Current Landscape of Patient-Centric Formulations in Generic Drug Development

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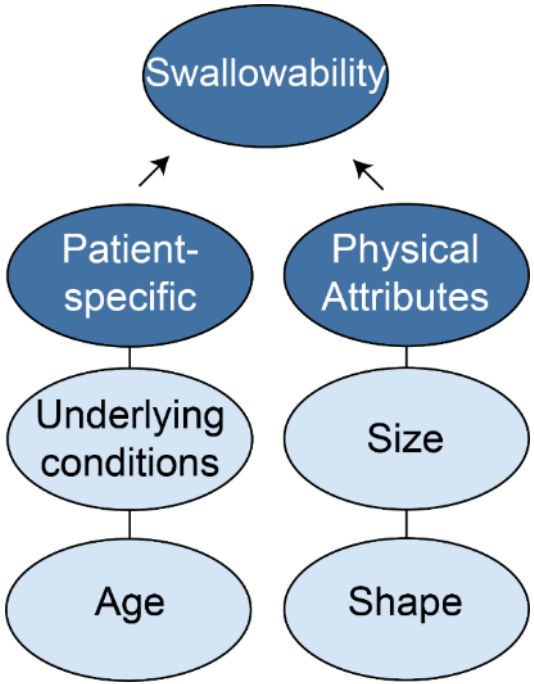
Purpose

- Discuss swallowability considerations for solid oral dosage forms (SODFs)
- Characterize the current landscape of patient-centric formulations based on Orange Book survey
- Highlight the utilization of suitability petitions for expanding access to patient-centric formulations
- Identify the key considerations for product-specific guidance (PSG) development of patient-centric formulations

SODFs and Swallowability Considerations

- SODFs are the most prevalent dosage forms due to several advantages including its ease of use and product stability
- Swallowability is a critical attribute for SODFs intended to be swallowed intact
  - Swallowability is defined as the “patient being able to take the drug without gagging or choking”[1]
- Based on survey studies[2,3], approximately 16% of the participants experience dysphagia at some point while around 40% of the general U.S. population experience a range of swallowing difficulties with SODFs
- Vulnerable populations including pediatrics, geriatrics, and patients with dysphagia face unique challenges with SODFs

Factors Affecting Swallowability



- Swallowability can be influenced by patient-specific factors and physical attributes of the drug product[4]
- Swallowability of SODFs is important to ensure patient compliance, therapeutic outcome, safety, and efficacy
  - Inappropriate manipulation/alteration of SODF may lead to medication errors or induce toxic effects (e.g., dose dumping)
  - Inability to swallow prescribed SODFs may result in treatment interruption or discontinuation

"***Patient centric pharmaceutical drug product design*** *can be defined as process of identifying the comprehensive needs of individuals or the target patient population and utilizing the identified needs to design pharmaceutical drug products that provide the best overall benefit to risk profile for that target patient population over the intended duration of treatment"* [5]

