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Review Article

Formulation and Evaluation of Paracetamol Fast Reconstituting Pediatric Dry Powder Susupension

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ABSTRACT

Dry powder for oral suspension provides an effective alternative by improving storage stability and allowing reconstitution immediately before administration. The formulation was prepared by the direct mixing method, in which accurately weighed and sieved ingredients were blended to obtain a uniform dry powder. Each batch contained 2.5 g of paracetamol for reconstitution to 100 mL, along with maltodextrin as a diluent, sodium carboxymethyl cellulose (Sodium CMC) as suspending agent. A factorial design approach was employed to optimize the concentration of critical formulation variables and to evaluate their influence on the physicochemical characteristics of the final product. The prepared powder was intended to be reconstituted with purified water before administration. The formulated dry powder was evaluated for pre-formulation parameters, including angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner ratio to assess powder flow characteristics. After reconstitution, the suspension was evaluated for appearance, pH, sedimentation volume, redispersibility, viscosity, reconstitution time, particle size, drug content, and in vitro drug release. The present study aimed to formulate and evaluate a pediatric paracetamol dry powder for oral suspension containing 125 mg of paracetamol per 5 mL after reconstitution. The optimized formulation is expected to provide satisfactory flow properties, rapid and uniform reconstitution, improved suspension stability, accurate dosing, and acceptable drug release. The developed dry powder for oral suspension may offer a stable, convenient, and patient-friendly dosage form for pediatric administration of Paracetamol while overcoming the limitations associated with conventional liquid formulations.

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INTRODUCTION

"A dry powder for oral suspension is a pharmaceutical dosage form composed of finely divided insoluble drug particles, generally ranging from 0.5 to 5 µm in size, that are reconstituted with a suitable aqueous vehicle to form a uniform suspension before use."[1]

Developing pharmaceutical formulations for pediatric patients is scientifically demanding because children have distinct physiological characteristics and therapeutic needs that differ from those of adults.[2] Oral suspensions are widely preferred for pediatric patients because they are easier to administer than solid dosage forms, especially for children who have difficulty swallowing tablets or capsules.[3] Compared with tablets and capsules, dry syrup may provide improved bioavailability since it is administered as a dispersed suspension after reconstitution, promoting more efficient drug dissolution and absorption.[4]

ADVANTAGE OVER CONVETIONAL SYRUP:

- The dry powder can be conveniently packaged in single-dose sachets or unit-dose containers, making it lightweight, portable, and easy to transport and administer.[5]
- Provides improved chemical stability for drugs that are unstable in aqueous media, thereby extending the product's shelf life before reconstitution.
- Ensures accurate dose administration, particularly when supplied in unit-dose sachets or measured containers, reducing the possibility of dosing errors.
- Can be reconstituted easily with a specified quantity of purified water to produce a uniform and readily administrable suspension.[6]

NEED FOR DRY POWDER FORMULATION

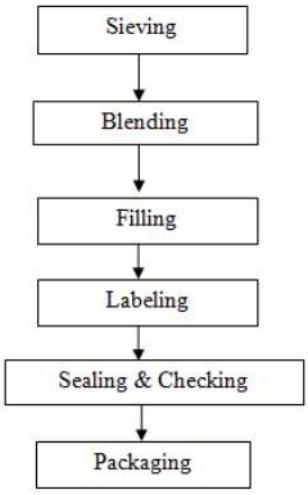
- May improve drug availability after reconstitution by allowing the medication to disperse rapidly in the gastrointestinal tract, making it easier to administer than conventional tablets or capsules.
- Enhances physical stability by minimizing problems such as ingredient incompatibility, pH-related instability, caking, and crystal growth during storage before reconstitution.[7]
- Improves the chemical stability of drugs that are unstable in aqueous media by storing them in a dry state until reconstitution.[8]

LIST OF EXCIPIENTS:

Ingredients	Function
Paracetamol	API
Maltodextrin	Diluent
Sodium CMC	Suspending agent
Aspartame	Sweetening agen
Sodium citrate	Buffer
SLS	Wetting agent
Sodium benzoate	Preservative
Purified water	For reconstitution

METHODOLOGY:

DIRECT METHOD: The flow chart for the direct method is given below.



- **Sieving:** All ingredients, including paracetamol, maltodextrin, sodium CMC, xanthan gum, sodium benzoate, aspartame, and SLS, were accurately weighed according to the formulation and passed through a #100 mesh sieve to obtain a uniform particle size and eliminate agglomerates.

