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Formulation Optimization and Evaluation of Aprepitant Orally Disintegrating Tablets

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A B S T R A C T

The present investigation was undertaken to develop and evaluate orally disintegrating tablets (ODTs) of Aprepitant as a rapid and patient-friendly dosage form for the management of chemotherapy-induced nausea and vomiting. Preformulation studies involving drug identification, solubility assessment, melting point determination, spectral characterization, and drug–excipient compatibility studies established the physicochemical characteristics of Aprepitant. The drug exhibited a high melting point of 254–256°C and poor aqueous solubility, being soluble in methanol, sparingly soluble in phosphate-buffered saline (PBS, pH 6.8), and practically insoluble in water. To overcome the solubility limitation, solid dispersions were prepared using PEG 4000, PEG 6000, and β-cyclodextrin as hydrophilic carriers. The prepared systems exhibited a substantial improvement in drug solubility and dissolution characteristics. Among the investigated formulations, SD4 containing Aprepitant and PEG 6000 in a 1:2 ratio demonstrated the most favorable characteristics, with a drug content of 99.31%, solubility of 3.91 mg/mL, and 97.17% drug release within 15 min. The optimized solid dispersion was subsequently incorporated into ODTs containing different superdisintegrants, namely crospovidone, sodium starch glycolate (SSG), and croscarmellose sodium (CCS). The prepared tablets were evaluated for hardness, friability, weight variation, thickness, drug content, disintegration time, wetting time, and in vitro drug release. All formulations demonstrated satisfactory pharmaceutical characteristics. Among the formulations, F3 containing crospovidone exhibited the fastest disintegration, with a disintegration time of 21 s, together with rapid drug release. Comparative assessment of the superdisintegrants indicated the dissolution performance order of crospovidone > sodium starch glycolate > croscarmellose sodium. Stability assessment of F3 under refrigerated, room-temperature, and accelerated conditions for three months showed no significant change in appearance or drug content. The findings indicate that the developed Aprepitant ODT formulation may provide a promising approach for rapid drug delivery and improved patient convenience in chemotherapy-induced nausea and vomiting.

I. Introduction

Chemotherapy-induced nausea and vomiting (CINV) is one of the most distressing adverse effects associated with anticancer therapy and can substantially affect treatment adherence, nutritional status, hydration, and overall quality of life. Effective antiemetic therapy is therefore an important component of supportive cancer care [1]. Aprepitant is a selective neurokinin-1 (NK1) receptor antagonist that is widely used as part of antiemetic therapy for the prevention and management of chemotherapy-induced nausea and vomiting. However, its poor aqueous solubility presents a significant pharmaceutical challenge and may limit dissolution and subsequent drug absorption [2].

The rate and extent of dissolution are particularly

important for drugs exhibiting poor water solubility. Conventional formulation approaches may not adequately overcome the dissolution-related limitation associated with hydrophobic drugs. Solid dispersion technology is an established pharmaceutical strategy for improving the dissolution behavior of poorly water-soluble compounds. In this approach, the drug is molecularly or finely dispersed within a hydrophilic carrier, which can improve wettability, reduce crystallinity, increase effective surface area, and consequently enhance dissolution [3].

Hydrophilic polymers such as polyethylene glycol (PEG) have frequently been employed as carriers for the preparation of solid dispersions because of their favorable aqueous solubility and ability to improve drug wetting. Cyclodextrins represent another important class of solubility-enhancing agents that can form inclusion complexes with suitable drug molecules. The incorporation of Aprepitant into such carrier systems may therefore provide an effective means of improving its dissolution characteristics [4].

Orally disintegrating tablets (ODTs) are solid dosage forms designed to disintegrate rapidly in the oral cavity, generally without the need for water. They provide several advantages over conventional tablets, particularly for patients experiencing nausea, vomiting, dysphagia, or difficulty swallowing. Rapid disintegration can facilitate quick dispersion of the drug and may contribute to an earlier onset of therapeutic action. ODTs may therefore be particularly advantageous for antiemetic therapy [5].

