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Development and evaluation of furosemide dry suspension formulation for the paediatric management of congenital heart disease

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Abstract

Background: Congenital Heart Disease (CHD) with volume overload is a common cause of pediatric heart failure, often necessitating the use of loop diuretics such as furosemide (FUR) to manage symptoms like pulmonary congestion. Despite its widespread clinical use, commercially available FUR formulations are primarily designed for adult patients (e.g., 10 mg tablets), making accurate pediatric dosing (typically 1–3 mg/kg body weight) difficult. This often leads to the preparation of extemporaneous suspensions in hospitals, which carries risks of dosing inaccuracies, microbial contamination, and treatment failure. These challenges are especially pronounced in low-resource settings, where access to proper compounding facilities is limited. A stable, pediatric-appropriate formulation of FUR is therefore urgently needed.

Broad Objective: To develop and evaluate a stable furosemide dry powder suspension formulation tailored for pediatric patients with CHD, focusing on optimizing stability, viscosity, and drug release characteristics using natural suspending agents.

Methodology: Twelve dry suspension formulations were prepared using different concentrations (0.05%, 0.1%, 0.2%, and 0.3%) of three suspending agents: xanthan gum, pectin gum, and guar gum. The formulations were evaluated based on the drug's chemical compatibility with excipients,

In vitro drug release using standard dissolution testing, Rheological behavior, focusing on flow and viscosity characteristics, pH and physical stability of reconstituted suspensions under various storage conditions and Release kinetics modelling to assess the drug release mechanism.

Results: The optimised formulation demonstrated an acceptable angle of repose between 23–25°, indicating good flowability. All trial formulations maintained moisture content below 1%, enhancing shelf stability. All suspensions displayed shear-thinning (pseudoplastic) behaviour, which is desirable for ease of administration. The pH of reconstituted formulations remained within an optimal range (6.6–6.8), ensuring drug stability and palatability.

Formulation F7, containing 0.2% pectin gum, exhibited the most promising profile: 65% cumulative drug release within 30 minutes. Visually stable without sedimentation or caking for the duration of the stability testing.

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Conclusion: The study successfully developed a pediatric-appropriate dry suspension formulation of furosemide that addresses the limitations of existing adult formulations. Formulation F7, containing 0.2% pectin gum, was identified as the optimal formulation among the twelve trial batches. It met pharmacopeial standards for flowability, moisture content, pH, and drug release behavior. The formulation offers a practical and stable alternative to extemporaneous preparations, minimizing risks related to dosing inaccuracies and contamination.

Recommendations: Further, in vivo evaluation should be conducted to confirm the optimised formulation's bioavailability and therapeutic efficacy in pediatric patients. Scale-up and validation studies are recommended for potential industrial manufacturing and regulatory approval.

Keywords: Dry suspension; Suspending agent; Furosemide; Congenital heart disease; Pediatric

1. Introduction

Congenital Heart Disease (CHD) encompasses various malformations of the heart and major vessels present at birth, and it is one of the most common congenital malformations (1). The global burden of disease is estimated at 80% of deaths from non-communicable diseases, including congenital heart disease (CHD), with a substantial increase of 1.35 million newborns with CHD every year, representing a major global health burden (1). In Africa, around 50 million children are born each year, and it is estimated that 500,000 of these children suffer from significant congenital heart disease (CHD) that requires cardiological care but has little or no access to treatment (2). In Tanzania, the prevalence of ventricular septal defects (VSD) and atrial septal defects (ASD) ranges from 10% to 34.6% (3).

Congenital heart disease (CHD) volume overload, a type of heart failure that is unique to pediatrics, can be treated with a general approach that includes the use of loop diuretics. Furosemide, a loop diuretic, remains a key treatment for managing volume overload conditions by alleviating pulmonary congestion (4). At present, Furosemide (FUR) is the preferred medication for managing volume overload in children with Congenital Heart Disease (CHD). Furosemide mainly works by inhibiting the reabsorption of sodium and chloride in the thick ascending limb of the Loop of Henle. This action leads to an increased elimination of potassium, magnesium, calcium, and, to a lesser extent, bicarbonates (5).

