Research Article
CODEN (USA): IJPLCP

ISSN: 0976-7126
Makwana *et al.*, 11(12):7139-7147, 2020

International Journal of Pharmacy & Life Sciences
Open Access to Researcher
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Formulation and Evaluation of Pantoprazole Solid Dispersion Tablet

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Article info

Received: 05/11/2020

Revised: 25/11/2020

Accepted: 25/12/2020

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www.ijplsjournal.com

Abstract

The term solid dispersion refers to a bunch of solid merchandise consisting of a minimum of two completely different parts, usual a deliquescent matrix and a hydrophobic drug. Additionally to bioavailability improvement, a lot of recent analysis on solid dispersion systems was directed towards the event of extended-release indefinite quantity forms. Data regarding behavior of solid dispersions throughout preparation, storage and dissolution will facilitate to tackle these issues. An intensive understanding of processes that happens place on the molecular level could be a requirement for rational and a lots of economical style of solid dispersions. However, development of solid dispersions has typically been a trial-and-error approach. Solid dispersion ready by physical mixture technique were subjected to dissolution study. Two freelance variables selected were HPMC E5 and PVP K30 in the ratio of 1:1, 1:2 and 1:3. The target achieved and these findings recommended that the preceding technique may be utilized with success for improvement of solubility profile and stability of Solid dispersions of poor water soluble drugs.

Keywords: Solid dispersion, Solubility, Pantoprazole, bioavailability, HPMC E5, PVP K30

Introduction

The oral route of drug administration is the most common and preferred method of delivery due to convenience and ease of ingestion but it is problematic if the drug is poorly soluble or poor membrane penetrability[1]. Although salt formation, solubilization, particle size reduction have commonly used to increase dissolution rate and thereby oral absorption and bioavailability of low water soluble drugs[2-4], there is practical limitation to these techniques. Among numerous ways of enhancing drug dissolution solid dispersion of drug in a water soluble polymer is one of the promising technique[5]. Solid dispersion (SD) is defined as the dispersion of one or more active ingredients in inert carriers at solid state prepared by fusion, solvent or solvent fusion methods[6-8].

Pantoprazole is a proton pump inhibitor, used in the treatment of digestive ulcers. It is a prodrug that degrades once protonated in acidic media. So, the drug protonation for activation must occur inside the gastric parietal cells, and the tetra cyclic form of Pantoprazole binds irreversibly to cystein residues of the proton pump (H+/K+ ATPase).

Solid dispersion technique has been used for a wide variety of poorly aqueous soluble drugs such as Nimesulide, Ketoprofen, Tenoxicam, Nifedipine, Aceclofenac, Valdecoxib using various hydrophilic carriers like polyethylene glycol, polyvinyl pyrrolidone, hydroxyl Propyl methyl cellulose, sugar, mannitol, urea etc.

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In this study pantoprazole was used as model drug and hydroxyl Propyl methyl cellulose and polyvinyl pyrrolidone K 30 were used as carriers in 1:3 ratios. Administering the drug in solid dispersion enhances the dissolution and immediate release, as oral administration of drug is used in peptic ulcer and heartburn.

Solid dispersion

The term solid dispersion alludes to a gathering of strong items comprising of at any rate two distinct segments, by and large a hydrophilic lattice and a hydrophobic medication. The most regularly utilized the hydrophilic transporters for the strong scatterings incorporate polyvinylpyrrolidone (Povidone, PVP), polyethylene glycols (PEGs), Plasdone-S630. Surfactants like Tween 80, docusate sodium, Myrj-52, Pluronic-F68, and sodium Lauryl sulfate (SLS) additionally discover a spot in the plan of strong scattering. The solvency of celecoxib, halofantrine, and ritonavir can be improved by strong scattering utilizing reasonable hydrophilic transporters like celecoxib with povidone (PVP) and ritonavir with gelucire. Different methods to set up the strong scattering of hydrophobic medications with expected to improve their watery dissolvability are recorded here.

Materials and Methods

Materials

Pantoprazole sodium was a gift from modern laboratories Pvt Ltd. Croscarmellose sodium, microcrystalline cellulose, Mannitol, Dicalcium Phosphate, Magnesium Stearate, Talc provided by the institution. All solvents used in the experiment are of analytical grade.