The performance of ODTs is strongly influenced by the nature and concentration of the superdisintegrant. Crospovidone, croscarmellose sodium, and sodium starch glycolate are commonly employed superdisintegrants that facilitate tablet breakup through different mechanisms, including wicking, swelling, and capillary action. Appropriate selection of the superdisintegrant is therefore essential for achieving rapid tablet disintegration and drug release [6].

In the present study, Aprepitant solid dispersions were prepared using PEG 4000, PEG 6000, and β-cyclodextrin with the objective of enhancing aqueous solubility and dissolution. The optimized solid dispersion was subsequently incorporated into ODT formulations using different superdisintegrants [7-8]. The developed formulations were comprehensively evaluated for pre-compression and post-compression characteristics, disintegration behavior, wetting characteristics, and in vitro dissolution performance. Stability studies were further conducted on the optimized formulation to assess its physical and chemical stability under different storage conditions.

MATERIALS AND METHODS

Materials

Aprepitant (APP) was obtained as a gift sample from Glenmark Pharmaceutical Limited, Indore, India. Crospovidone, croscarmellose sodium (CCS), sodium starch glycolate (SSG), and aspartame were procured from S.D. Fine Chemicals, Mumbai, India. Microcrystalline cellulose (MCC) was obtained from LOBA Ltd. Mannitol and magnesium stearate were procured from Qualigen, Mumbai, India. β-Cyclodextrin, PEG 4000, and PEG 6000 were used as carriers for preparation of the solid dispersion systems. Methanol and other analytical-grade reagents were used throughout the investigation.

Preparation of Aprepitant Solid Dispersions

Aprepitant solid dispersions were prepared by the solvent evaporation method using PEG 4000, PEG 6000, and β-cyclodextrin as hydrophilic carriers. Drug-to-carrier ratios of 1:1 and 1:2 were investigated.

The required quantity of the selected carrier was dissolved in 20 mL of methanol. Aprepitant was subsequently added gradually to the carrier solution with continuous stirring to achieve uniform mixing. The solvent was removed by evaporation until a solid mass was obtained. The dried mass was pulverized and passed through sieve No. 100 to obtain a uniform powder. The prepared solid dispersions were transferred to airtight containers and stored in a desiccator containing fused calcium chloride until further evaluation [9-10].

Determination of Solubility of Prepared SD

The apparent solubility of Aprepitant, physical mixtures, and prepared solid dispersions was determined in PBS (pH 6.8). Samples equivalent to 10 mg of Aprepitant were transferred into 10 mL volumetric flasks containing PBS. The flasks were sealed and maintained in a temperature-controlled shaking water bath at 25°C for 24 h to establish equilibrium. After equilibration, the samples were filtered through 0.45 µm membrane filters. Suitable dilutions were prepared using PBS (pH 6.8), and the absorbance was measured at 264 nm using a UV-visible spectrophotometer. Solubility was calculated from the corresponding calibration curve [11].

Formulation of Aprepitant orally disintegrating tablets (ODTs):

The optimized solid dispersion, SD4, was selected for incorporation into the ODT formulations on the basis of its superior solubility and drug-release characteristics. The quantity corresponding to 30 mg of Aprepitant was used for preparation of each tablet formulation. Crospovidone, SSG, and CCS were incorporated individually at concentrations of 2–6% to investigate their effects on tablet disintegration and drug release. The required quantity of solid dispersion was initially blended with the respective superdisintegrant. The mixture was subsequently blended with MCC, mannitol, and aspartame to improve compressibility, diluent properties, mouthfeel, and palatability [12-13].

The powder mixture was blended for 20 min to obtain

uniform distribution. Magnesium stearate and talc were then incorporated and mixed for an additional 10 min to provide adequate lubrication. The final powder blend was compressed using an 8-mm flat-faced punch on a suitable tablet compression machine [14]. Each formulation was designed to contain 30 mg equivalent of Aprepitant (Table 1).

