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Research Paper

Formulation and Evaluation of Fast Dispersible Pellets of Deferasirox

Smit Patel*, Dr. Anand Patel, Shraddha Tiwari

Department of Pharmaceutics, A.P.M.C. College of Pharmaceutical Education and Research, Motipura, Himmatnagar.

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ABSTRACT

The present study was aimed at the formulation and evaluation of fast dispersible pellets of Deferasirox to improve its dispersion and dissolution characteristics. Deferasirox, being a poorly water-soluble drug, was selected for the development of a multiparticulate dosage form to enhance its in vitro performance and patient convenience. Fast dispersible pellets were prepared by Extrusion Spheronizer using suitable excipients including microcrystalline cellulose, mannitol, PVP K30, Kyron T-314, and talc.The prepared pellets were evaluated for micromeritic properties, percentage yield, hardness, friability, drug content, dispersion/disintegration time, and in vitro dissolution profile. The results of pre-formulation studies indicated satisfactory flow properties of the pellet formulations. Post-formulation evaluation revealed acceptable physical properties, good mechanical strength, uniformity in drug content, and rapid dispersion behaviour. Among all the trial batches, the optimized formulation exhibited the most desirable characteristics and showed enhanced drug release during dissolution study.The study concluded that fast dispersible pellets of Deferasirox can be successfully developed with acceptable physicochemical and performance characteristics. The optimized formulation may provide advantages such as rapid dispersion, improved dissolution profile, and better patient compliance, thereby representing a promising oral delivery system for Deferasirox.

INTRODUCTION

PELLETS:

Pellets are defined as spherical or near-spherical granules with excellent flow properties and a narrow particle size distribution, typically ranging from 500 to 1500 µm in pharmaceutical applications. These multiparticulate systems are commonly prepared through pelletization processes, in which a powder blend containing the

***Corresponding Author:** Smit Patel
Address: *Department of Pharmaceutics, A.P.M.C. College of Pharmaceutical Education and Research, Motipura, Himmatnagar..*
Email : smitpatel24082002@gmail.com
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active pharmaceutical ingredient (API) and excipients is agglomerated to form uniform, dense granules. Following production, pellets are usually filled into hard gelatin capsules or may be compressed into tablets, depending on the intended dosage form design. Pellets offer significant versatility in formulation development, as they can be designed for immediate drug release or modified to provide sustained or controlled release over an extended period. Additionally, they can be coated with functional polymers to enable site-specific drug delivery within the gastrointestinal tract. This adaptability makes pellets highly advantageous for achieving targeted therapeutic outcomes. One of the key benefits of pelletized systems is their flexibility in dose adjustment. Different dose strengths can be achieved without altering the core formulation or manufacturing process. Moreover, pellets allow for the combination of incompatible drugs within a single dosage form, as well as the blending of particles with different release characteristics to achieve either simultaneous or site-specific drug release. The free-flowing nature of pellets facilitates efficient handling, uniform filling, and ease of packaging. Their spherical geometry and relatively low surface area-to- volume ratio contribute to the formation of uniform and consistent coating layers, which is essential for controlled release formulations. Importantly, pellets help to minimize the risk of dose dumping, thereby ensuring a more uniform plasma concentration profile and gradual drug absorption compared to conventional tablets. This controlled release behavior ultimately reduces the likelihood of adverse effects and enhances the overall safety and efficacy of the drug delivery system.[1]