Preparation of solid dispersion [14]

Solid dispersion of Pantoprazole was prepared by melting and solvent method.

Table 1: Composition of Solid Dispersion

Formulation	Code Carrier	Drug carrier	Method
SD HPMC1 SD HPMC2 SD HPMC3	HPMC	1:1 1:2 1:3	Solid dispersion (Melting method)
SD PVP 4 SD PVP 5 SD PVP 6	PVP K 30	1:1 1:2 1:3	Solid dispersion (solvent evaporation method)
PM HPMC1 PM HPMC2 PM HPMC3	HPMC	1:1 1:2 1:3	Physical mixture
PM PVP 1 PM PVP 2 PM PVP 3	PVP K 30	1:1 1:2 1:3	Physical mixture

In melting method the drug and carrier polyethylene glycol 6000 were mixed in 1:1, 1:2, and 1:3 ratios in a china dish and heated on a paraffin bath. The mixture was poured on a tile and cooled. The resulted solidified mass was dried pulverized and passed through sieve # 100. In solvent evaporation method, the drug and carrier polyvinyl pyrolidone K 30 were mixed in 1:1, 1:2 and 1:3 ratios in methanol. Solvent was removed by evaporation under reduced pressure. The mass was pulverized and passed through sieve # 100.

Preparation of physical mixtures

For the sake of comparison, physical mixtures having the same composition of the solid dispersions were prepared by simply triturating the drugs and the polymers in a porcelain mortar. The mixtures were then sieved (420 μm) and stored in amber-glass capped containers.

Evaluation of Solid Dispersion

Estimation of drug content: The formulation equivalent to 40 mg of Pantoprazole was weighed and diluted suitably with distilled water. The absorbance was measured at 293 nm and the amount of drug in each formulation was calculated.

Differential Scanning Calorimetry: Differential scanning calorimetry was performed by Differential scanning calorimeter 60 shimadzu to obtain suitable thermograms. The accurately weighed sample was placed in an aluminium pan and an empty aluminium pan was used as reference. The experiment was performed under nitrogen flow, at a scanning rate 300C/min. in range of 50-3500C.

Infra red spectrum: Infra red studies was carried out to rule out interaction between drug and carrier used in formulation of solid dispersion by potassium bromide disc method using Infra red spectrophotometer.

Thermal studies: It was carried out to ascertain the effect of heating on stability of the drug. It is based on thaw point melt method by heating drug in capillary melting point tube and allowing it to solidify. The melting point of rapidly solidifying

ISSN: 0976-7126
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mass was noted.

Aqueous solubility studies: [15] it was carried out to determine solubility of terbinafine hydrochloride alone in aqueous medium and also in presence of carriers like polyethylene glycol 6000 and polyvinyl pyrolidone K30. This was done by dissolving excess drug in different flasks containing different concentration of carrier in distilled water. The flasks were shaken thoroughly for 6 hours and kept aside for 24hours. The suspensions were filtered, diluted suitably and absorbance was measured at 283nm.

Dissolution Studies: The in vitro dissolution studies were done to compare the rate of dissolution of solid dispersions with that of pure drug pantoprazole and physical mixtures. The test was performed in USP paddle apparatus using 900ml phosphate buffer solution at pH 7.4 and temperature 37+ 10C.

Tablet preparation and characterization: Composition containing equivalent of 500 mg of pantoprazole were compressed on single punch rotary tabletting press using 12.7mm round flat beveled punch by direct compression technique.

