventional long-acting SSRIs. The European Association of Urology guideline describes a rapid time to maximum concentration of approximately 1.3 h and a short systemic persistence, supporting its on-demand use. Clinical trials and meta-analyses have consistently demonstrated improvements in IELT and related patient-reported outcomes with 30- and 60-mg doses. Importantly, a formulation review should distinguish clinical efficacy from pharmaceutical performance. A tablet that disintegrates faster does not automatically produce a clinically faster onset. The relationship between disintegration, dissolution, gastric emptying, absorption and systemic exposure must be demonstrated experimentally. Therefore, fast-dissolving dapoxetine should be presented as a formulation strategy intended to improve the drug-release step, not as proof of superior clinical efficacy.

Fast-Dissolving and Orally Disintegrating Tablets: Fast-dissolving tablets (FDTs), orally disintegrating tablets (ODTs), mouth-dissolving tablets and related terms describe immediate-release oral systems designed to break up rapidly in the oral cavity. Contemporary reviews emphasize their usefulness for patients with swallowing difficulties and for situations in which water is inconvenient.

Formulation performance depends on a balance among rapid liquid penetration, tablet porosity, mechanical strength, lubrication, particle properties, taste and mouthfeel. Direct compression is attractive because it can reduce processing steps and facilitate scale-up. However, the formulation must provide sufficient compactability while preserving rapid liquid ingress.

Excessive compression force, hydrophobic lubrication, poor particle packing or inappropriate excipient selection can increase disintegration time. Conversely, an extremely porous tablet may have inadequate mechanical integrity. This balance is one reason why superdisintegrant concentration and type are important formulation variables.

Role of Superdisintegrants: Sodium starch glycolate, croscarmellose sodium and crospovidone are among the widely used superdisintegrants.

Their actions involve combinations of swelling, wicking, strain recovery and rapid water uptake. The relative contribution of each mechanism depends on particle morphology, concentration, compression conditions, excipient interactions and the dissolution medium.

Table 1: Role of Superdisintegrants

Superdisintegrant	Principal formulation role	Potential advantage	Important consideration
Sodium starch glycolate	Rapid swelling and water uptake	Effective at relatively low levels	Overuse can produce viscous gel-like barriers in some systems
Croscarmellose sodium	Swelling plus wicking	Rapid water penetration and breakup	Performance depends on grade and compression
Crospovidone	Wicking/capillary action and strain recovery	Good flow and rapid liquid uptake	Particle structure and compression history influence performance
Kyron T-104	Superdisintegrant system used in the authors' formulation	Produced the best observed F9 performance in the reported screen	Exact mechanistic superiority should be confirmed statistically

Solid Dispersion as a Dissolution-Enhancement Strategy: Solid dispersions distribute a drug within a carrier matrix and can improve dissolution through increased wettability, reduced effective particle size, disruption of crystal packing and, in suitable systems, conversion to a higher-energy amorphous state. PVP-based systems are widely investigated because povidone can interact with drug molecules and promote wetting and dispersion.

Solvent evaporation is one established preparation route. The term 'amorphous solid dispersion' should

not be used solely because dissolution increased. Definitive claims about amorphization require solid-state evidence such as DSC, powder X-ray diffraction and, where appropriate, spectroscopic or microscopic characterization. Furthermore, an amorphous system may be thermodynamically unstable and can recrystallize during storage. Consequently, formulation papers should connect dissolution data with solid-state characterization and stability results.

Table 2: Critical Quality Attributes for Dapoxetine FDTs

Quality attribute	Why it matters	Recommended interpretation
Weight variation	Ensures manufacturing consistency	Pharmacopoeial compliance
Hardness	Controls mechanical integrity and may influence disintegration	Optimize rather than maximize
Friability	Indicates resistance to handling damage	Should remain within applicable limits
Wetting time	Reflects initial liquid penetration	Lower values generally favor rapid breakup
Disintegration time	Critical performance attribute for FDTs	Rapid and reproducible performance
Drug content/assay	Confirms dose accuracy	Report mean ± SD and validated method
Dissolution	Measures drug-release performance	Use discriminatory, validated method
Taste/mouthfeel	Determines patient acceptability	Essential for true patient-centric ODT development
Stability	Assesses physical and chemical robustness	Link to packaging and solid-state stability

Analytical and Solid-State Characterization: The authors study reports UV analysis at 291 nm with a 2–20 µg/mL calibration range and an excellent reported calibration R^2. FTIR and DSC were used for drug–excipient compatibility. The reported DSC peak temperature was approximately 178 °C for pure dapoxetine and 177.9°C for the drug–excipient physical mixture, with relatively small changes in thermal parameters.

These observations support compatibility within the investigated mixture but do not, by themselves, establish the physical state of the drug in the final solid dispersion. For a stronger review-to-research translation, future work should include PXRD to quantify changes in crystallinity, DSC for thermal transitions, FTIR or Raman spectroscopy for molecular interactions, and SEM/TEM or other suitable microscopy for morphology. If an amorphous solid dispersion is claimed, the analytical package should directly demonstrate the solid-state change and its persistence during storage.