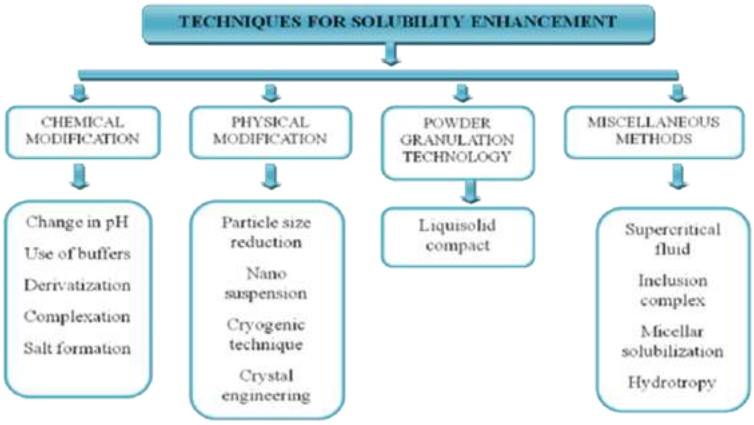


Figure 1: Solubility Enhancement technique

INTRODUCTION OF DRUG:

DEFERASIROX:

Commonly marketed under the brand name Exjade, is an orally administered iron-chelating agent. It is primarily used to manage chronic iron overload in patients who undergo frequent blood transfusions, particularly those suffering from conditions such as Beta-thalassemia and other long-term anemias. Notably, it was the first oral drug approved in the United States for the treatment of transfusion-related iron overload. [2,3]

WHAT DOES DEFERASIROX DO?

- The half-life of deferasirox is between 8 and 16 hours allowing once a day dosing. Two molecules of deferasirox are capable of binding to 1 atom of iron which are subsequently eliminated by fecal excretion.
- Its low molecular weight and high lipophilicity allows the drug to be taken orally unlike deferoxamine which has to be administered

by IV route (intravenous infusion). Together with deferiprone, deferasirox seems to be capable of removing iron from cells (cardiac myocytes and hepatocytes) as well as removing iron from the blood.

OBJECTIVES

To formulate fast dispersible pellets of Deferasirox for improved patient compliance and rapid onset of action.To enhance the solubility of deferasirox by solvent evaporation method.To optimize the formulation parameters (such as binder, disintegrant) to achieve rapid dispersion and acceptable physical characteristics.

To evaluate the prepared pellets for:Particle size and shape , Flow properties , Disintegration time ,Drug content uniformity , In vitro dissolution profile. To perform stability studies on the optimized batch as per ICH guidelines to assess formulation stability over time.

METHEDOLOGY

Preparation of pellets

The method of preparation of Fast Dispersible pellets. Weigh all the ingredients accurately in the weigh Balance. Then mix the API with Super disintegrant and MCC PH 102 , Mannitol then pass the mixture threw the sieve no. 40. Then Prepare PVP K30 solution. Add the Solution slowly to the dry blend while mixing. Pass the wet Mass through an extruder to form cylindrical extrudates. Transfer the extrudates into a spheronizer. Dry the Wet Pellets Using hot air oven. To reduce moisture to improve pellets strength. Pass the Dried Pellets Through Standard sieves. A uniform size is collected for evaluation and filling.[4,5]

Methods used in present work Solid dispersions

Solid dispersions of Deferasirox with Polyvinylpyrrolidone were prepared in different ratios (1:1 to 1:3) using a modified solvent evaporation technique. The drug was first dissolved in a small quantity of ethanol, followed by the addition of the required amount of PVP. The mixture was stirred for about one hour and then evaporated on a water bath at 45–50°C until nearly dry. The obtained product was further dried and stored in a desiccator containing anhydrous calcium chloride until a constant weight was achieved.[6,7]

Table 1: Drug polymer ratio

Formulation code	Ingredient	Ratio
1	Dfx: PVP	1:1
2	Dfx: PVP	1:1.5
3	Dfx: PVP	1:2
4	Dfx: PVP	1:2.5
5	Dfx: PVP	1:3

Formulation of Preliminary batches of Deferasirox fast Dispersible pellets

Ingredient (mg)	T1	T2	T3	T4	T5*	T6	T7	T8	T9
API:Polymer	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**
Crosspovidone (%)	**3**	**6**	**9**	**-**	**-**	**-**	**-**	**-**	**-**
Kyron T-314 (%)	**-**	**-**	**-**	**3**	**6**	**9**	**-**	**-**	**-**
Croscarmellose Sodium(ccs) (%)	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**6**	**9**
MCC PH -102 (%)	**23**	**20**	**17**	**23**	**20**	**17**	**23**	**20**	**17**
Mannitol (mg)	**25.5**	**25.5**	**25.5**	**25.5**	**25.5**	**25.5**	**25.5**	**25.5**	**25.5**
Pvpk30 (mg)	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**