Preformulation study of powder material

Bulk density: The bulk density of the drug was evaluated using a bulk density apparatus. It was expressed in gm/ml and is given by

$$\text{Bulk Density } (\rho b) = \frac{\text{Mass of the powder (m)}}{\text{Volume of the bulk powder (vb)}}$$

Tapped density: It is the ratio of total mass of powder to the tapped volume of powder. The tapped volume was measured by tapping the powder to constant volume. It is expressed in gram/ml and is given by

$$\text{Tapped Density } (\rho t) = \frac{\text{Mass of the powder (m)}}{\text{Tapped volume of the powder (vt)}}$$

Compressibility Index or car's index: It is indirectly related to the relative flow rate, cohesiveness and particle size. It is simple, popular and fast method of predicting powder flow characteristics. It is based on the apparent bulk density and the tapped density, the percentage compressibility of the bulk drug was determined by the following formula.

$$\text{\% compressibility index} = \frac{\text{Tapped bulkdensity - Initial bulkdensity}}{\text{Tapped bulkdensity}} \times 100$$

Hausner's ratio: The ratio of the tapped density to bulk density is called as Hausner's ratio. It is an indirect index of ease of powder flow. It is calculated by the following formula.

$$\text{Hausner's ratio} = \frac{\text{Tapped density (Dt)}}{\text{Bulk density (Db)}}$$

Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25)

Angle of repose: Angle of repose was determined by Neumann's method and calculated using the formula, for unlubricated as well as lubricated granules.

$$\text{Tan } \theta = \frac{h}{r}$$

Where, h = height of pile, r = radius of the pile base

Calibration Curve of Pantoprazole

Measurement of spectra of Pantoprazole was done by using UV visible 1600 shimadzu double beam spectrophotometer. Absorbance was observed at 293 nm.

Standard stock solution

For standard stock solution(1000µg/ml), accurately weighed 100 mg of pantoprazole and transferred to a volumetric flask and 5ml methanol was added and then volume make up to the 100 ml by distilled water.

Dilutions preparation

From the standard stock solution of Pantoprazole, different dilutions were prepared. Seven different dilutions of 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml, 12µg/ml, and 14µg/ml were prepared from 1000µg/ml standard stock solution.

Procedure

After preparation of standard and sample solutions, measurement of the absorbance of different dilutions (2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml, 12µg/ml, 14µg/ml) in 1 cm cuvette by using UV-visible spectrophotometer.

Table 2: Formulation of Solid Dispersion of Pantoprazole

Formulation code	Pantoprazole	SLS	HPMC (15cps)	PVP K30
F1	5gm	125	5gm	
F2	5gm	250	5gm	
F3	5gm	375	5gm	
F4	5gm	475	5gm	
F5	5gm	125		5gm
F6	5gm	250		5gm
F7	5gm	375		5gm
F8	5gm	475		5gm

Ternary dispersions of Pantoprazole in were prepared using like PVP, HPMC as carriers and SLS as ternary agent. In formulations ratio of drug: carrier was maintained in constant ratio of 1:1 and SLS concentration was varied as shown in Table. The methods used for preparation of these dispersions were physical mixing and solvent evaporation methods.

Physical mixture

The physical mixtures were prepared by weighing the calculated amounts of Pantoprazole, carriers and SLS, then mixing them in a glass mortar by triturating. The resultant physical mixtures were passed through 44-mesh sieve and stored in desiccators until used for further studies.

Saturation solubility study

Solubility study was conducted as per the method reported by Higuchi and Connors. Excess quantity of the drug and TSD were taken for study. The solubility of Pantoprazole in pure drug and TSD was determined in 0.1N Hcl. Drug and TSD were weighed accurately and added to solvents in screw capped bottles separately. The bottles were shaken in an orbital shaker at 37 0C for 24 hrs. The sample was then filtered through Whatman filter paper and the filtrate was assayed spectrophotometrically at 293 nm.

Drug – Excipient interaction study

Physical observation of sample was done visually at every week for any change in the sample mixture for 4 weeks.

Discoloration

For discoloration study, drug was mixed with all the excipients and observed for any discoloration for 4 weeks.

Interaction

The compatibility of drug and various excipients was studied by Thin Layer Chromatography (TLC) technique. For study purpose, Pantoprazole sodium 10 mg was mixed thoroughly by mortar and pestle with excipient in ratio of 1:5 respectively and placed in tightly closed glass vials.

All the vials were kept at 40^0C for 4 weeks. The sample was analyzed by physical observation and thin layer chromatography before and after storage.

