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FLUNARIZINE FAST DISSOLVING TABLETS CREATED AND STUDIED USING SUPERDISINTEGRATED COMBINATIONS AND SUBLIMATED MATERIALS

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ABSTRACT
Modern medicine, the formulation requirements were rigorous, and tablet and capsule medication has many advantages over powder and pill medications. Tablets are the most popular form of pharmaceutical dosage form in the world, taking up the largest share of all pharmaceutical dosage forms. Deliver drugs with low molecular weight and high permeability. It is also possible to improve powder compressibility during tablet formation by using powder granulations, which provide this free flow, increase material density, and increase material density during tablet formation.

Key words: Modern medicine, Solid dosage form, Fast dissolving tablets, Flunarizine Hydrochloride.

INTRODUCTION

The solid unit dosage forms, even those that contain several normal doses of medication but are administered as a single unit, are referred to together as solid unit dosage forms because they contain the same amount of medication. In modern medicine, the formulation requirements were rigorous, and tablet and capsule medication has many advantages over powder and pill medications [1].

Approximately 70% of all medicines were dispensed as tablets; they are the most popular dosage form. Based on the medicinal substance and the intended mode of administration, tablets came in a variety of shapes, sizes, and weights.

Tablets are the most popular form of pharmaceutical dosage form in the world, taking up the largest share of all pharmaceutical dosage forms.

It is important that many factors are taken into consideration when designing and optimizing a perfect and successful tablet [2].

Types of tablets

In order to make a good tablet, many excipients can be added to a drug when it comes to excipients. There is a key point to be considered when it comes to the mechanical and chemical properties of excipients.

Depending on the method of drug delivery, tablet dosage forms can be classified into the following categories:

Simple uncoated tablets, Coated tablets, Effervescent tablets, Buccal and sublingual tablets, Chewable tablets, Fast disintegrating tablets, Vaginal tablets, Osmotic tablets, Controlled release tablets, Multicomponent tablets, Sugarcoated tablets [3].

Tablet manufacturing operations

Compression of tablet tablets can be achieved in three ways: wet granulation, dry granulation, and direct compression. To provide the desired characteristics for tablet manufacture and efficacy, powdered medicinal agents require excipients such as diluents, binders, disintegrants, and lubricants.

High-speed compression of powder mix into tablets requires flowability of drug mixture from the hopper of the tablet press into the dies [8]. It is also possible to improve powder compressibility during tablet formation by using powder granulations, which provide this free flow, increase material density, and increase material density during tablet formation [4].

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Advantages of ODTs

- When saliva passes down the esophagus, pharynx, and mouth into the stomach, it enhances bioavailability, resulting in reduced dosage and improved clinical performance [9].
- Motion sickness, allergic attacks or coughing that requires rapid action may benefit from it.
- The perfect solution for patients who can't access water right away while traveling
- Deliver drugs with low molecular weight and high permeability.
- A minimum number of ingredients makes them cost-effective for manufacturing insoluble and hydrophobic drugs are more bioavailable when dissolving in tablets because of rapid disintegration and dissolution [5].

METHODOLOGY

Procurement of Active drug and excipients

Flunarizine Hydrochloride

Flunarizine Hydrochloride was procured from Angle Biopharma, Gujarat, India.

Excipients

The excipients which utilised for the formulation was procured from local supplier, Telengana, Andhra Pradesh

Equipment used

A. Preparation of Standard calibration curve of flunarizine

Preparation of Buffer solution:

Simulated gastric fluid (SGF) without enzyme was prepared according to the USP. 2.0 g of sodium chloride was dissolved in 7.0 mL of hydrochloric acid and sufficient DI water added to make 1000 mL, 1.2 of pH adjusted using digital pH meter.

Preparation of Standard stock solution

Standard stock solution was prepared by accurately weighed 10 mg of flunarizine using digital balance and transferred to a 500 ml volumetric flask. 250 mL of simulated gastric fluid was added to the same volumetric flask and swirled for solublization.

The drug was dissolved completely and the final volume was adjusted with SGF up to 500mL. This solution has a concentration 20 µg/mL and was used as standard stock solution.

From this standard stock solution, serial dilutions were made by using SGF in order to have a concentration of 2, 4, 6, 8, 10, 15, and 20 µg/mL, and the absorbance of the diluted solutions were measured to construct the calibration curve.