In paediatrics, FUR has been used as an off-label drug, with a recommended dosage of 1-3 mg/kg of body weight daily, up to a maximum dose of 40 mg/kg (6). Currently, the available formulation is a solid dosage form in the form of a 40 mg tablet, which is commonly split for extemporaneous preparations in low- and middle-income countries (LMICs) (5). Additionally, compounding extemporaneous preparations as a solution for the challenge, as mentioned earlier, presents several drawbacks, including uneven drug distribution, risk of microbial contamination, calculation errors, patient acceptability issues, and a high risk of cross-contamination that may lead to treatment failure(7).

The objective of this work is to develop a dry suspension powder that can be reconstituted into a stable suspension using various concentrations of suspending agents, specifically xanthan gum, pectin gum, and guar gum, at levels of 0.05%, 0.1%, 0.2%, and 0.3%. Throughout this process, the amounts of all other ingredients will remain constant. This study presents a dry suspension formulation of FUR that may help address challenges associated with extemporaneous medication compounding and could enhance child health outcomes in low- and middle-income countries (LMICs).

2. Materials and Methods

2.1. Materials

Analytical-grade reagents and chemicals were sourced from Sigma-Aldrich Life Science Company in Bergen, Norway. These included FUR powder, xanthan gum, pectin gum, guar gum, sodium citrate monohydrate, sodium citrate tribasic dihydrate, sodium benzoate, D-mannitol powder, and acetonitrile.

2.2. Chemical compatibility

A method previously described by Diyya et al 2020(8), with minor modifications. A Fourier transform infrared spectrophotometer (FTIR) assessed the chemical compatibility between Furosemide and excipients in a 1:1 ratio mixture. The FTIR spectra were obtained using a Bruker Alpha Spectrophotometer, equipped with IR Solution software. The sample powder was thoroughly blended by triturating it with potassium bromide (KBr) in a glass mortar with a pestle. After blending, the mixture was compacted into disks using a hydraulic press. The recording covered a spectral

range from 4000 to 400 cm^{-1} with a resolution of 4 cm^{-1}, and data were accumulated from 20 scans per sample. The FTIR spectra were analysed on the 1st and 28th days (9).

2.3. Formulation of the dry suspension

Twelve trial formulations of dry suspensions labelled F1 through F12 were prepared as powder blends by varying the ratios of suspending agents while maintaining consistent quantities of Furazolidone (FUR) and other excipients across all formulations. The final pharmaceutical product was designed to contain 0.2 g of FUR in a bottle, which, when reconstituted to 100 ml, would provide a dosage of 10 mg of FUR per 5 ml of the reconstituted product. This formulation strength allows for dosage individualisation based on the child's body weight. The excipients used in preparing these formulations included xanthan gum, pectin gum, guar gum, and sodium citrate in varying concentrations of 0.05%, 0.1%, 0.2%, and 0.03%, as well as sodium benzoate and mannitol, all within pharmaceutically acceptable ranges. The master formula is presented in Table 1.

Table 1 Composition of Furosemide formulations F1-F12 up to 100 mL (%w/v)

Ingredients	**F 1**	**F 2**	**F 3**	**F 4**	**F 5**	**F 6**	**F 7**	**F 8**	**F 9**	**F 10**	**F 11**	**F 12**
Furosemide	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Xanthan gum	0.05	0.1	0.2	0.3	-	-	-	-	-	-	-	-
Pectin gum	-	-	-	-	0.05	0.1	0.2	0.3	-	-	-	-
Guar gum	-	-	-	-	-	-	-	-	0.05	0.1	0.2	0.3
Sodium citrate monobasic	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sodium benzoate	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Mannitol	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Sodium citrate tribasic dihydrate	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Total	7.05	7.1	7.2	7.3	7.05	7.1	7.2	7.3	7.05	7.1	7.2	7.3

2.4. Evaluation of the formulated dry suspension

2.4.1. Powder flowability

The angle of repose (AR), bulk density (BD), tapped density (TD), compressibility index (CI), and Hausner's ratio (HR) were employed to assess the flowability of all powder blend formulations, as outlined by Shah et al. and in the USP protocol document number 1174(10).

2.4.2. Dissolution test and Mechanism of Kinetic drug release

The drug dissolution profile was examined in accordance with the USP monograph, utilising a type 2 paddle apparatus operated at 50 rpm. (11). The dissolution medium consisted of 900 mL of purified water, equilibrated at 37 ± 0.5 °c. A powder blend equivalent to 10 mg of the active pharmaceutical ingredient (API) was placed in dissolution vessels 1 to 6. Vessel 7 served as a blank, while vessel 8 contained 10 mg of a reference standard of the API for comparison. A 2 mL sample was transferred from each formulation using disposable syringes, and the vessels were replenished with fresh dissolution medium. The samples were filtered through a 0.45 µm membrane filter and analysed using an HPLC method, employing the area under the curve approach to determine the drug content (12).