Table 3: Mobile phase preparation: Methanol: Ammonia are taken in the ratio of 70:30

Formula of Pantoprazole Sodium Tablet

Formulation code	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)
Pantoprazole Solid Dispersion	84 mg	84 mg	84 mg	84 mg	84 mg	84 mg
Croscarmellose sodium	2 mg	4 mg	6 mg	8 mg	10 mg	12 mg
Microcrystalline cellulose	28 mg	30 mg	32 mg	34 mg	36 mg	38 mg
Mannitol	50 mg	44 mg	38 mg	32 mg	26 mg	20 mg
Dicalcium Phosphate	30 mg	32 mg	34mg	36mg	38mg	40mg
Magnesium Stearate	4 mg	4 mg	4 mg	4 mg	4 mg	4 mg
Talc	2 mg	2 mg	2 mg	2 mg	2 mg	2 mg
Unit weight (mg)	200	200	200	200	200	200

Results and Discussion

Preformulation Parameter:

Table 4: Preformulation Parameter

S. no.	Parameter	Inference
1	Bulk density (g/cm^3)	0.65± 0.12
2	Tapped density (g/cm^3)	0.38± 0.34
3	Hausner's ratio	0.5846±0.012
4	Carr's index	41.5384±0.024
5	Angle of repose (^{0})	33±0.32

Results are presented in Mean ± S.E.M (n=3)

Calibration curve:

Table 5: Calibration Curve of Pantoprazole

S.No.	Conc. (µg/ml)	Abs.
1	0	0
2	2	0.123
3	4	0.387
4	6	0.512
5	8	0.723
6	10	0.912
7	12	1.01

ISSN: 0976-7126
Makwana *et al.*, 11(12):7139-7147, 2020

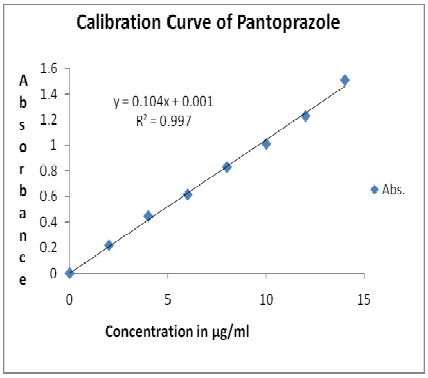

Figure 1: Calibration Curve of Pantoprazole

Drug-Excipients Compatibility Study

Physical Observation

The physical compatibility was observed visually. The study reveals that the drug and the excipients were physically compatible with each other as there was no change of color. The excipients are compatible with the drug selected for the formulation.

Table 6: Physical Compatibility of Pantoprazole and Excipients

S.No.	Drug + Excipients	Description and Condition	Room Temperature and 40ºC/75% RH in days		
			Initial	15th	30th
1.	**Pantoprazole**	White powder	NC	NC	NC
2.	**Croscarmellose sodium**	White crystalline powder	NC	NC	NC
3.	**Microcrystalline cellulose**	Colorless crystalline	NC	NC	NC
4.	**Mannitol**	Yellow to white	NC	NC	NC
5.	**Dicalcium Phosphate**	White powder	NC	NC	NC
6.	**Talc**	White fine powder	NC	NC	NC
7.	**Mg stearate**	White fine powder	NC	NC	NC

Thin Layer Chromatography (TLC)

The Chemical compatibility was determined using TLC. The study reveals that the drug and the excipients were chemically compatible with each other as there was no significant change in the Rf values. The excipients are compatible with the drug selected for the formulation.

Table 7: Chemical Compatibility of Pantoprazole and Excipients

S.No.	Pantoprazole +Excipients	Room Temperature 40ºC & 75% RH in days						Result
		Initial		15th		30th		
		Rf_1	Rf_2	Rf_1	Rf_2	Rf_1	Rf_2	
1.	**Pantoprazole**	0.59	0.51	0.51	0.46	0.51	0.58	NC
2.	**P* + Croscarmellose sodium**	0.56	0.55	0.52	0.40	0.55	0.63	NC
3.	**P* + Microcrystalline cellulose**	0.44	0.61	0.50	0.36	0.53	075	NC
4.	**P* + Mannitol**	0.42	0.46	0.63	0.61	0.61	0.50	NC
5.	**P* + Dicalcium Phosphate**	0.72	0.76	0.52	0.45	0.61	0.50	NC
6.	**P* + Talc**	0.46	0.42	0.45	0.41	0.38	0.59	NC
7.	**P* + Mg stearate**	0.82	0.79	0.66	0.52	0.60	0.53	NC

