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Development and Evaluation of Solid Dispersion-Based Press-Coated Pulsatile Tablets of Ibuprofen for Enhanced Solubility and Chronotherapeutic Drug Delivery

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Abstract: *The present study aimed to improve the solubility of Ibuprofen by preparing solid dispersions and to develop press-coated pulsatile tablets for delayed drug release. Solid dispersions were prepared using β-cyclodextrin and Plasdone K30 by the spray-drying method. The drug and formulations were characterized by UV spectroscopy, FTIR, DSC, PXRD, and SEM analysis. The prepared solid dispersions were evaluated for practical yield, drug content, saturation solubility, and in vitro drug release. The optimized formulation (SD6) showed improved solubility and approximately 93% drug release within 60 minutes. The optimized solid dispersion was used to prepare immediate-release core tablets and press-coated tablets. The optimized press-coated formulation showed a suitable lag time followed by rapid drug release, indicating its potential for chronotherapeutic management of inflammatory conditions*

Keywords: Ibuprofen, Solid Dispersion, Press-Coated Tablet, Chronotherapy, Solubility Enhancement.

I. INTRODUCTION

Ibuprofen is a widely used non-steroidal anti-inflammatory drug (NSAID) that is effective in the treatment of pain, inflammation, rheumatoid arthritis, osteoarthritis, and fever. It acts by inhibiting cyclooxygenase enzymes and reducing prostaglandin synthesis (1). Although Ibuprofen is highly effective, it belongs to Biopharmaceutical Classification System (BCS) Class II because of its poor aqueous solubility, which limits its dissolution rate and oral bioavailability (2).

Several formulation approaches have been developed to improve the solubility of poorly water-soluble drugs. Among these, solid dispersion is one of the most successful techniques because it disperses the drug within hydrophilic carriers, resulting in reduced crystallinity, improved wettability, and enhanced dissolution (3). Hydrophilic carriers such as β-cyclodextrin and Plasdone K30 have been widely used to increase drug solubility and stability (4).

Chronotherapy is an advanced drug delivery approach in which the drug is released according to the body's biological rhythm. Pulsatile drug delivery systems provide a predetermined lag time followed by rapid drug release, making them suitable for diseases such as rheumatoid arthritis where symptoms are more severe during early morning hours (5).

In the present study, Ibuprofen solid dispersions were prepared by the spray-drying method using β-cyclodextrin and Plasdone K30. The optimized solid dispersion was incorporated into immediate-release core tablets and further developed into press-coated pulsatile tablets. The formulations were evaluated for physicochemical properties, drug release, and tablet characteristics to develop an effective chronotherapeutic drug delivery system.

Materials and Methods

Ibuprofen was used as the model drug. β-Cyclodextrin and Plasdone K30 were selected as hydrophilic carriers for the preparation of solid dispersions using the spray-drying method (6). The drug was initially evaluated for organoleptic

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properties, melting point, UV spectroscopy, FTIR, DSC, and powder X-ray diffraction (PXRD). The maximum absorption wavelength (λmax) of Ibuprofen was found to be 223 nm, and a calibration curve was prepared in 0.1 N HCl (pH 1.2) according to Beer–Lambert's law (7).

Different batches of solid dispersions were prepared using varying drug-to-polymer ratios. The prepared formulations were evaluated for percentage practical yield, drug content, saturation solubility, and in vitro dissolution. The optimized batch (SD6) was further characterized using FTIR, DSC, and scanning electron microscopy (SEM) to confirm improved drug dispersion and reduced crystallinity (8).

Immediate-release core tablets containing the optimized solid dispersion were prepared by direct compression and evaluated for pre-compression parameters, hardness, friability, disintegration time, and in vitro drug release (9). These core tablets were then press-coated using suitable coating materials to obtain pulsatile tablets. The press-coated tablets were evaluated for physical properties, FTIR compatibility, and dissolution studies to determine lag time and subsequent drug release. The optimized formulation was selected based on delayed release followed by rapid drug liberation, making it suitable for chronotherapeutic drug delivery (10).