2.4.3. Moisture content of furosemide dry suspension formulations

Moisture content was determined using the loss on drying method outlined in the USP monograph document no. 731(13). For this procedure, 1 gram of each powdered formulation was heated at 105 °C for three hours. After heating, the samples were cooled in a desiccator, and the weight change was recorded.

2.4.4. Rheology of the furosemide reconstituted dry suspension

The rheological behaviour of the reconstituted suspensions was determined using an IKA Rotavisc low-viscosity viscometer. The viscosity of the prepared solutions was measured with a 10 ml sample. Measurements were conducted using spindle number 5 and sheared at 3, 5, 7, 10, 30, 50, 70, and 100 rpm while maintaining the temperature at 22°C.

The viscosity readings were taken directly after 60 seconds. The rheological properties were analyzed by plotting viscosity (mPa·s) against shear rate (rpm).

2.4.5. pH of reconstituted furosemide dry suspension

The pH measurement was conducted in accordance with USP document number 791, with minor modifications as described by Zahalka et al. The reconstituted suspensions were stored in refrigeration at 4°C and 25°C, and the change in pH was recorded at 0, 7, 14, and 28 days.

3. Results

3.1. Chemical compatibility

Furosemide (FUR) was identified using FTIR spectroscopy, with results compared to those of a marker compound. The infrared (IR) spectrum analysis, as shown in Figure 1, facilitated this identification. In the spectrum of pure furosemide, characteristic peaks were observed at 3647.5 cm^{-1} (O-H stretch), 3286.8 cm^{-1} (N-H stretch), 3147.1 cm^{-1} (C-H stretch), 1568.2 cm^{-1} (C=O stretch), 1672.3 cm^{-1} (N-H bending), and 1263.4 cm^{-1} (S=O asymmetric stretch).