Preparation of Sample solution

5 mL sample solutions were prepared to have a concentration of 2, 4, 6, 8, 10, 15, and 20 µg/mL. The standard stock solution was used as the highest concentration of the linearity range study. The required concentrations of sample solutions were prepared from the standard stock solution based on the following equation 1

Amount of drug (µg) = Conc. of drug (µg/ml) X Vol. (ml)

Measurement of Absorbance and calibration curve

Flunarizine hydrochloride is a UV absorbing molecule that has specific chromophore which absorb at a particular wavelength. It was successfully quantified by using Agilent G UV-Vis Spectrophotometer.

The absorbance of solutions containing 10µg/ml was determined in UV range 200-800 nm using SGF as blank. The λ max was found to be at 295nm. At this wavelength maximum, calibration curve was drawn by plotting graph between absorbance and concentration.

Calibration curve data were constructed in the range concentrations 2 to 20 µg/mL. Beer's law was obeyed over this concentration range. According to the law, the absorbance is directly proportional to the path length (b) and the concentration (c) of the absorbing material.

For a quantitative determination of analyte species of unknown concentrations in a solution, a calibration curve of absorbance versus concentration of known analyte concentrations must be constructed with linear regression.

The absorbance for the Flunarizine can be measured using UV-Vis and the concentration can be extrapolated from the calibration curve [6].

B. Preparation of Flunarizine powder mixtures with Superdisintegrants

Preparation of Flunarizine hydrochloride orodispersible tablets was occurred by using two super disintegrants excipients Primojel and Polyplasdone XL.

Preparation of orodispersible tablets containing 100 mg of powder mixtures were mixed according to tablet 3 for the super disintegrants Primojel and Polyplasdone XL.

C. Preformulation studies to evaluate powder mixture

Angle of Repose [7]

The angle of repose was determined according to a recommended procedure described in USP 36. Therefore, the height of the funnel should be maintained approximately 2-4 cm from the top of the powder pile as it is being formed in order to minimize the impact of the falling powder on the tip of the cone.

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The angle of repose was then calculated according to the USP by measuring the height and the base of the heap of powder formed and using equation: 2

$$\Theta = \tan^{-1} \times \text{height} / 0.5 \times \text{base}$$

Bulk Density

This is the ratio of the total mass of powder to the bulk volume of powder. Accurately weigh a portion of powder mixture (40 g) and transfer it to a 100 ml graduated cylinder.

The mixture was carefully levelled without compacting, and read as the unsettled apparent volume (Vo). Loose bulk density can be calculated based on equation: 3 and expressed in g/ml:

Bulk density = Mass of powder/ unsettled volume Vo

Tapped Bulk density

This is the ratio of total mass of the powder to the tapped volume of the powder. Accurately weigh some quantity of powder mixture (40g) and transfer it to a 100 ml graduated cylinder.

The cylinder containing the sample was manually tapped. The final tapped volume (V_f) was then measured to the nearest graduated units. Tapped bulk density can be calculated based on equation: 4 and expressed in g/ml:

Tapped Bulk density = Mass of powder/ final tapped volume V_f

Carr's Index

Equation: 5 describe the calculation of the compressibility Index of the powder mixture by using bulk density and tapped density. It measures the powder flowability and is expressed in percentage

$$\text{Compressibility Index (\%)} = 100 \times \frac{\rho tapped - \rho bulk}{\rho tapped}$$

Hausner's ratio

The Hausner ratio is a number that is correlated to the flowability of a powder or granular material. It is an indirect index to measure the ease of powder flow.

Equation 6 describes the calculation of Hausner's Ratio

$$\text{Hausner's ratio} = \frac{\rho tapped}{\rho bulk}$$

D. Formulation of Orodispersible tablets of Flunarizine

By using direct compression methods

After the preparation of flunarizine hydrochloride powder mixture, orally disintegrating tablets of flunarizine were prepared according to the formula given in table 3 by direct compression method. A 100 mg of Flunarizine ODTs were manufactured by compressing the powder blend with 5.64 mm round, convex tableting punch set using a Manesty A28 Tableting Press. The compression force was adjusted to produce tablets with a hardness of 35-45 N.

E. Evaluation of Orodispersible tablets of Flunarizine

Tablets Appearance

Twenty tablets of each formulation were tested to check any discoloration or surface roughness in tablet formulation.