Result

Organoleptic Properties-

Physical appearance of drug examined by various organoleptic properties is as shown below-

a. Color: White

b. Odour: Odorless

c. Taste: Bitter

d. State: Fine crystalline powder

Melting point of Ibuprofen-

The temperature at which solid drug changes into liquid was noted as the melting point of the Ibuprofen. It was found to be 75–78°C.

Spectroscopic Analysis:

Determination of λmax of Ibuprofen

The standard solution of Ibuprofen of concentration 10 µg/mL showed maximum absorbance at the wavelength of 223 nm.

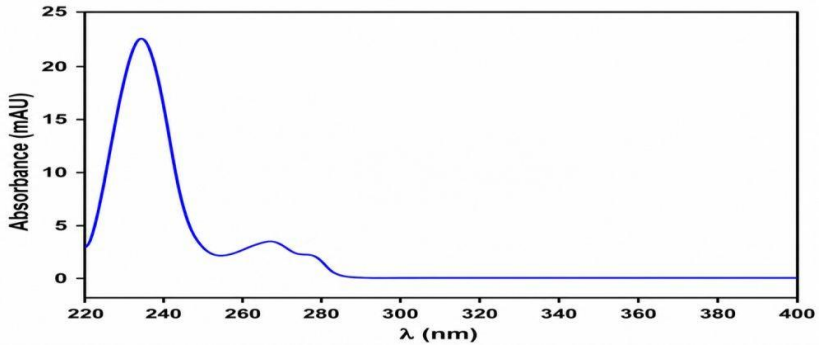

Fig. 1: λmax of Ibuprofen Plotting of Calibration curve for Ibuprofen -

The calibration curve of Ibuprofen in 0.1 N HCl (pH 1.2) exhibited good linearity and passed through the origin (Table No. 8.1). The Beer–Lambert's law was obeyed in the concentration range of 2–16 µg/mL, indicating a direct proportional relationship between absorbance and concentration within the studied range.

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Table No.1: Data for calibration curve of Ibuprofen in 0.1N HCl

Concentration (µg/ml)	Absorbance*
0	0.0000±0.012
2	0.0875±0.011
4	0.1874±0.013
6	0.2515±0.011
8	0.3581±0.013
10	0.4312±0.014
12	0.4962±0.012
14	0.5681±0.013
16	0.6620±0.013

*All values are expressed as mean±SD (n=3)

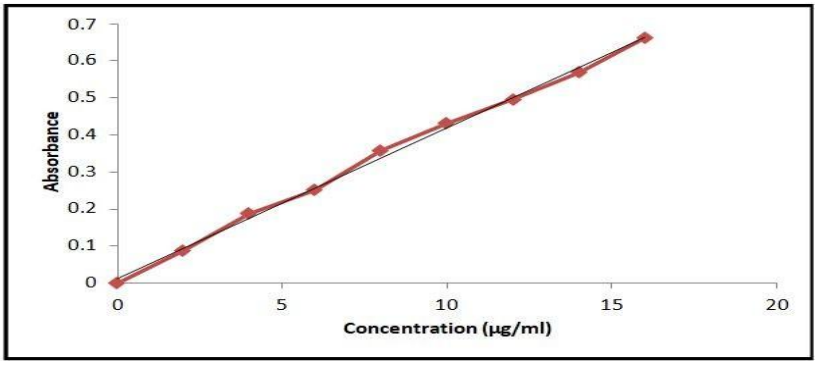

Fig. 2: Calibration Curve of Ibuprofen in 0.1 N HCl (pH 1.2)

This equation indicates a linear relationship between the concentration of Ibuprofen and its absorbance in the concentration range studied. The correlation coefficient (RZ) was found to be close to unity, confirming good linearity and compliance with Beer–Lambert's law.

Saturation solubility of Ibuprofen -

Solubility of Ibuprofen was determined in solution of 0.1N HCl (pH 1.2), distilled water and phosphate buffer (pH 6.8).