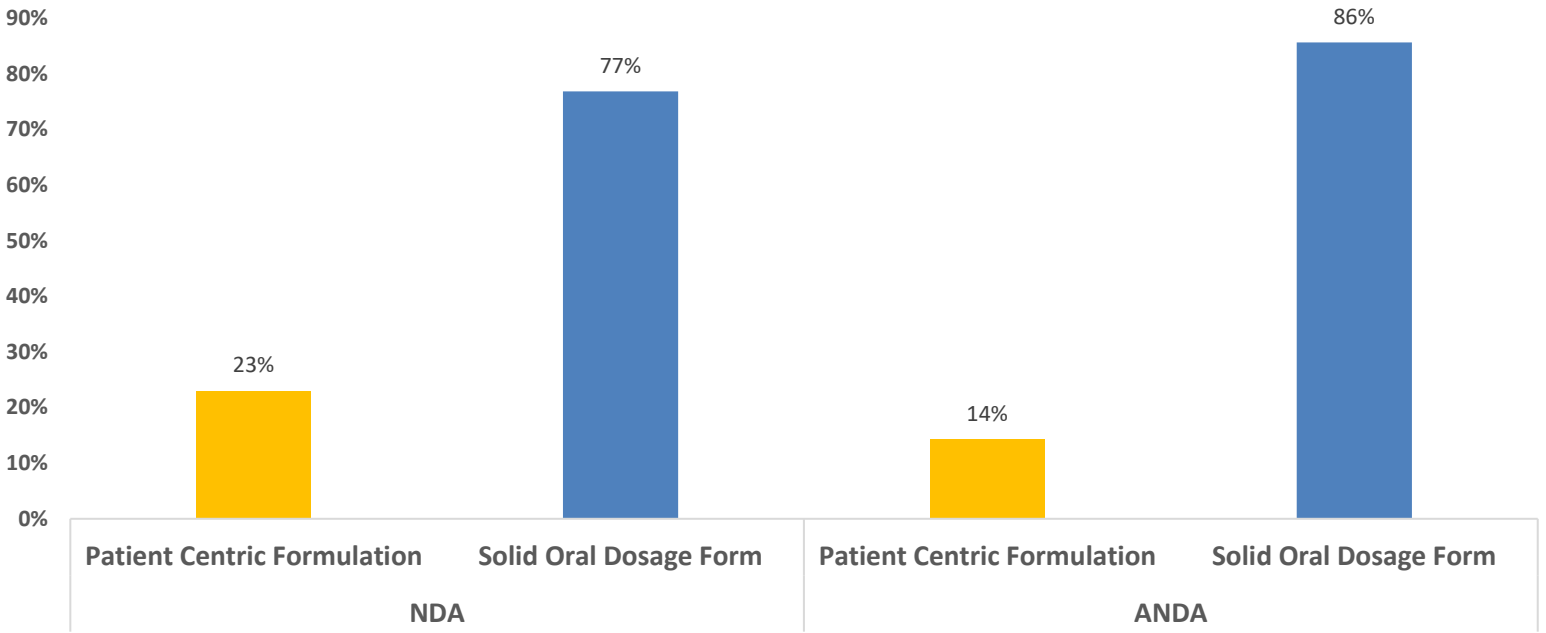
Key Design Considerations for Patient-Centric Formulations[6]

- Type of dosage form (e.g., chewable tablets, orally disintegrating tablets)
- Route of administration (e.g., buccal or sublingual)
- Palatability and sensory attributes (e.g., taste, smell, mouth feel, and appearance matter)
- Ease of use and administration
- Patient-related characteristics (e.g., identifying age-appropriate formulations)
- Packaging of drug products

Benefits of Patient-Centric Formulations

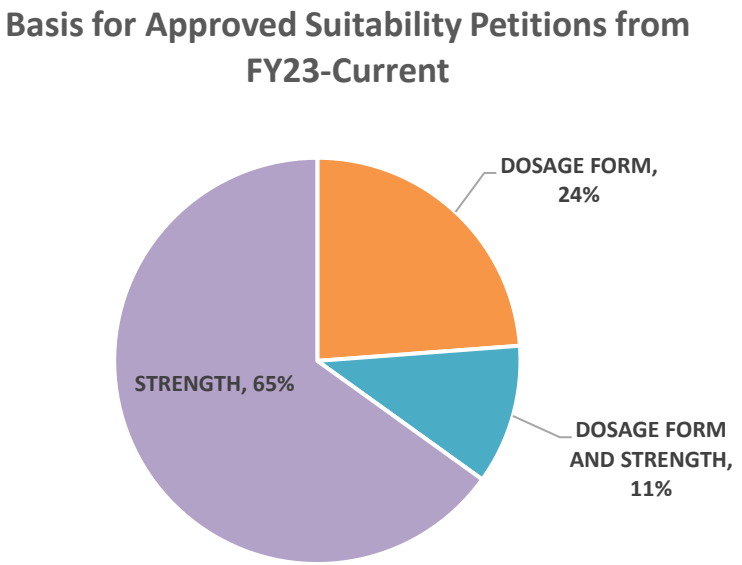
- Non-SODFs including suspension and orally disintegrating tablets can reduce the burden on patients who have difficulty swallowing conventional tablets or capsules
- Allows for dose flexibility and individualization (weight-based or body surface area-based)
- Potentially improved palatability compared to SODFs to promote adherence
- Ensuring the availability of age-appropriate non-SODFs is a critical factor that directly impacts patient outcomes in vulnerable populations