Table 1. Composition of Aprepitant ODTs

Formulation code	F1	F2	F3	F4	F5	F6	F7	F8	F9
Aprepitant SD	112	112	112	112	112	112	112	112	112
Crospovidone	4	8	12	-	-	-	-	-	-
SSG	-	-	-	4	8	12	-	-	-
CCS	-	-	-	-	-	-	4	8	12
Mannitol	39	35	31	29	25	21	29	25	21
MCC	30	30	30	30	30	30	30	30	30
Aspartame	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Mag stearate	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Talc	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Tablet weight (mg)	200	200	200	200	200	200	200	200	200

Pre-compression characterization

The prepared powder blends were evaluated for flow and compressibility characteristics before compression. A representative quantity of 25 g of each powder blend was accurately weighed and subjected to evaluation [15-16].

Angle of Repose

The angle of repose was determined using a suitable fixed-funnel method. The powder was allowed to flow through the funnel onto a flat surface to form a conical heap. The height and radius of the powder heap were measured, and the angle of repose was calculated using the standard relationship:

$\theta = \tan^{-1}(h/r)$

where h is the height and r is the radius of the powder heap.

Bulk and Tapped Density

Bulk density was determined by transferring a known mass of powder into a graduated cylinder and recording its initial volume without tapping. Tapped density was determined after mechanically tapping the cylinder until a constant volume was achieved.

Compressibility Index

The compressibility index was calculated from bulk and tapped density using:

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

Hausner's Ratio

Hausner's ratio was calculated using:

Hausner's Ratio = Tapped density / Bulk density

These parameters were used to assess the flowability and compressibility of the powder blends.

Evaluation of prepared tablets

Tablet Hardness

Hardness was measured using a Monsanto hardness tester. The force required to break each tablet diametrically was recorded in kg/cm². The test was performed to determine the mechanical strength of the prepared ODTs [17-20].

Friability

Friability was determined using a Roche friabilator. Twenty tablets were accurately weighed and placed in the friabilator, which was operated at 25 rpm for 4 min. The tablets were removed, dedusted, and reweighed. Percentage friability was calculated from the difference between initial and final tablet weights[17-20].

Weight Variation

Twenty tablets from each formulation were weighed individually and the average tablet weight was calculated. Individual tablet weights were compared with the average weight to determine the percentage deviation [17-20].

Tablet Thickness

Tablet thickness was measured using a vernier caliper. Measurements were obtained from randomly selected tablets from each formulation and expressed in millimeters [17-20].

Disintegration Time

Disintegration time was determined using a USP disintegration apparatus (Electrolab ED-2L, Mumbai, India). The tablets were placed in the disintegration medium maintained at 37 ± 2°C. The time required for complete disintegration of each tablet was recorded [21-22].

Drug Content

Ten tablets from each formulation were crushed and powder equivalent to 30 mg of Aprepitant was accurately weighed. The powder was dissolved in PBS (pH 6.8), suitably diluted, and filtered through Whatman filter paper.

The absorbance of the resulting solution was determined spectrophotometrically at 264 nm using PBS as the blank. Drug content was calculated from the calibration curve [23-25].

Wetting Time

Wetting time was determined using the tissue-paper method. A piece of tissue paper was placed in a Petri dish containing PBS, and a tablet was carefully placed on the moistened tissue. The time required for complete wetting of the tablet surface was recorded [26-27].

In vitro dissolution studies

The in vitro dissolution behavior of the prepared Aprepitant ODTs was investigated using a USP Type II dissolution apparatus (Electrolab TDT-08). The dissolution medium consisted of 900 mL PBS (pH 6.8), maintained at 37 ± 0.5°C. The paddle rotation speed was maintained at 50 rpm. At predetermined intervals, 5 mL aliquots were withdrawn and immediately replaced with an equal volume of fresh dissolution medium maintained at the same temperature. The withdrawn samples were filtered through 0.45 µm membrane filters and suitably diluted. Drug concentration was determined spectrophotometrically at 264 nm. The cumulative percentage drug release was calculated [28-30].

RESULTS AND DISCUSSION

Solubility Enhancement of Aprepitant

Aprepitant exhibited poor aqueous solubility, which may adversely affect its dissolution and oral absorption. Therefore, solid dispersion technology was explored as a means of improving its aqueous solubility. PEG 4000 and PEG 6000 were selected as hydrophilic carriers, while β-cyclodextrin was investigated for its potential inclusion-complexation properties.