Talc (mg)	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**
Total (mg)	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

Full Factorial Design

Full Factorial Design		
Batch No.	**X1 Amount of Kyron T-314**	**X2 Amount of MCC PH -102**
F1	-1	-1
F2	-1	0
F3	-1	+1
F4	0	-1
F5	0	0
F6	0	+1
F7	+1	-1
F8	+1	0
F9	+1	+1

Translation of coded level in actual limit			
	Level		
Independent variables	**Low (-1)**	**Medium (0)**	**High (+1)**
Amount of Kyron T-314 (%) X1	4	6	8
Amount of MCC PH-102 (%) X2	15	20	25

All 9 batches were evaluated for the Drug release (%) (Y1) and Disintegration time (Y2) to find out effect of both parameters (X1, X2)

❖ **Independent variables**: ✓ X1- Amount of Kyron T-314 (%)

X2- Amount of MCCPH-102 (%)

❖ **Dependent variables** :✓ Y1- Drug release (%)

Y2- Disintegration time (sec.)

Composition Of Formulation (F1 –F9) optimized batches

Ingredients	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Deferasirox+Polymer (mg)	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**	**1:1.5**
Kyron T-314 (%)	4	4	4	6	6	6	8	8	8
MCC PH -102 (%)	15	20	25	15	20	25	15	20	25
Mannitol (mg)	50	32	15	43	25	8	36	18	1
Pvpk30 (mg)	5	5	5	5	5	5	5	5	5
Talc	4	4	4	4	4	4	4	4	4
Total weight: 350mg									

Evaluation of deferasirox Fast Dispersible Pellets :

Particle size distribution

A narrow particle size distribution is essential to achieve uniform coating thickness and to support efficient mixing, especially when different types of pellets are combined. The most commonly used technique for evaluating particle size distribution is sieve analysis with a mechanical sieve shaker. In this method, approximately 100 g of pellets are accurately weighed using an electronic balance and placed on a series of sieves with varying mesh sizes. The sieves are then agitated, allowing particles to separate based on size. After completion, the amount of material retained on each sieve is measured and expressed as a percentage to determine the particle size distribution.[8]

Friability test

A 10 g sample of pellets was accurately weighed and introduced into the drum of a friability tester along with 200 glass beads of 4 mm diameter. The apparatus was operated at 100 rpm for a duration of 4 minutes. After the test, the pellets were passed through a 250 µm sieve for 5 minutes to separate and remove the fines. The remaining pellets were weighed, and the friability was then calculated based on the loss in weight.[9]

Drug Content Uniformity

100mg pellets are weighed. Crush the pellets in mortal pestle. 50mg powder weighed. In 50 ml methanol dissolve the powder by sonication. 1ml in 10 ml methanol. 1ml in 10 ml methanol. Check the absorbance by using UV.[10]

Disintegration time

Pellet disintegration was evaluated using a USP tablet disintegration apparatus. A 300 µm mesh was fixed at the base of each tube in the basket-rack assembly to prevent the pellets from escaping. Approximately 100 mg of pellets was then placed into each of the six tubes. Water maintained at 37 ± 2°C was used as the immersion medium, and the volume was adjusted to 700 mL (instead of 800 mL) to ensure the pellets remained within the tubes during the test. The time taken for the pellets to pass through the 300 µm mesh was recorded as the disintegration time (DT).[11]