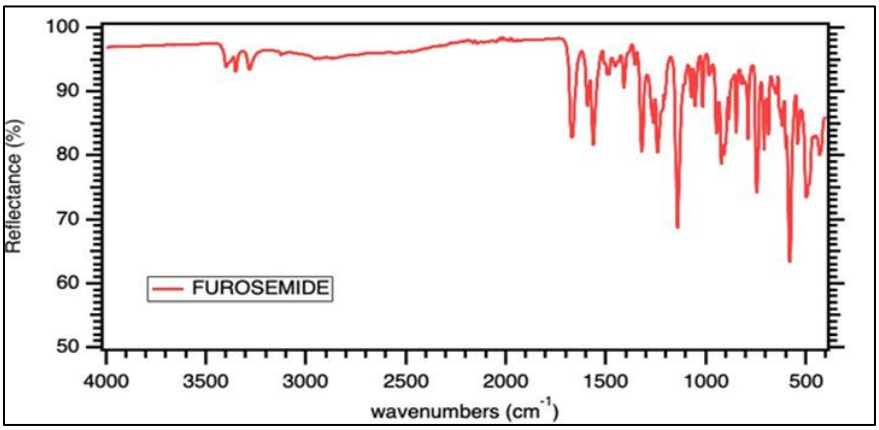

Figure 1 IR spectrum of furosemide

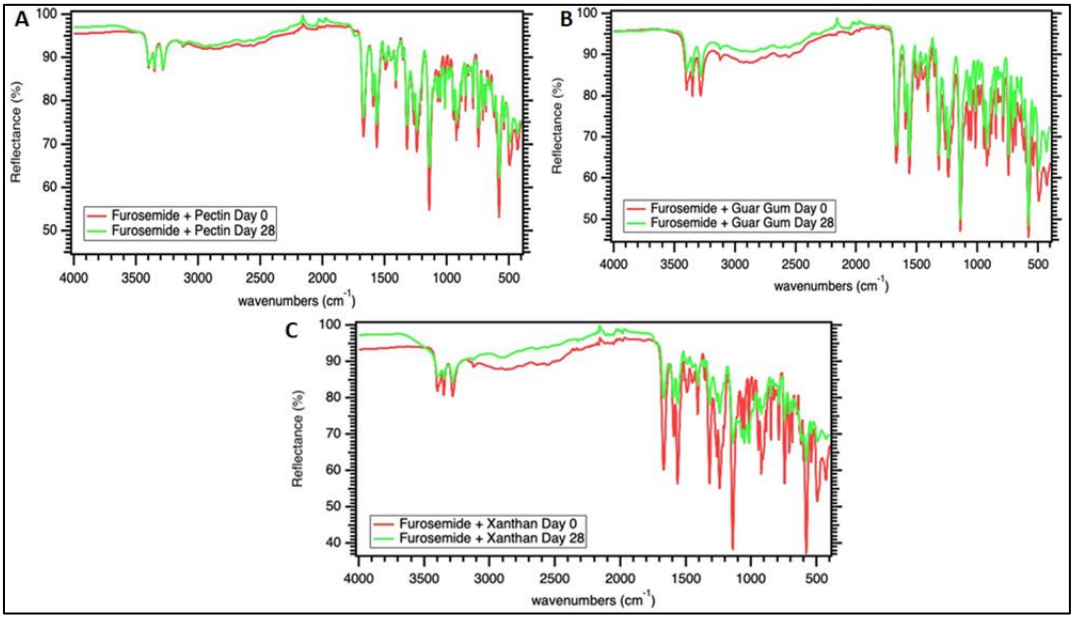

Figure 2 IR spectrum of furosemide and excipients. Furosemide combined with pectin (A), furosemide combined with guar gum (B), and furosemide combined with xanthan (C)

All excipients were chemically compatible with furosemide (FUR), as demonstrated by the similar FT-IR spectra wave numbers observed from day one to day 28. The FT-IR spectra of furosemide, both in its pure form and in blended mixtures, showed no significant changes over time. Additionally, the FT-IR spectra of the furosemide formulation with excipients showed no substantial shifts in functional group positions. This suggests no potential interactions exist between furosemide and the excipients in the formulation. The results are illustrated in Figure 2.

3.2. Evaluation of the formulated dry suspension

3.2.1. Flowability of Powder Blends

The angle of repose values indicate that the powder blend possesses favourable flowability. The bulk density for all formulations ranges from 0.59 ± 0.03 g/ml, confirming good flowability. Additionally, the tapped density value of 0.725 ± 0.015 further emphasises the powder's robust flowability. The compressibility index is calculated at 19.54 ± 0.13, supporting the conclusion of good flowability for the powders (Table 2).

Table 2 Flowability of various powder blends

Formulation	**Flowability indicating parameters**				
	Angle of Repose	**Bulk density (g/mL)**	**Tapped density (g/mL)**	**Compressibility index (%)**	**Hausner's ratio**
F1	25.11	0.61	0.74	17.39	1.21
F2	26.46	0.57	0.71	20.00	1.25
F3	25.20	0.56	0.72	23.08	1.30
F4	25.36	0.59	0.70	16.00	1.19
F5	25.11	0.59	0.71	16.67	1.20
F6	25.87	0.57	0.71	20.00	1.25
F7	25.29	0.58	0.72	20.00	1.25
F8	25.87	0.57	0.70	19.23	1.24
F9	22.54	0.62	0.74	17.39	1.21
F10	24.86	0.59	0.71	16.67	1.20
F11	23.81	0.60	0.73	16.67	1.20
F12	21.10	0.61	0.74	16.67	1.20
REMARKS	Excellent	Less air accumulation	Less air accumulation	Good flowability	Good flowability

3.2.2. Dissolution test and Mechanism of Kinetic drug release

All formulated powder blends underwent 30-minute dissolution testing. Among these, formulation F7, which contains 0.2% (w/v) pectin gum, showed a higher percentage of drug release than the other formulations with either lower or higher pectin gum concentrations. In F7, more than 65% of the drug was released within 30 minutes (Figure 3). The rapid release behaviour observed with pectin gum can be attributed to the polymer's lower binding properties, which lead to a burst release of the drug upon immersion in the dissolution media.