The prepared systems were evaluated for solubility and drug content. The solubility of the developed formulations ranged from 0.81 to 3.91 mg/mL, demonstrating a substantial improvement compared with the poorly water-soluble drug. Drug content ranged from 97.24% to 99.31%, indicating satisfactory incorporation and distribution of Aprepitant within the carrier systems.

Among the investigated formulations, SD4 showed the highest solubility of 3.91 mg/mL and drug content of 99.31%. The superior performance of SD4 may be attributed to the hydrophilic nature of PEG 6000, which can improve drug wetting and dispersion and facilitate dissolution. The enhanced solubility obtained with SD4 justified its selection for subsequent ODT formulation.

Table 2. Solubility and drug content of Aprepitant solid dispersion systems

Formulation	Solubility (mg/mL)	Drug content (%)
SD1	0.81	97.24
SD2	1.42	97.93
SD3	1.82	98.96
SD4	3.91	99.31
DC1	0.92	97.55

The progressive improvement in solubility observed in the solid dispersion systems suggests that selection of carrier type and drug-to-carrier ratio had a significant influence on the apparent aqueous solubility of Aprepitant. SD4, prepared using PEG 6000 at a 1:2 drug-to-carrier ratio, demonstrated the most pronounced enhancement.

Pre-compression Characteristics

The flow properties of the powder blends were assessed using angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio. The angle of repose values ranged from 25.5° to 29.6°, indicating acceptable flow characteristics. Bulk density values varied between 0.36 and 0.45 g/mL, whereas tapped density ranged from 0.45 to 0.56 g/mL. Carr's index was found to range from 8.69% to 30.35%, while Hausner's ratio ranged from 1.09 to 1.43.

Formulation F4 exhibited the lowest Carr's index and Hausner's ratio, indicating comparatively better flow and compressibility. Although some variation was observed among the formulations, the powder blends were considered suitable for compression into tablets under the employed processing conditions.

Table 3. Pre-compression characteristics of Aprepitant ODT powder blends

Formulation	Angle of repose (°)	BD (g/mL)	TD (g/mL)	CI (%)	HR
F1	28.2	0.36	0.49	26.53	1.36
F2	25.5	0.39	0.56	30.35	1.43
F3	28.1	0.39	0.48	18.75	1.23
F4	29.6	0.42	0.46	8.69	1.09
F5	25.7	0.40	0.46	13.04	1.15
F6	27.2	0.38	0.45	15.55	1.18

F7	27.1	0.41	0.53	22.64	1.29
F8	27.8	0.39	0.46	15.21	1.17
F9	27.4	0.45	0.54	16.66	1.20

Post-compression Evaluation

The prepared ODTs were evaluated for physical and pharmaceutical quality attributes. Hardness values ranged from 2.7 to 3.1 kg/cm², indicating adequate mechanical strength. The relatively low hardness of the tablets was considered advantageous because ODTs require sufficient integrity during handling while maintaining rapid disintegration.

Friability values ranged from 0.62% to 0.68%, remaining below the commonly accepted pharmacopeial limit of 1%. This indicates that the prepared tablets possessed satisfactory resistance to mechanical abrasion. The tablet weights showed acceptable uniformity, with individual formulations exhibiting average weights between 97.4 and 100.8 mg in the reported evaluation. Tablet thickness ranged from 2.2 to 2.5 mm, indicating relatively uniform compression.

Drug content ranged from 95.20% to 98.84%, demonstrating satisfactory uniformity of Aprepitant throughout the formulations. The differences in drug content among formulations were relatively small and remained within an acceptable formulation-development range. Disintegration time was markedly affected by the type and concentration of superdisintegrant. The fastest disintegration was observed with F3, containing crospovidone at the highest investigated concentration, with a disintegration time of 21 s. The corresponding wetting time was also comparatively low at 30 s.

The rapid disintegration of crospovidone-containing formulations may be associated with its strong wicking action, which facilitates rapid penetration of the dissolution medium into the tablet matrix. In contrast, the formulations containing SSG and CCS exhibited relatively longer disintegration times under the investigated conditions.