In-vitro drug release (dissolution) studies

In-vitro drug release studies for each formulation were performed using a USP type II dissolution apparatus under controlled conditions. The dissolution medium consisted of 900 mL phosphate buffer (pH 6.8), maintained at 37 ± 0.5 °C, with a stirring speed of 50 rpm. Samples were withdrawn at specific time intervals of 5, 10, 15, 20, and 30 minutes. At each interval, 5 mL of the dissolution medium was collected and replaced with an equal volume of fresh medium to maintain constant conditions. The collected samples were suitably diluted, and the drug content was analyzed using a UV–visible spectrophotometer at 245 nm.[12,13]

RESULT AND DISCUSSION

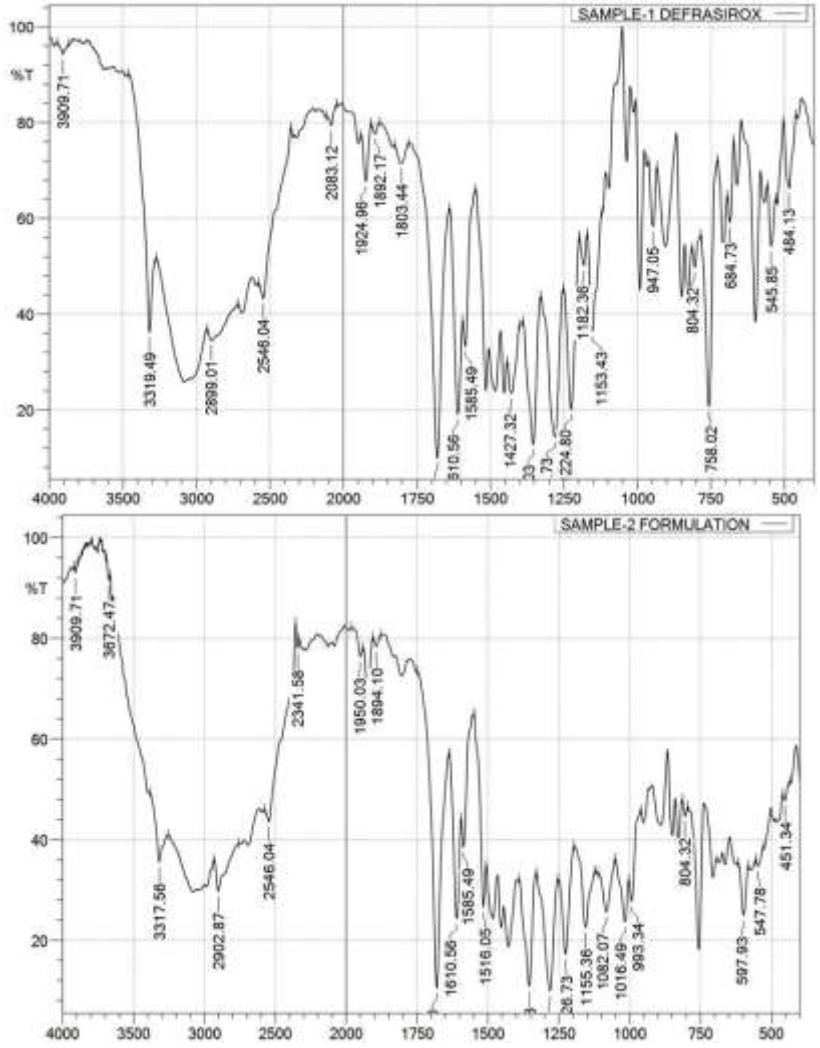
Solubility study

Various ratio of Drug and polymer mixture	Soluility in pH 6.8 buffer solution (n=3, ± SD)	Solubility in distiled water(n=3, ± SD)	Solubility increase in water (times)
1:1	0.595 ± 0.50	0.601 ± 0.12	15.02
1:1.5	**0.620 ± 0.28**	**0.612 ± 0.64**	**15.3**
1:2	0.602 ± 0.25	0.598 ± 0.50	14.95
1:2.5	0.520 ± 0.75	0.535 ± 0.49	13.37
1:3	0.543 ± 1.25	0.530 ± 0.65	13.25

FTIR STUDY

The FT-IR spectra of Deferasirox and the final formulation were evaluated to assess potential interactions between the drug and excipients. The characteristic peaks corresponding to the functional groups of Deferasirox were retained in the formulation spectrum without any significant shifts or disappearance. This observation suggests the absence of chemical interaction between the drug and excipients, indicating their compatibility. The FT-IR spectra of pure Deferasirox and the formulated product are illustrated in the figure Shown below.