Table No.2: Saturation solubility of Ibuprofen in different solvents

Sr. No.	Solvent	Saturation Solubility (mg/mL)
1	Distilled Water	0.08 ± 0.01
2	0.1 N HCl (pH 1.2)	0.12 ± 0.02
3	Phosphate Buffer pH 6.8	2.45 ± 0.08
4	Phosphate Buffer pH 7.4	5.86 ± 0.12
5	Methanol	185.40 ± 2.15

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Compatibility Study between Drug and Excipients:

FTIR spectra of Ibuprofen -

Fig.8.3 shows the typical Fouriertrans form-infrared (FTIR) spectrum of Ibuprofen in the range of 4000 to 400cm−1.

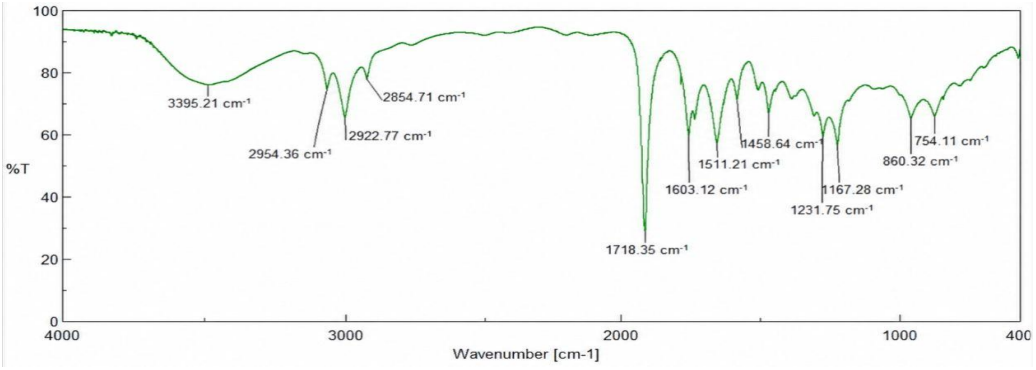

Fig.3:FTIR Spectrum of Ibuprofen

Table No.3: Interpretation of FTIR spectra of Ibuprofen

Wavenumber (cm^{-1})	Functional Group
3400–2950	O–H stretching (Carboxylic acid)
2955	C–H stretching
2924	C–H stretching
2868	C–H stretching
1720	C=O stretching
1605	Aromatic C=C stretching
1510	Aromatic C=C stretching
1458	CH_3 bending

Differential Scanning Calorimetry (DSC) study of Ibuprofen -

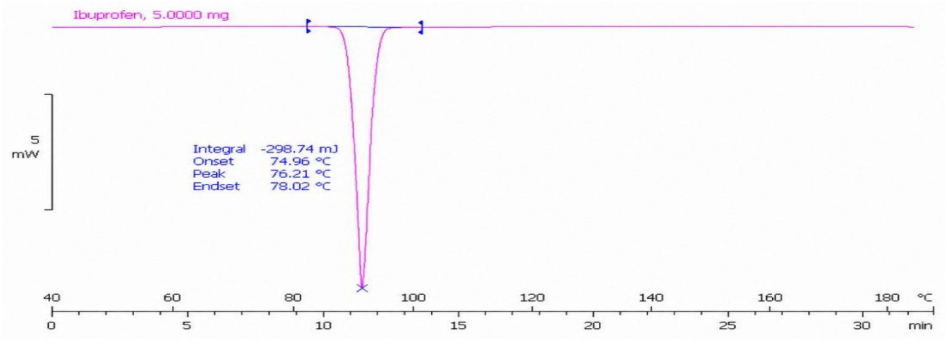

Fig.4:DSC curve of Ibuprofen Powder X-Ray diffraction (PXRD) study of Ibuprofen –