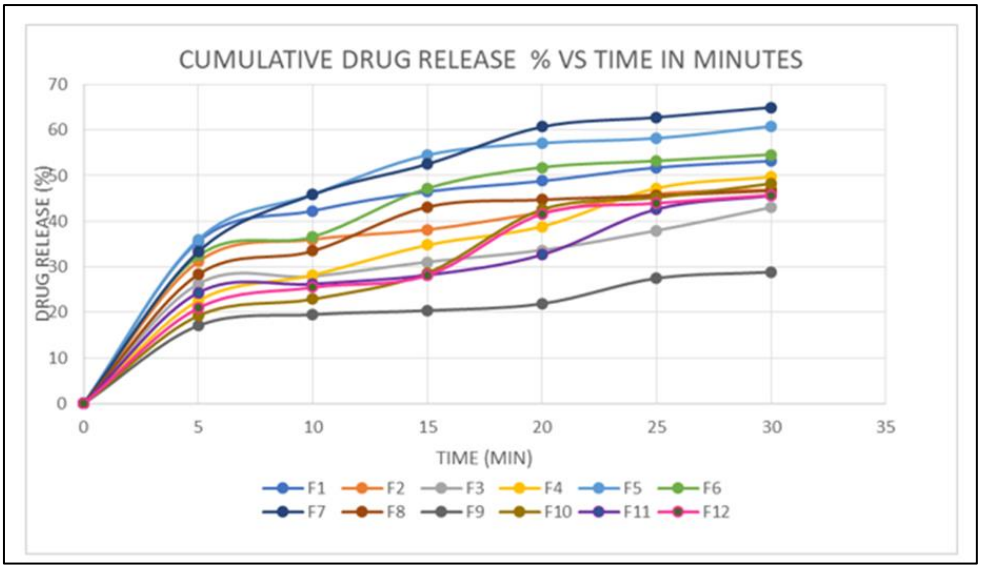

Figure 3 *In-vitro* drug release profile of all formulations

The data obtained from furosemide's in vitro drug release from the suspension of the optimised formulation (F7) were analysed using various mathematical models. This analysis involved plotting the data on appropriate graphs. The results were evaluated using the coefficient of determination (R^2) to assess the 'goodness-of-fit' for each kinetic release model. The model with the highest R^2 value was deemed the best fit for the specific release kinetics. The drug release rate from the furosemide suspension follows first-order kinetics (Table 3).

Table 3 Summary of the model kinetic Drug release

Model	Furosemide
	R^2
Zero-order	0.6582
First-order	0.9105
Higuchi model	0.6344
Korsmeyer-Peppas	0.9063
Hixson-crowell	0.8809

3.2.3. Moisture content

The moisture content of all developed formulations was found to be within the pharmaceutically acceptable limit of 5%. This indicates good stability and a reduced likelihood of microbial growth or moisture-related degradation. The determined moisture content values for each formulation are presented in Table 4, highlighting the effectiveness of the drying and formulation processes in maintaining optimal moisture levels.

Table 4 Moisture content of the formulations

Formulation	Moisture content (%)	Remarks
F1	0.06	Complies
F2	0.08	Complies
F3	0.09	Complies
F4	0.27	Complies
F5	0.12	Complies
F6	0.13	Complies
F7	0.60	Complies
F8	0.21	Complies
F9	0.15	Complies
F10	0.18	Complies
F11	0.11	Complies
F12	0.13	Complies