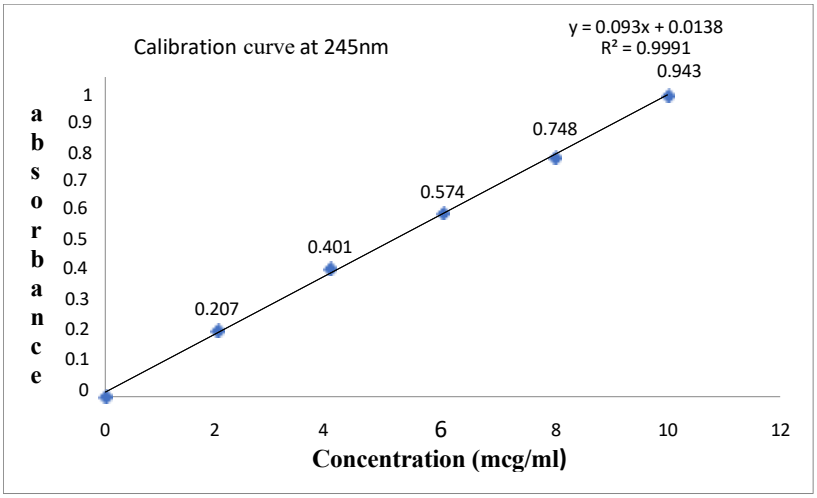
FTIR spectra of Deferasirox



FTIR spectra of optimized formlation of Deferasirox

Functional Groups of drug & formulation

Functional Groups	Standard Frequency (cm^{-1})	Deferasirox Peak (cm^{-1})	Final Formulation Peak (cm^{-1})
N–H stretching	3200–3600	3319.49	3317.56
C–H stretching	2850–2950	2889.01	2902.87
C=O stretching	1700–1750	1710	1710
Aromatic C=C stretching	1500–1600	1585.49	1585.49, 1516.05



Calibration curve of Deferasirox

Standard Calibration Curve of deferasirox

Sr. No.	Concentration (µg/ml)	Absorbance
1	0	0
2	2	0.207±0.003
3	4	0.401±0.004
4	6	0.574±0.002
5	8	0.748±0.004
6	10	0.943±0.006