Weight variation

Ten (10) tablets of each batch formulation were selected randomly and weighed in grams individually and accurately using digital balance. Figure 6 illustrates an Intelligent Weighing Technology's model PM-300 balance.

Hardness and Thickness

It is the force required to break the tablet into halves by compression in the diametrical direction.

Ten (10) tablets were selected randomly and measured individually for thickness and hardness using Sotax Hardness Tester.

The tablets measured in mm for the thickness and Newton (N) for the breaking force using USP Standard method.

Friability test

The tablet friability test determination was achieved accodring to the United States Pharmacopeia and National Formulary (USP 36-NF 31) using an Erweka Friability Apparatus. The test measured to simulate shipping and packaging stress. The USP 36 recommends the total tablet sample should be taken corresponding as near as possible to 6.5 g for tablets with a unit weight equal to or less than 650 mg.

The tablets were carefully dedusted prior to testing. Accurately the tablet samples were weighed (recorded as initial weight), and placed in the drum. The drum was rotated up to 100 revolutions at 25 rpm for 4 minutes.

After that time lapse, any loose dust was removed from the table samples by using a brush, and accurately reweighed (recorded as final weight). Equation 7 describes the calculation of friability percentage

$$\text{Friability (\%)} = \frac{(\text{Weight initial} - \text{weightfinal})}{\text{Weight initial}} \times 100$$

If obviously cracked, cleaved, or broken tablets were present in the tablet sample after tumbling, the sample fails the test. If the results are difficult to interpret or if the weight loss is greater than the targeted value, the test should be repeated twice and the mean of the three tests determined.

The maximum mean weight loss from the three samples is not more than 1.0% which is considered acceptable for most products.

In vitro Disintegration test

The test was carried out on six tablet using DI water at 37±5 °C as a medium and Erweka disintegration apparatus according to USP 36-NF 31standard basket method with disks.

Each tablet should be placed in each of the six tubes of the disintegration basket apparatus; one disc was added to each tube, and run for disintegration time. In case if one or two tablets fail to disintegrate completely, the test must be repeated at least on 12 additional tablets. The USP requires at least 16 of the total of 18 tablets that tested are disintegrated.

In vitro Dissolution test

In vitro dissolution test of flunarizine hydrochloride ODT was performed triplicate for each batch using simulated gastric fluid (SGF) and AT 7smart Dissolution Apparatus from SOTAX. It is a dissolution apparatus that compliant with all pharmacopeia methods including USP 1,2,5,6. 900 mL of the hydrochloric acid buffer of pH 1.2 was used as dissolution medium. The paddle speed was adjusted to rotate at 50 rpm. The temperature of dissolution medium was maintained at 37±0.5ºC throughout the experiment. One flunarizine orally disintegrating tablet was placed in each flask of dissolution apparatus. Aliquot of 5 mL was withdrawn at predetermined time interval (10, 20, 30, 40, 50 seconds, 1, 2, 4 and 6 min.). The collected samples were analyzed at λ max 295 nm using the dissolution medium (SGF) as blank in order to determine metoclopramide hydrochloride concentration. The cumulative percentage amount of drug release was calculated and plotted against time.

RESULTS AND DISCUSSION

Flunarizine Hydrochloride orodispersible tablets were prepared using various ratios of super disintegrants by direct compression. The super disintegrants Primojel and Polyplasdone XL were used in various concentrations, namely 3%, 5%, and 7% to formulate the orally disintegrating tablets. The absorbance of the diluted solutions for flunarizine was measured using UV-Vis and the concentrations were extrapolated from the calibration curve. Table 3 represents the linearity range study of flunarizine in simulated gastric fluid at 295 nm. Figure 9 illustrates the constructed calibration curve for flunarizine. The linearity was found to be between 2-20 µg/mL. Equation 8 describes the regression equation that was obtained from the sample solutions. The correlation coefficient (R2) of the standard curve was found to be 0.999 which established high linearity.

For direct compression, the flowability of the powder blend is very important. Therefore, two methods were used for powder flowability measurements.

The bulk density and tapped density for the powder blends were determined to calculate the Hausner ratio and Carr's index.

Angle of Repose

Table 4 provides the data obtained for the angle of repose for all the batches prepared. The values were found to be in the range of 30.96 to 33.82, which indicates good flow property for the powder blend according to the USP.