3.2.4. Rheology of reconstituted dry syrups

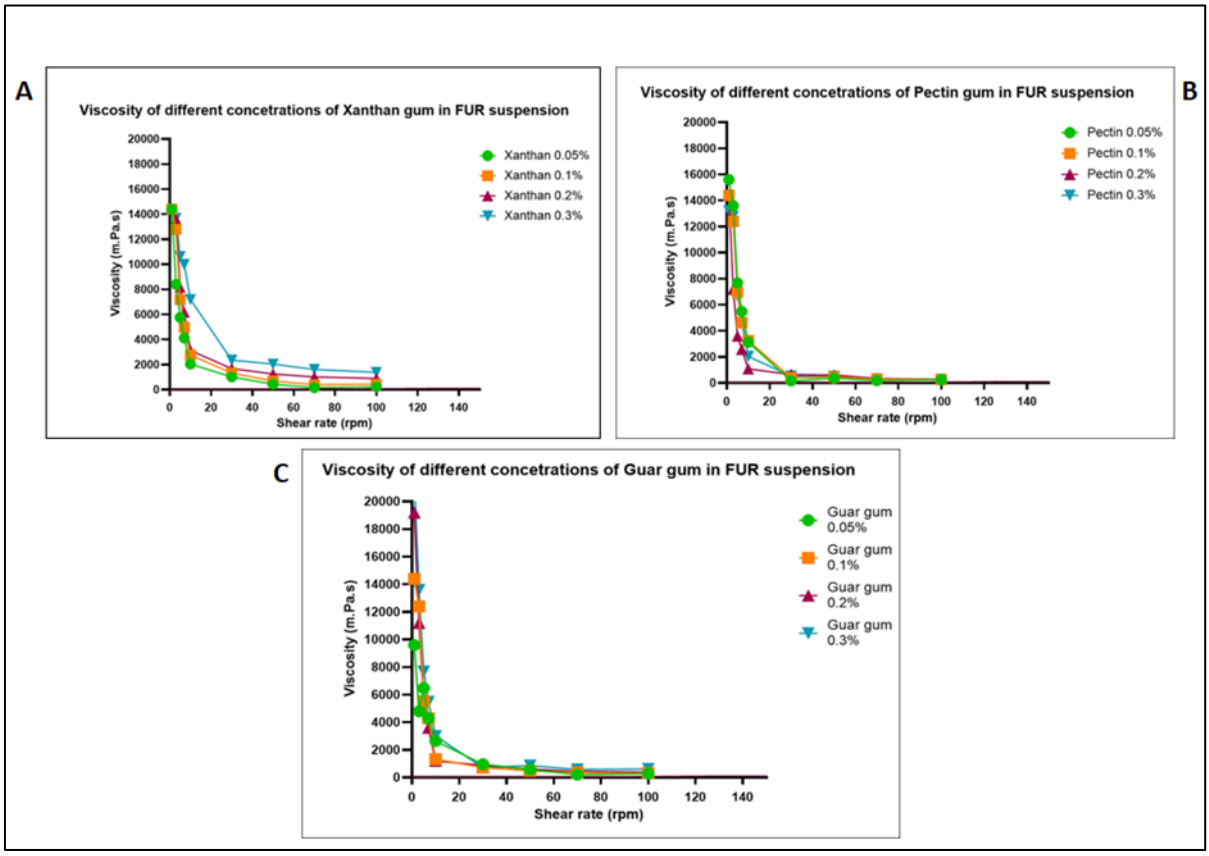

Figure 4 Rheology of reconstituted dry syrups: Viscosity versus shear rate of different concentrations of Xanthan gum (A), Viscosity versus shear rate of different concentrations of Pectin gum (B), Viscosity versus shear rate of different concentrations of Guar gum

The reconstituted dry syrups exhibited shear-thinning behaviour, characterised by a decrease in viscosity with increasing shear rate. This rheological property is advantageous, as it facilitates ease of pouring, dosing, and

administration, particularly in paediatric and geriatric populations. In the present study, all reconstituted formulations demonstrated pseudoplastic flow behaviour, a hallmark of shear-thinning systems. This type of non-Newtonian flow is highly desirable for pharmaceutical suspensions and solutions, as it ensures adequate viscosity during storage to prevent sedimentation while allowing the product to flow easily upon shaking or pouring. The observed pseudoplasticity reflects the stability and functional performance of the formulated syrups, supporting their suitability for oral administration. The results are shown in Figure 4

3.2.5. pH of the reconstituted dry syrup

The reconstituted syrups, when stored under both refrigerated (4 °C) and ambient (22–25 °C) conditions for 28 days, consistently met the United States Pharmacopoeia (USP) pH specifications, which stipulate an acceptable range of 5-8. Throughout this storage period, the formulations maintained a stable pH of 6.6 to 6.8. This narrow and consistent pH range indicates the chemical stability of the suspension, suggesting that the formulation components did not undergo significant degradation or interaction that could alter the pH. Such stability is crucial for ensuring the safety, efficacy, and shelf-life of the reconstituted product.