- **Preparation of Premix:** Aspartame, sodium benzoate, and SLS were mixed with a small quantity of maltodextrin by geometric dilution to prepare a uniform premix. This ensured even distribution of the low-dose excipients throughout the formulation.

- **Addition of Suspending Agents:** Sodium CMC and xanthan gum were gradually incorporated into the premix and blended thoroughly using a mortar and pestle to achieve uniform distribution of the suspending agents.

- **Geometric Addition of Paracetamol:** Paracetamol was added to the blended excipients in three equal portions using the geometric dilution technique. The mixture was blended thoroughly after each addition to ensure uniform drug distribution.

- **Final Blending:** The remaining quantity of maltodextrin was added, and the entire formulation was blended for 15–20 minutes using a mortar and pestle until a homogeneous dry powder mixture was obtained.

- **Packaging:** The prepared dry powder blend was filled into clean, dry, airtight amber glass bottles or HDPE containers. The containers were properly sealed and labeled with instructions to add the required quantity of purified water before use to obtain the oral suspension.[9,10]

PRE-FORMULATION STUDIES:

1. Organoleptic Evaluation: To assess the physical and sensory characteristics of the formulation.The prepared formulation was visually examined under normal lighting for color and appearance. Odor and taste were evaluated carefully to determine the overall acceptability of the formulation.[11]

2. Angle of Repose: To evaluate the flow properties of the dry powder blend.The angle of repose was determined using the funnel method by allowing the powder to flow freely onto a flat surface to form a cone. The height (h) and radius (r) of the cone were measured, and the angle of repose was calculated using the formula: $\theta = \tan^{-1}(h/r)$. Lower values indicate better flowability of the powder blend.

3. Bulk Density: To determine the packing ability of the dry powder under loose conditions.A known quantity of powder was transferred into a graduated cylinder without tapping, and the initial volume (V_0) was recorded. Bulk density was calculated using the formula:

Bulk Density = Weight of Powder / Bulk Volume (g/mL).

4. Tapped Density: To determine the packing ability of the powder after mechanical tapping. The graduated cylinder containing the powder was mechanically tapped until a constant volume was obtained. The final tapped volume (Vt) was recorded, and tapped density was calculated using:

Tapped Density = Weight of Powder / Tapped Volume (g/mL).

5. Carr's Compressibility Index: To evaluate the compressibility and flow characteristics of the powder blend. Carr's Compressibility Index was calculated using the bulk density and tapped density values according to the formula;

Carr's Index (%) = [(Tapped Density − Bulk Density) / Tapped Density] × 100.

6. Hausner's Ratio: To assess the flow behavior and interparticle friction of the powder blend. Hausner's Ratio was calculated using the bulk density and tapped density values according to the formula:

Hausner's Ratio = Tapped Density / Bulk Density.[12]

POST RECONSTITUTION EVALUATION:

1. pH of the suspension: The pH of the prepared suspension was measured using a calibrated digital pH meter at room temperature.[13]

2. Appearance: The prepared suspension was visually examined for color, clarity, uniformity, and the absence of lumps or caking.

3. Viscosity: Viscosity was measured using a Brookfield viscometer with a suitable spindle at a predetermined rotational speed (rpm).

4. Sedimentation Volume: The reconstituted suspension was stored in a graduated cylinder, and the sedimentation volume was recorded at specified time intervals. It was calculated using F = Vu/Vo, where *Vu* is the ultimate sediment volume and *Vo* is the original suspension volume.

5. Redispersibility: The number of manual inversions required to obtain a uniform suspension after sedimentation was recorded.

6. Stability Study: The formulation was stored at 25 ± 2°C/60 ± 5% RH and 40 ± 2°C/75 ± 5% RH**,** and evaluated periodically for appearance, pH, drug content, and dissolution.

7. In-vitro Dissolution Study: Dissolution was carried out using USP Apparatus II (Paddle method) at 37 ± 0.5°C**,** with samples withdrawn at predetermined intervals and analyzed using a UV–Visible spectrophotometer.[14]

CONCLUSION

The literature review suggests that paracetamol dry powder for oral suspension is a suitable dosage form for pediatric patients due to its improved stability and ease of administration. The selection of appropriate excipients is essential to achieve good palatability, reconstitution, and physical stability. Evaluation parameters such as flow properties, pH, viscosity, sedimentation volume, and drug content are important for ensuring product quality. Overall, the reviewed studies support the development of a safe, stable, and effective pediatric paracetamol dry powder suspension.

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