Table 4. Post-compression evaluation of Aprepitant ODTs

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Hardness (kg/cm²)	2.8	2.7	2.8	3.1	2.9	2.9	3.0	2.8	2.7
Weight (mg)	97.8	97.8	99.2	97.4	98.5	98.2	100.8	98.6	97.5
Thickness (mm)	2.5	2.4	2.4	2.5	2.3	2.2	2.5	2.5	2.4
Friability (%)	0.68	0.66	0.62	0.67	0.66	0.62	0.68	0.65	0.63
Drug content (%)	95.20	98.84	98.84	98.15	98.02	98.26	97.58	98.18	98.37
Disintegration time (s)	63	46	21	74	57	35	64	48	36
Wetting time (s)	42	34	30	44	38	31	44	39	32

In Vitro Drug Release

The dissolution behavior of the Aprepitant ODT formulations was investigated in PBS (pH 6.8). All formulations exhibited relatively rapid drug release, demonstrating the combined influence of solid dispersion technology and superdisintegrant incorporation. The solid dispersion component improved the wettability and apparent dissolution of Aprepitant, while the superdisintegrants facilitated rapid breakup of the compressed tablet matrix. Faster tablet disintegration increased the surface area of the dispersed drug available to the dissolution medium, thereby contributing to enhanced drug release. Among the three superdisintegrants examined, crospovidone-containing formulations demonstrated the most favorable dissolution behavior. The overall dissolution performance followed the order:

Crospovidone > Sodium starch glycolate > Croscarmellose sodium

The superior performance of crospovidone may be related to its rapid wicking mechanism and porous structure, which promote rapid penetration of dissolution medium into the tablet. F3 exhibited the most favorable overall performance, combining the shortest disintegration time with rapid drug release. More than 80% drug release was achieved within 5 min for most formulations, with F1 showing comparatively slower release. The optimized formulation F3 demonstrated rapid dissolution and approximately complete drug release within 15 min. These results demonstrate that combining an optimized Aprepitant solid dispersion with a suitable superdisintegrant can effectively address the drug's poor aqueous solubility while producing a rapidly disintegrating dosage form (Figure 1-3).

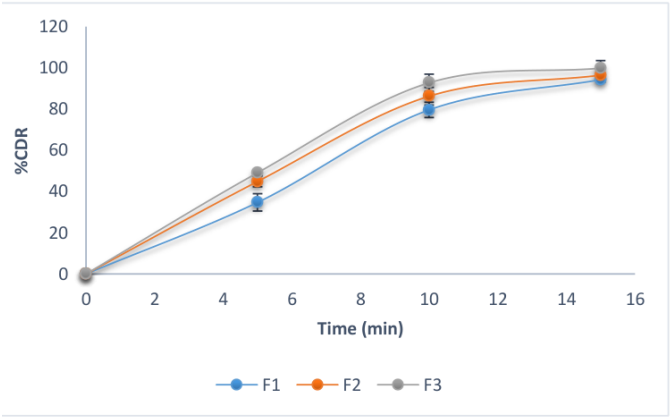

Figure 1. Comparative in vitro drug release profiles of Aprepitant ODT formulations F1-F3.

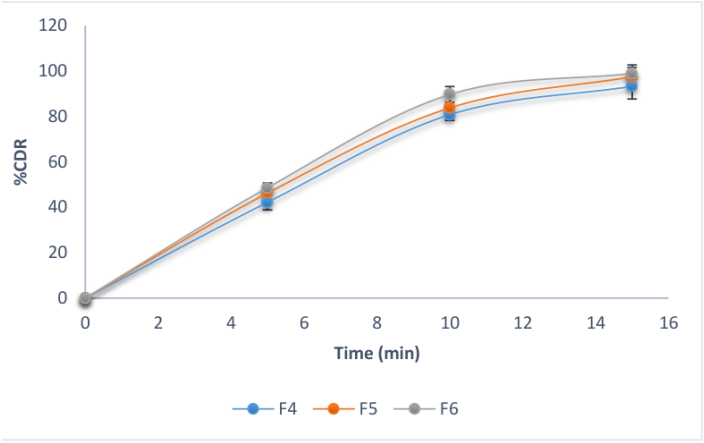

Figure 2. Comparative in vitro drug release profiles of Aprepitant ODT formulations F4-F6.