Bulk density and Tapped Bulk density

The bulk density and tapped density for all the batches varied from 0.38 to 0.45 g/mL and 0.52 to 0.64 g/mL mentioned in the table 5

Carr's index and Hausner's ratio

Carr's index values were found to be in the range of 21.86 to 24.77, which is satisfactory for the powders as well as implies that the blends have good compressibility. Hausner's ratio values obtained were in the range of 1.20 to 1.25, which shows a passable flow property for the powder blend based on the USP. The result has shown below table: 6

Evaluation of Orodispersible tablets of Flunarizine

The evaluation parameters for flunarizine hydrochloride tablets such as appearance, weight variation, thickness, hardness, friability, disintegration and dissolution has been studied

Tablets Appearance

ODTs were prepared and examined visually for shape and colour. A white colour and concaved surface with circular shape was observed after compressing the formulations.

Weight variation

All tablets passed the weight variation test and were found to be within the acceptable limit according to the USP (±10%). The table 8 show the result of weight variations of ODTs.

Hardness and Thickness

The results for tablet thickness for all batches were found to range from 4.72 to 4.75 mm, respectively. Hardness or breaking force of tablets for all batches was found to range from 33.8 to 42.6 N. Tablet formulations must show good mechanical strength with sufficient hardness in order to handle shipping and transportation. The result has shown in table 8

Friability test

Friability values for all the formulations were found to be in the range of 0.23 % to 0.39 %. The results obtained were found in table 10 showing the acceptable

range (<1%), indicating sufficient mechanical integrity and strength for the prepared tablets according to the USP

***In vitro* Disintegration test**

The disintegration time test was used based on the USP. According to the test, all of the tablet formulations should disintegrate completely within one minute which indicates faster disintegration.

The per cent drug content for all the formulation was calculated by measuring the absorbance at the wavelength 295 nm, and was found to be between 97.50% to 101.18%, which is within the acceptable limits as per USP.

The result was found in table 10

In vitro Dissolution test

Table 11 provides the *in vitro* drug release profile for all the formulation (F1 to F6). The ODT formulation for flunarizine showed an average range of 97.50 to 101.2 % drug release at the end of 6 minutes.

Figure 2 illustrates the comparative *in vitro* drug release profile for flunarizine HCl for formulations F1 to F6. It was observed that only the formulations with Polyplasdone XL (F1, F2, and F3) took the shortest time to release more than 91% of the drug at the end of 1 minute.

TABLE 1: Equipment used for preparation and evaluation.

S. No	Equipment	Model
1	Analytical digital balance	Intelligent Weighing Technology's model PM-300
2	Hardness tester	Sotax Hardness tester
3	Friability test apparatus	Erweka model
4	Tablet punching machine	Manesty Tableting Press, Liverpool No. 2L187
5	Disintegration apparatus	Erweka model
6	Dissolution apparatus	Sotax At model
7	UV-Spectrophotometer	Agilent G1103A

TABLE 2: Orodispersible tablets of formulation included the API and excipients.

Ingredients	Quantity per tablet in mg					
	F1	F2	F3	F4	F5	F6
Flunarizine HCl	10	10	10	10	10	10
Microcrystalline cellulose	40	40	40	40	40	40
Trehalose	43	41	39	43	41	39
Crospovidone (Polyplasdone XL)	3	5	7	-	-	-
Primojel (sodium starch glycolate)	-	-	-	3	5	7
Talc	3	3	3	3	3	3
Magnesium stearate	1	1	1	1	1	1
Total weight	100	100	100	100	100	100

TABLE 3: Linearity range study at 295nm

Sample number	Concentration	Absorbance (nm)			Average
		Reading I	Reading II	Reading III	
1	20	0.7429	0.7436	0.7462	0.7444
2	15	0.5463	0.5457	0.5524	0.5478
3	10	0.3529	0.3550	0.3557	0.3547
4	8	0.2821	0.2813	0.2950	0.2858
5	6	0.2032	0.2044	0.2053	0.2043
6	4	0.1243	0.1281	0.1283	0.1268
7	2	0.0561	0.0567	0.0567	0.0566

Table 4: Flow properties of flunarizine powder.