Quality-by-Design and Statistical Optimization: QbD provides a stronger framework than selecting a formulation solely because it gives the highest observed dissolution or shortest disintegration time. A QbD-based development program begins with the Quality Target Product Profile (QTPP), identifies critical quality attributes (CQAs), establishes material and process risks, and uses Design of Experiments (DoE) to understand factor-response relationships. For the nine-batch formulation screen described in the authors' work, the next analytical step should be recovery of the original Design-Expert output. The final article should report the experimental design matrix, factor levels, ANOVA for each response, model F-value, p-value, lack-of-fit, R^2, adjusted R^2 and predicted R^2, together with regression equations and response-surface plots. A numerical desirability function should define how multiple responses were balanced. Finally, the predicted optimum should be prepared independently and the predicted and experimental responses compared with percentage prediction error.

Dissolution and Release Kinetics: Dissolution is central to the proposed dosage form because the sequential strategy is intended to address both drug dissolution and tablet disintegration. The authors' work used USP apparatus II with phosphate buffer pH 6.8 at 37 ± 0.5 °C and 50 rpm. The final publication should report method validation, apparatus qualification, sampling schedule, replicate number and analytical validation details from the laboratory records. Kinetic models can help describe dissolution behavior but should not be over interpreted. Model selection based only on the highest R^2 can be misleading when datasets have few points or when the assumptions of the model are not met. For rapidly dissolving tablets, the pharmaceutical interpretation should prioritize the dissolution profile, disintegration behavior and mechanistic evidence rather than assigning a prolonged-release mechanism to a rapidly disintegrating matrix.

Stability Considerations: The thesis-derived F9 formulation was monitored for three months at 25 ± 2 °C/60 ± 5% RH and 40 ± 2 °C/75 ± 5% RH. The reported changes were modest: drug content decreased from 99.84% initially to 99.32% under long-term conditions and 98.86% under accelerated conditions; 15-min release remained 96.8% and 96.1%, respectively. Disintegration changed from 16 s to 17 and 18 s.

These results are encouraging for short-term formulation stability but should not be interpreted as evidence of commercial shelf life. A complete

stability report should identify batch numbers, packaging configuration, chamber qualification, sampling intervals, assay method, degradation products where relevant, and the final statistical or trend analysis.

Conclusion

Dapoxetine is a clinically established on-demand pharmacological option for premature ejaculation, and its rapid pharmacokinetic profile provides a rational basis for investigating fast-dissolving oral dosage forms. Modern FDT development requires a balance between rapid disintegration, mechanical integrity, dissolution, taste, stability and manufacturability. Solid-dispersion technology can address the dissolution component, while superdisintegrants and direct compression can address rapid tablet breakup. The authors' thesis-derived formulation work illustrates this sequential concept: the reported 1:3 dapoxetine: PVP K30 dispersion increased saturation solubility and dissolution, while the F9 fast-dissolving tablet provided rapid wetting, 16-s disintegration and high in-vitro release. The most important next step for publication-quality evidence is not simply adding more formulation batches, but strengthening statistical optimization, solid-state characterization, dissolution benchmarking and translational validation. This integrated approach can convert a promising laboratory formulation into a scientifically defensible patient-centric pharmaceutical development platform.

References

1. McMahon CG. Dapoxetine: a new option in the medical management of premature ejaculation. Ther Adv Urol. 2012;4(5):233–251.
2. Russo A, Capogrosso P, Ventimiglia E, La Croce G, Boeri L, Montorsi F, et al. Efficacy and safety of dapoxetine in treatment of premature ejaculation: an evidence-based review. Int J Clin Pract. 2016;70(9):723–733.
3. Martins F, et al. Efficacy and safety of dapoxetine for premature ejaculation: an updated systematic review and meta-analysis. Int J Impot Res. 2020.
4. Lee HY, Pyun JH, Shim SR, Kim JH. Efficacy of various treatment in premature ejaculation: systematic review and network meta-analysis. World J Mens Health. 2024;42(2):338–346.
5. Saleh R, Majzoub A, Abu El-Hamd M. An update on the treatment of premature ejaculation: a systematic review. Arab J Urol. 2021; 19(3):281–302.
6. European Association of Urology. EAU Guidelines on Sexual and Reproductive Health: Disorders of Ejaculation. EAU; current guideline resource.
7. Ghourichay MP, Kiaie SH, Nokhodchi A, Javadzadeh Y. Formulation and quality control of orally disintegrating tablets (ODTs): recent advances and perspectives. Biomed Res Int. 2021;2021:6618934.
8. Berardi A, Bisharat L, Quodbach J, Abdel Rahim S, Perinelli DR, Cespi M. Advancing the understanding of the tablet disintegration phenomenon—an update on recent studies. Int J Pharm. 2021;598:120390.
9. Khadivi Y, Monajjemzadeh F. Advancement in the formulation and development of orally disintegrating tablets: innovation, challenges, and future perspective. J Drug Deliv Sci Technol. 2025;108:106965.
10. Advancing Drug Delivery Paradigms: Polyvinyl Pyrrolidone (PVP)-Based Amorphous Solid Dispersion for Enhanced Physicochemical Properties and Therapeutic Efficacy. 2024.
11. International Council for Harmonisation. Q1A(R2): Stability Testing of New Drug Substances and Products.
12. US Food and Drug Administration. Disso lution Testing of Immediate Release Solid Oral Dosage Forms. Guidance for Industry.
13. US Food and Drug Administration. M9 Biopharmaceutics Classification System-Based Biowaivers. Guidance for Industry. 2021.
14. Recent formulation advances and therapeutic usefulness of orally disintegrating tablets. Pharmaceutics. 2020.
15. Dapoxetine and the treatment of premature ejaculation. Ther Adv Urol. 2016.