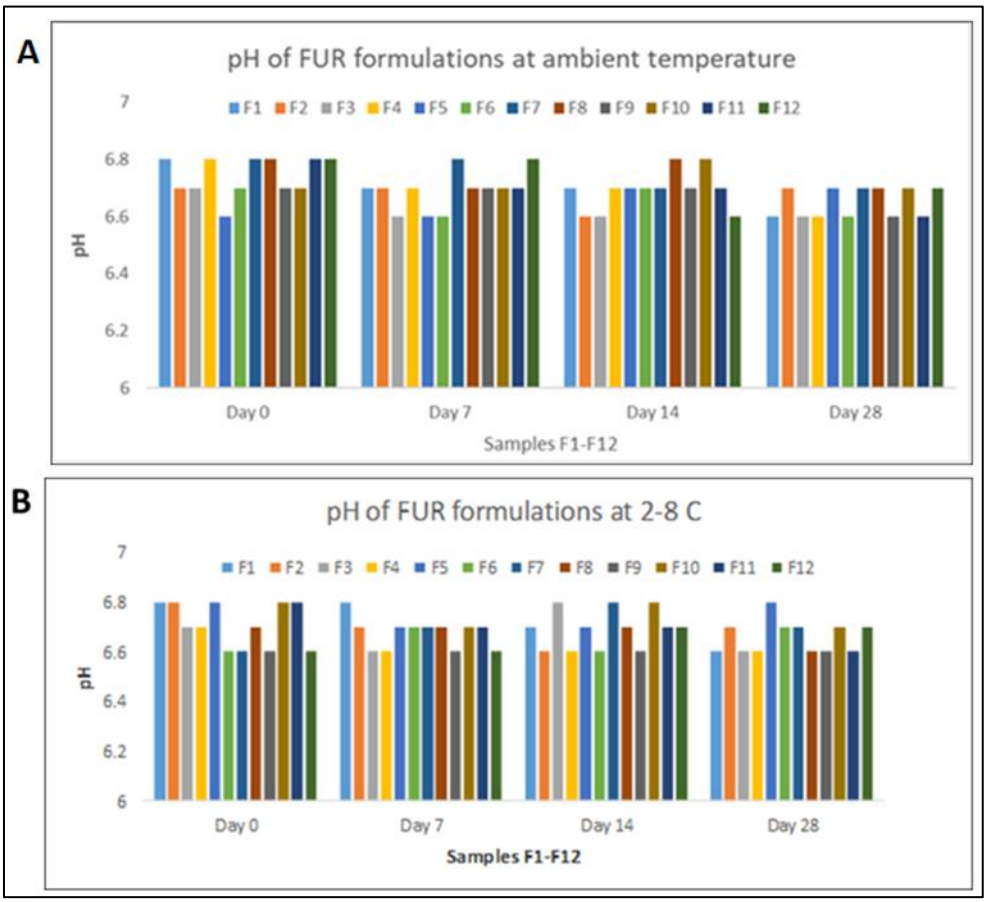

Figure 5 pH of the reconstituted dry syrup; pH of samples at ambient temperatures (A), pH of samples at 2-80C (B)

4. Discussion

The present study aimed to develop and evaluate a dry suspension of Furosemide for the treatment of congenital heart disease in paediatric patients. Multiple batches of the suspension were formulated using varying concentrations of xanthan gum, pectin gum, and guar gum as stabilising agents. To ensure consistency, the quantities of all other excipients were standardised across all preparations. Formulation development consists of several stages that ensure the final product meets the desired efficacy and safety standards for consumers. A critical aspect of pre-formulation studies is assessing the compatibility of chemical and physical excipients with the active pharmaceutical ingredient (API). It is essential to confirm that the selected excipients do not compromise the safety or stability of the active ingredient.

The FT-IR analysis confirmed the compatibility between the drug and its excipients. The spectra collected on day zero and day 28 remained unchanged, showing no shifts in wavenumbers. This stability suggests the absence of chemical interactions or reactions between Furosemide (FUR) and the excipients. These findings align with previously reported studies(14). The API's chemical compatibility with all potential excipients suggests that a chemically stable FUR dry suspension formulation is achievable.

The flowability values met USP specifications, indicating that the material has the required flowability for its intended use. (10). Powder flowability is a critical factor in both dry and wet granulated pharmaceutical powders, as it directly affects the efficiency and precision of powder filling into primary containers. This, in turn, plays a significant role in ensuring consistent dosage uniformity across the final product. Enhanced flowability not only facilitates smoother processing but also minimizes the risk of dosage variability, contributing to the overall quality and reliability of the pharmaceutical formulation.

All formulations exhibited a moisture content (MC) below 1%, comfortably within the acceptable limit for pharmaceutical powders, which is capped at 5%. This low moisture content highlights the formulations' suitability for maintaining stability and quality. (9). Higher moisture content can negatively impact the chemical stability and flowability of the powder.