Formulation	Flow properties	
	Angle of repose	According to USP
F1	30.96±0.28	Good
F2	31.49±0.79	Good

F3	31.58±0.36	Good
F4	33.82±0.86	Good
F5	32.79±0.95	Good
F6	33.31±1.04	Good

Table: 5 Bulk density and tapped density of flunarizine powder

Formulation	Density (g/ml)	
	Bulk density	Tapped density
F1	0.41±0.002	0.57±0.001
F2	0.38±0.001	0.52±0.002
F3	0.40±0.001	0.57±0.002
F4	0.44±0.001	0.63±0.005
F5	0.45±0.001	0.64±0.001
F6	0.45±0.001	0.64±0.002

Table: 6 Carr's index and Hausner's ratio of powder.

Formulation	Flow properties		
	Carr's index	As per USP	Hausner's ratio
F1	23.30±0.15	Pass	1.22±0.003
F2	21.86±0.20	Pass	1.20±0.004
F3	24.25±0.32	Pass	1.24±0.006
F4	24.64±0.51	Pass	1.24±0.009
F5	24.67±0.851	Pass	1.24±0.015
F6	24.77±0.30	Pass	1.25±0.006

Table: 7 Weight variations of ODTs

Formulation	Weight variation$^{\alpha}$ (mg)
F1	100.9±3.09
F2	103.8±1.20
F3	100.4±2.35
F4	103.5±1.19
F5	102.2±1.79
F6	099.9±1.09

α = each value represents the mean ± standard deviation (n=10).

Table: 8 Hardness and Thickness of ODTs

Formulation	Thickness$^{\alpha}$	Hardness$^{\alpha}$ (N)
F1	4.75±0.05	33.8±3.57
F2	4.73±0.03	39.8±5.02
F3	4.74±0.04	38.8±1.90
F4	4.72±0.04	42.8±1.96
F5	4.73±0.03	34.2±1.77
F6	4.75±0.02	37.5±8.52

α = each value represents the mean ± standard deviation (n=10).

Table: 9 Friability test of ODTs

Formulation	Friability test (%)
F1	0.39
F2	0.23
F3	0.28
F4	0.39
F5	0.26
F6	0.23

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Table: 10 Disintegration time and per cent of drug content of ODTs

Formulation	Disintegration time*	% Drug content$^{\beta}$
F1	18.10±1.0	99.95±5.02
F2	14.72±1.25	101.18±1.84
F3	11.71±1.24	100.49±1.65
F4	37.2±4.71	97.77±0.45
F5	23.73±1.51	100.01±1.45
F6	49.70±2.49	97.50±0.75

β: each value represents the mean ± standard deviation (n=3).
***: Disintegration time must be less than 1 minute according to the USP monograph**

Table: 11 Cumulative percent Drug release of all formulation.

Time (min)	Cumulative percent Drug release of all formulation					
	Polyplasdone XL 3% (F1)	Polyplasdone XL 5% (F2)	Polyplasdone XL 7% (F3)	Primojel 3% (F4)	Primojel 5% (F5)	Primojel 7% (F6)
0	0	0	0	0	0	0
0.08	4.32±1.95	4.51±0.74	5.77±1.36	5.76±1.25	6.28±0.35	6.38±0.05
0.16	6.33±2.32	10.75±1.15	6.77±1.06	5.88±1.13	7.41±1.35	6.59±1.25
0.25	13.01±2.06	22.55±8.36	16.02±3.25	6.75±2.15	11.50±4.25	7.85±0.05
0.33	30.17±0.69	41.25±12.95	25.23±6.18	9.0±3.15	13.63±8.19	8.57±1.05
0.41	47.79±8.46	52.20±9.95	44.49±10.98	11.24±4.98	19.43±8.15	9.59±1.01
0.5	70.88±5.15	68.14±5.98	62.09±16.98	17.23±9.12	27.89±10.96	13.08±1.12
0.66	82.95±3.02	81.15±4.12	75.51±6.87	26.55±13.94	50.26±21.99	18.84±1.85
0.83	89.82±1.84	88.27±0.58	88.34±1.45	38.09±21.06	61.25±26.92	25.70±3.54
1	**93.40±1.23**	**91.97±1.39**	**94.34±1.05**	**50.89±23.65**	**73.26±29.65**	**28.67±2.58**
2	98.74±4.76	99.45±1.49	99.35±1.45	87.13±6.95	96.30±2.45	49.40±9.51
4	99.19±5.12	100.53±1.25	100.37±1.59	96.37±0.25	99.09±1.15	86.44±13.2
6	99.9±5.87	101.20±1.58	100.60±1.69	97.86±0.45	100.03±2.18	97.52±0.74