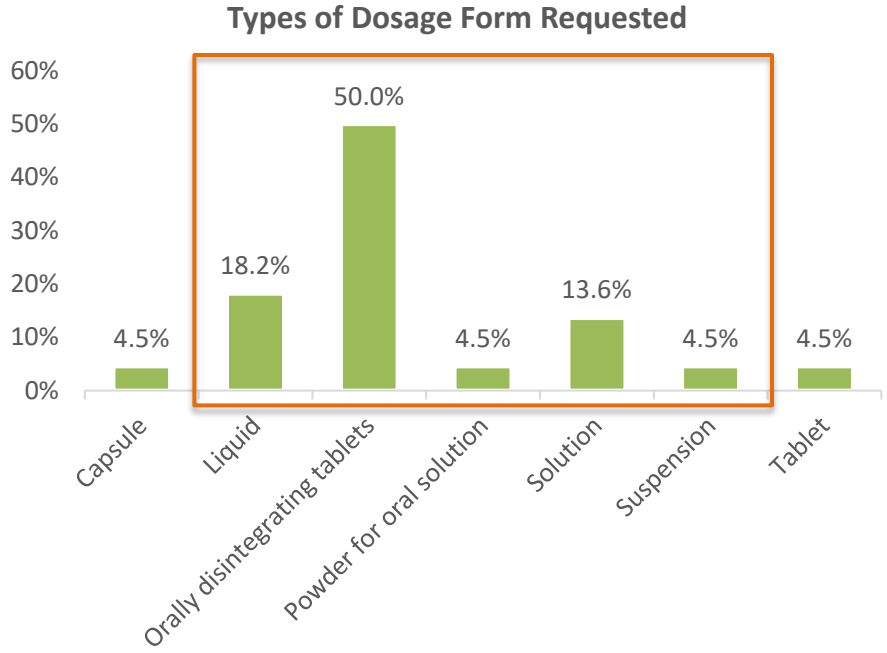
Patient-Centric Formulations from NDAs and ANDAs in Comparison with SODFs – Orange Book Survey



Patient-centric formulations include non-SODFs and buccal/sublingual/transmucosal routes.
SODFs include tablets and capsules.
Marketed drug products as of April 2026 from Orange Book.

Enabling Access to Patient-Centric Formulations Through Suitability Petition





35% of the suitability petitions requested a change in dosage form

Among suitability petitions requesting a dosage form change, ~90% were for patient-centric formulations

Based on FDA internal SP database

Rationales for Requested Dosage Form Change in Approved Suitability Petitions

- Convenient dosing and administration
- Dosing accuracy
- Dosing flexibility
- For patients with swallowing difficulty
- Reducing the size of tablets
- Administration without water for orally disintegrating tablets

Considerations Beyond the Standard Bioequivalence Study Design for Patient-Centric formulation

- Dose selection for liquid formulations (e.g., suspension)
- Specific administration methods (e.g., sprinkle on soft food)
- Study population considerations
- In vitro feeding tube studies
- Alternative BE approaches (e.g., PBPK modeling)

Summary

- SODFs remain the dominant dosage form in the market; however, swallowability presents a challenge for certain population with swallowing difficulties
- Patient centric formulations offer significant clinical benefits, including improved swallowability, dose flexibility, and palatability
- Suitability petition is a pathway to expand access to patient centric generic formulations
- Continued efforts in PSG development are essential to support the growth of patient-centric generic formulations

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