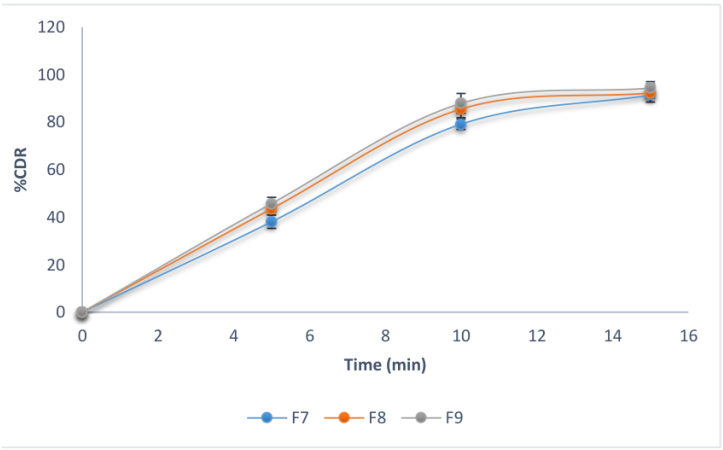

Figure 3. Comparative in vitro drug release profiles of Aprepitant ODT formulations F7-F9.

Selection of Optimized Formulation

Based on the combined evaluation of tablet characteristics, disintegration time, wetting behavior, and dissolution performance, formulation F3 was selected as the optimized Aprepitant ODT formulation. F3 contained crospovidone as the superdisintegrant at the highest investigated concentration. The formulation exhibited a hardness of 2.8 kg/cm², friability of 0.62%, drug content of 98.84%, disintegration time of 21 s, and wetting time of 30 s. These characteristics demonstrate a desirable balance between tablet mechanical strength and rapid disintegration.

The rapid drug release from F3 can be attributed to the synergistic effect of the optimized PEG 6000-based solid dispersion and crospovidone. The solid dispersion enhanced the apparent solubility and dissolution of Aprepitant, whereas crospovidone promoted rapid tablet disintegration and exposure of the drug particles to the dissolution medium.

Conclusion

The present study successfully demonstrated the development of Aprepitant orally disintegrating tablets using a solid dispersion-based solubility enhancement approach. The major formulation challenge associated with

Aprepitant, namely its poor aqueous solubility, was addressed through incorporation of the drug into hydrophilic carrier systems.

Among the prepared solid dispersions, SD4 containing Aprepitant and PEG 6000 at a 1:2 ratio exhibited the most favorable characteristics, including enhanced solubility of 3.91 mg/mL, high drug content of 99.31%, and rapid drug release. The optimized solid dispersion was subsequently used for the preparation of ODTs containing different concentrations and types of superdisintegrants.

All developed ODT formulations exhibited satisfactory physical and pharmaceutical characteristics. The hardness, friability, tablet thickness, weight variation, and drug content were within acceptable ranges. The type of superdisintegrant substantially influenced the disintegration and dissolution behavior of the tablets.

Among the investigated superdisintegrants, crospovidone provided the most favorable performance. Formulation F3 demonstrated the shortest disintegration time of 21 s, a wetting time of 30 s, satisfactory mechanical strength, and high drug content. The dissolution studies further confirmed the superior performance of crospovidone-containing formulations, with the overall dissolution efficiency following the order crospovidone > sodium starch glycolate > croscarmellose sodium.

Stability assessment of F3 for three months under refrigerated, room-temperature, and accelerated conditions demonstrated no significant physical changes and only minimal variation in drug content. Therefore, the optimized Aprepitant ODT formulation may represent a promising patient-oriented dosage form capable of providing rapid tablet disintegration and enhanced dissolution of Aprepitant.

The developed formulation has potential advantages for patients requiring antiemetic therapy, particularly those who experience difficulty swallowing conventional tablets or require a dosage form capable of rapid oral disintegration. Further pharmacokinetic and clinical investigations would be necessary to establish whether the enhanced in vitro dissolution characteristics translate into improved in vivo bioavailability and therapeutic performance

Conflicts of Interest: The authors declare that there are no conflicts of interest.

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