Figure 1: standard calibration curve of Flunarizine hydrochloride

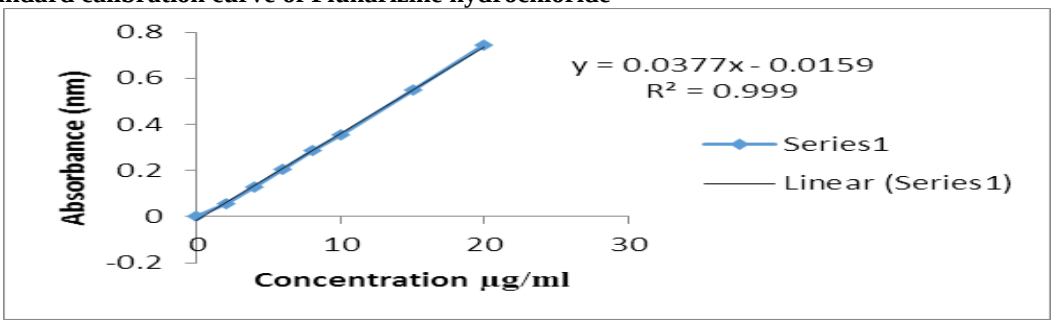
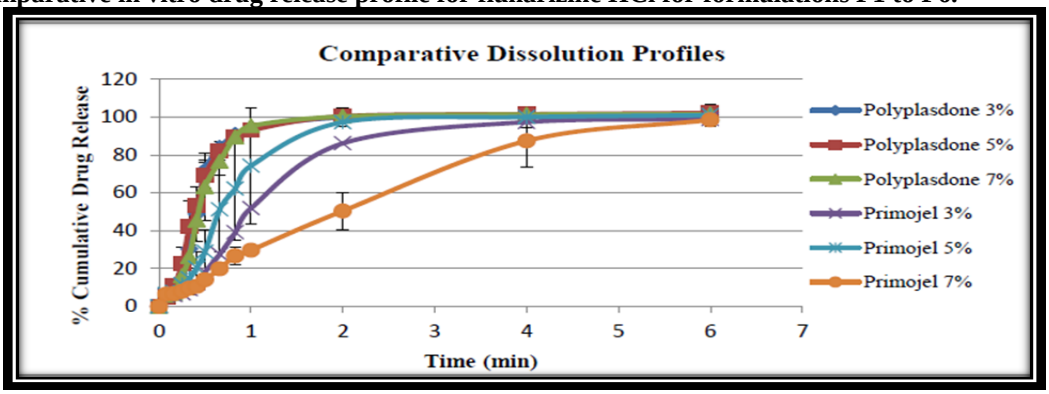


Figure 2: comparative in vitro drug release profile for flunarizine HCl for formulations F1 to F6.



SUMMARY AND CONCLUSION

Flunarizine HCl orally disintegrating tablets were successfully formulated. We prepared the formulation by direct compression using different ratios of super disintegrants. For the optimal batch, Primojel® and Polyplasdone XL® were used at various concentrations, namely 3%, 5%, and 7%.

As a pre-compression parameter, we analyzed Bulk density, Tapped density, Carr's index, Hausner's ratio, and Angle of repose of flunarizine tablets prepared with the above super disintegrant excipients. For the optimized batch, parameters such as weight variation, hardness, friability, disintegration time, dissolution analysis, and uniformity of drug content should be analyzed after compression.

Initially, powder blends for formulations were evaluated according to their flow ability. Also, the powder blends had satisfactory Carr's index values, indicating that they were compressible. On the basis of the USP, Hausner's ratio values were determined to be passable flow properties for the powder blend based on the values obtained.

For oral disintegrating tablets to survive shipping and transportation, they were compressed so that they would have sufficient structural strength and integrity. USP guidelines were met (less than one minute disintegration time) by the formulation.

Compression and mixing of powders resulted in an acceptable limit for drug content. Based on the dissolution profile and the disintegration time, an optimized batch containing 7% Polyplasdone XL was determined.

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