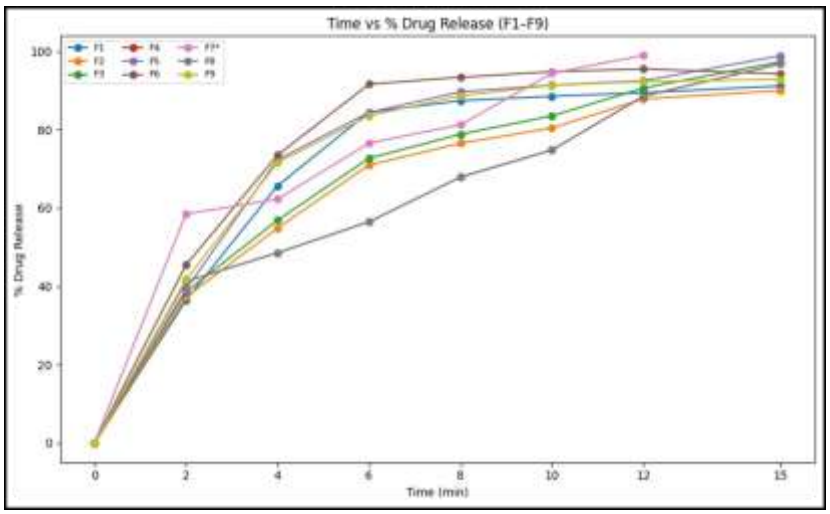
Evaluation for Factorial batches F1-F9

Formulation Code	Particle Size (mm) ± SD	Drug Content (%) ± SD	Disintegration Time (sec) ± SD	Friability (%) ± SD (n=3)
F1	1.19±0.15	98.2 ± 0.6	42 ± 2.1	0.92 ± 0.05
F2	1.56±0.22	99.0 ± 0.5	38 ± 1.8	0.78 ± 0.04
F3	0.97±0.26	99.5 ± 0.4	34 ± 1.5	0.65 ± 0.03
F4	1.47±0.25	98.8 ± 0.5	30 ± 1.6	0.88 ± 0.06
F5	1.55±0.22	99.3 ± 0.4	26 ± 1.4	0.70 ± 0.05
F6	1.20±0.23	99.7 ± 0.3	24 ± 1.2	0.58 ± 0.04
F7	1.11±0.23	98.9 ± 0.5	22 ± 1.3	0.80 ± 0.05
F8	1.43±0.30	99.4 ± 0.4	20 ± 1.1	0.62 ± 0.03
F9	1.11±0.16	99.8 ± 0.3	18 ± 1.0	0.50 ± 0.02

Drug release of factorial batches F1 – F9

Time (min)	F1	F2	F3	F4	F5	F6	F7*	F8	F9
0	0	0	0	0	0	0	0	0	0
2	36.43 ± 1.19	37.25 ± 1.16	38.55 ± 1.63	41.25 ± 1.25	39.25 ± 0.86	45.44 ± 1.07	58.49 ± 1.67	41.25 ± 1.25	41.74 ± 0.85
4	65.66 ± 1.25	54.87 ± 1.19	56.86 ± 1.52	48.56 ± 1.36	72.32 ± 1.08	73.49 ± 1.11	62.26 ± 1.43	48.56 ± 1.36	71.55 ± 1.04
6	84.48 ± 0.87	70.99 ± 1.14	72.68 ± 1.44	56.48 ± 1.23	84.39 ± 1.13	91.62 ± 1.30	76.57 ± 1.31	56.48 ± 1.23	83.60 ± 0.99
	87.42 ±	76.53 ±	78.86 ±	67.89 ±	89.67 ±	93.40 ±	81.26	67.89 ±	88.70 ±

8	1.49	1.30	1.31	1.27	1.25	0.94	±1.27	1.27	0.81
10	88.55 ± 1.15	80.44 ± 1.32	83.54 ± 1.12	74.82 ± 0.99	91.40 ± 1.01	94.83 ± 0.89	94.43 ± 1.14	74.82 ± 0.99	91.35 ± 1.11
12	89.45 ± 0.69	87.88 ± 1.11	90.65 ± 1.23	88.56 ± 1.17	92.51 ± 0.84	95.53 ± 1.12	99±1.0	88.56 ± 1.17	92.30 ± 0.62
15	91.19 ± 0.53	90 ± 1.1	97.35 ± 0.97	96.84 ± 1.12	98.91± 0.40	94.26 ± 0.80		96.84 ± 1.12	92.86 ± 0.38



Profile of Cumulative % Drug Release of F1-F9

CONCLUSION

Optimization was carried out using a 3^2 full factorial design, with Kyron T-314 and MCC PH-102 selected as independent variables. Their influence on drug release and disintegration time was systematically studied. Another set of nine batches (F1–F9) was developed and evaluated, all of which showed acceptable performance.

Among the optimized batches, F7 was identified as the best formulation, showing a disintegration time of 22 seconds and complete drug release within 12 minutes. It also satisfied all evaluation criteria, including appropriate hardness, particle size, friability, wetting time (9 seconds), and drug content (98.9%).

Overall, the optimized formulation demonstrated desirable characteristics and was found to be suitable for achieving rapid drug release and improved patient compliance.

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