Rf_1* = standard value & Rf_2* = sample value. P*= Pantoprazole
NC* - No Change

Table 8: Precompression Data

Batch No.	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Carr's Index (I_C)	Hausner's Ratio (H_R)	Angle of Repose
F1	0.3432±0.04	0.4165±.05	21.35±0.07	1.21±0.03	24.92±0.08
F2	0.3648±0.06	0.4262±0.03	16.83±0.01	1.16±0.08	29.48±0.10
F3	0.3322±0.04	0.3950±0.04	16.94±0.07	1.18±0.05	25.24±0.17
F4	0.3655±0.05	0.4156±0.06	13.70±0.07	1.13±0.07	26.07±0.18
F5	0.3655±0.05	0.4156±0.06	13.70±0.07	1.13±0.07	26.07±0.18
F6	0.3432±0.04	0.4165±.05	21.35±0.07	1.21±0.03	24.92±0.08

Table 9: Evaluation of post Compression Parameters of Tablet Characteristics

Batch no.	Average wt. (mg)	Thickness (mm)	Diameter (mm)	Hardness (kg/cm^2)	Friability (%)
F1	203±0.22	4.20±0.03	12.10±0.05	7.50±0.01	0.78±0.041
F2	203±0.18	4.35±0.04	12.08±0.02	8.40±.02	0.77±0.039
F3	202±0.19	4.20±0.02	12.05±0.03	9.0±0.04	0.75±0.044
F4	201±0.20	4.40±0.04	12.06±0.02	7.0±0.03	0.66±0.039
F5	200±0.30	4.20±0.03	12.10±0.05	7.50±0.01	0.78±0.041
F6	203±0.25	4.20±0.02	12.05±0.03	9.0±0.04	0.75±0.044

Table 10: Dissolution of prepared pantoprazole tablet

Time (mins)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
10	27.45±0.335	25.45±0.828	24.66±0.326	24.03±0.233	22.85±0.755	19.54±0.576
20	42.84±0.295	38.93±0.625	37.51±0.147	36.35±0.427	35.64±0.030	32.25±0.264
30	61.55±0.294	58.21±0.644	55.4±0.268	55.25±0.071	52.38±0.331	51.01±0.554
40	78.08±0.132	78.15±0.211	74.0±0.275	72.50±0.212	70.59±0.309	67.96±0.982
50	86.08±0.113	85.46±0.243	82.89±2.05	83.15±0.363	81.90±0.288	76.27±1.32
60	95.28±0.716	91.08±0.141	86.92±0.956	87.35±0.458	84.76±0.251	82.80±0.788