The viscosity of a pharmaceutical suspension is a critical parameter during production, storage, dosing, and administration(15). The rheological studies of suspensions made with pectin gum indicate that these suspensions are pseudoplastic, meaning their viscosity decreases with increasing shear rate. All formulations exhibited pseudoplastic flow, a desirable viscosity property for pharmaceutical suspensions.

Viscosity analysis demonstrated that all suspension formulations displayed shear-thinning behaviour, a desirable property in pharmaceutical suspensions. At low shear rates, the suspension maintains a relatively higher viscosity due to the stabilization provided by the entanglement of polymer chains. This structural network contributes to the formulation's ability to resist flow under minimal force. However, under high shear conditions, such as during shaking or pouring, these polymer chains align and disentangle in the direction of the applied shear. This alignment reduces intermolecular interactions, leading to a substantial decrease in viscosity. This behavior enhances ease of administration while ensuring uniform suspension during storage, making it a critical characteristic for pharmaceutical formulations(16).

At a critical shear rate, viscosity experiences a notable decrease, indicating the onset of the shear-thinning region. At low shear rates, molecular interactions and Brownian motion allow the suspended gum to maintain its irregular structure. However, at higher shear rates, the macromolecules of the gum begin to stretch and align with the flow. This alignment diminishes intermolecular interactions, resulting in a decrease in viscosity(17).

The shear-thinning property of these formulations allows for a decrease in viscosity upon shaking, preparing the drug for release upon administration. Sedimentation refers to the partial separation of suspended solid particles from a liquid due to gravity. This process is influenced by factors such as particle size, liquid viscosity, and the densities of both the solid particles and the solution. The sedimentation rate is also affected by floc characteristics, including shape, size, density, and permeability. Generally, a suspending agent is added to the formulation to reduce the sedimentation rate of the dispersed particles. This is achieved by increasing the apparent viscosity of the continuous phase, which slows the settling of particles according to Stokes' Law (18).

All formulations displayed dissolution profiles that were potentially within acceptable USP limits, although the test was conducted for only 30 minutes. Formulation F7 (0.2% pectin gum) showed the highest drug release (65%) within 30 minutes, suggesting it might meet USP criteria (>85% in 60 min) if tested longer. Conversely, formulation F9 (0.05% guar gum) showed the lowest release (29%), suggesting guar gum at low concentrations may not be suitable for pharmaceutical suspensions compared to xanthan and pectin gums.

The F7 formulation demonstrated a higher correlation coefficient (R^2 = 0.9105) for first-order kinetics. This indicates that the overall drug release mechanism from the suspension follows first-order kinetics for furosemide. In the Korsmeyer-Peppas model, the value of "n" provides insight into the release mechanism. Specifically, a value of 0.43 suggests a diffusion-controlled (Fickian) release, while a value of 0.85 indicates a release mechanism governed by polymer swelling. (19). This indicates that the FPP will release sufficient medication at the absorption site.

The formulations stored at 4 °C and 25 °C over 28 days exhibited strong stability, achieving drug release levels ranging from 95% to 104%. These results align with the findings of Zahalka et al(20), confirming that variations in the

concentration of the suspending agent do not impact the drug's extraction following storage and reconstitution. This highlights the robustness of the formulation in maintaining its performance under different storage conditions.

The dry suspension's capacity to maintain a consistent pH over the 28 days following reconstitution indicates that the active pharmaceutical ingredient (API) remained stable and did not undergo significant hydrolysis or chemical degradation. This pH stability further supports the formulation's suitability for paediatric use, ensuring efficacy and safety throughout its shelf life.

5. Conclusion

The dry suspension of Furosemide (FUR) was successfully developed, with batch F7 identified as the optimal formulation, containing 0.2% pectin gum as a suspending agent. This formulation demonstrated superior micromeritic properties and strong compatibility between the active pharmaceutical ingredient and the selected excipients. Based on these attributes, F7 is strongly recommended for further optimisation and scale-up processes.

Notably, this paediatric-friendly formulation represents a significant advancement in pharmaceutical development, offering enhanced dosing accuracy, improved safety profiles, and a reduced risk of complications often associated with extemporaneously prepared medicines. Moreover, it addresses critical public health challenges in low- and middle-income countries (LMICs), such as limited access to medicines, high costs, and accessibility barriers. As such, the formulation has the potential to become a practical, affordable, and accessible therapeutic option for paediatric patients, contributing meaningfully to global improvements in healthcare.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

The authors declare that they have no conflict of interest.

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