ISSN: 0976-7126
Makwana *et al.*, 11(12):7139-7147, 2020

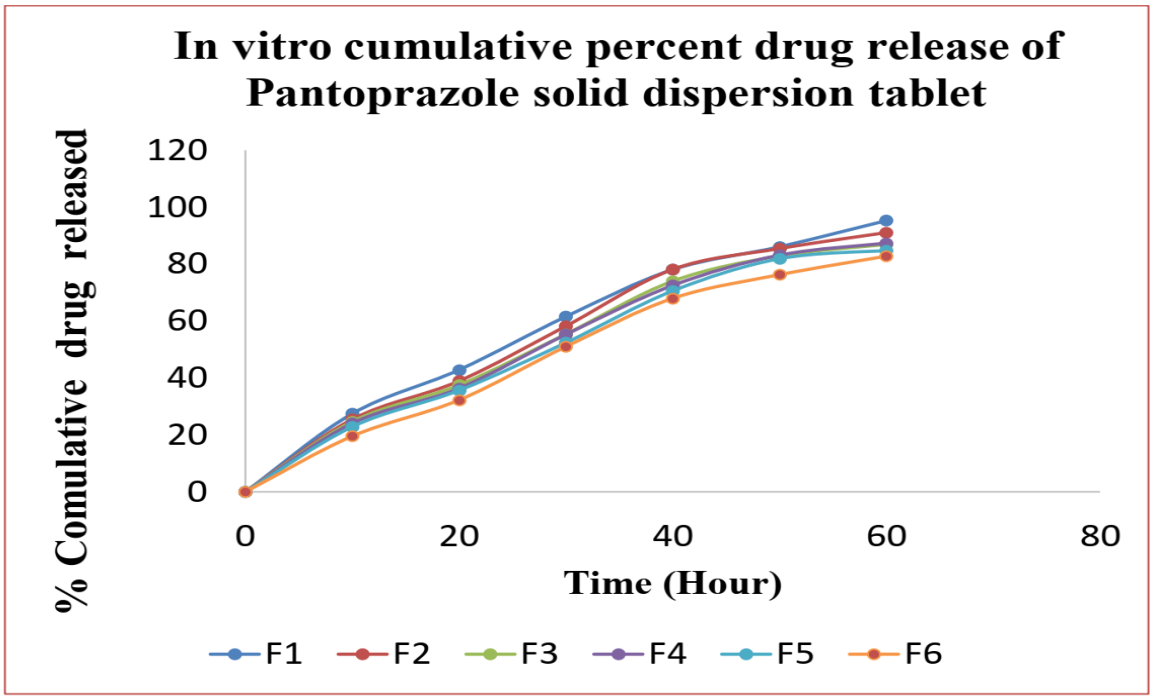

Figure 2: Calibration Curve of Pantoprazole

Conclusion

Solid dispersions represent a useful pharmaceutical technique for increasing the dissolution, absorption, and therapeutic efficacy of drugs in dosage forms. The term solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug.

The applicability of the solid dispersion technique as a method for enhancing the GI absorption of a drug has been explored in order to achieve better dissolution characteristics and better bioavailability for poorly soluble drugs.

Solubility studies on Pantoprazole was performed with PVP, HPC and HPMC and found to be more soluble in polyvinyl pyrrolidone and Hydroxy Propyl cellulose in comparison with hydroxyl Propyl methyl cellulose.

The formulations were evaluated for their flow properties like Angle of repose, Carr index and Hausner's ratio. These values indicate that the solid dispersions prepared having the good flow properties.

The release rate of Pantoprazole from the resulting complexes was determined from dissolution studies and dissolution characteristics were carried out for solid dispersion formulations, pure drug and physical mixtures. The results indicated that dissolution of optimized formulation showed significantly higher than pure drug and physical mixtures.

In order to get evidence on the possible interactions of drug with the carrier, FTIR analysis was used. The optimized formulation displayed the characteristic peaks at wave numbers nearer to that of pure Pantoprazole, there was no alteration in the characteristic peaks of Pantoprazole suggesting that there was no interaction between the drug and polymers. DSC studies revealed that absence of drug peak in the free flowing solid dispersion formulation indicating the drug was in amorphous form.

The rate of dissolution of Pantoprazole from free flowing solid dispersion optimized formulation was found to be significantly higher than drug alone. Thus, a free flowing solid dispersion formulation of Pantoprazole with increased dissolution efficiency was successfully developed.

After oral administration of Pantoprazole (40 mg kg−1) to either sex Wistar rats, these formulations (free flowing solid dispersion) showed superior absorption profile than the suspension of pure drug. The relative bioavailability of free flowing

solid dispersion formulations were enhanced in comparison with pure drug suspension. Calculated concentration was found to be more for solid dispersion formulations compared with pure drug of Pantoprazole at maximum concentrations.

It can be concluded that the present study successfully illustrates the potential utility of free flowing solid dispersion formulation for the delivery of poor water-soluble compounds such as Pantoprazole. The optimized formulation (F1) shows good results and is best.

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Cite this article as:
Makwana V., Koshta A., Joshi A., Malviya S. and Kharia A. (2020). Formulation and Evaluation of Pantoprazole Solid Dispersion Tablet, *Int. J. of Pharm. & Life Sci.*, 11(12): 7139-7147.
Source of Support: Nil
Conflict of Interest: Not declared
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