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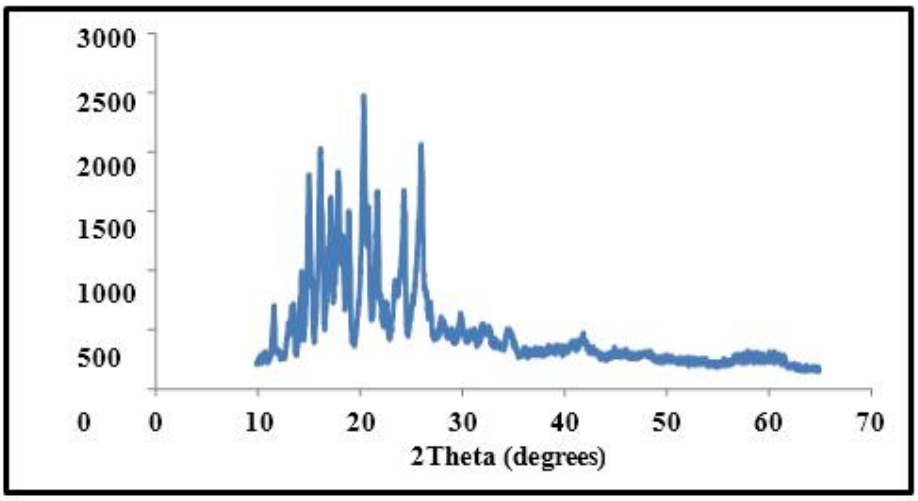

Fig.5:PXRD curve of Ibuprofen

Characterization of Solid Dispersions:

Percentage Practical Yield-

The results of percent practical yield studies are shown in Table No.8.8. The % practical yield of the prepared solid dispersions by spray dryer method was found to be maximum for batch SD4 (69.73%).

Table No. 4: Percentage Practical Yield of Various Batches of Solid Dispersion

Sr. No.	Batch code	Percentage Yield
1	SD1	62.85%
2	SD2	57.49%
3	SD3	65.28%
4	SD4	69.73%

The drug content in the4 prepared solSidD4dispersions was72fo.3u8n%d to be in the range of 66.87% to 87.53% succesSsfDu5l incorporation 7o9f.96I%buprofen into the carrier matrix. The percentage 6 drug contenStD6of Ibuprofen i8n7.5t3h%e solid dispersions was observed to increase with an increase in the concentration of hydrophilic carriers, sSuagtugreasttiionng Siomlupbriolviteyd ofdrPurgepaernetdrapSmoleidnt Daisnpdersuionnifsorimn VdairsitoruibsutSionlvenwtisthin the carrier system.

Table No.6:Saturation Solubility of various batches of solid dispersion

Batch Code	Polymer Table	Drug:Polymer No.5:Drautgioconten	Solvents		
			t of Dsoislitdilleddisp water*	ersio0n.1NHCl (pH 1.2)*	Phosphate buffer (pH 6.8)*
SD1	β-cyclodextrin	1:1	0.3854±0.2	0.8754±0.3	0.6749±0.4
SD2		1:2	0.6749±0.2	0.9916±0.2	0.8443±0.1
SD3		1:3	0.8357±0.4	1.2837±0.4	1.3786±0.1
SD4		1:1	0.3774±0.3	1.8412±0.3	0.7692±0.2

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SD5	Plasdone K-30	1:2	0.8576±0.4	2.6348±0.4	1.0428±0.3
SD6		1:3	1.1729±0.4	4.1587±0.2	1.4287±0.2

*All values are expressed as mean±SD(n=3)

Table No.7: Cumulative% drug release data of Solid dispersion batches

Sr. No	Time (min)	%Cumulative drug release*						
		Puredrug	SD1	SD2	SD3	SD4	SD5	SD6
1	0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
2	10	3.31±0.03	12.45±0.05	19.34±0.06	26.47±0.05	32.67±0.03	39.57±0.03	43.56±0.03
3	20	5.73±0.01	33.48±0.06	39.37±0.03	37.46±0.02	48.29±0.01	47.67±0.03	58.26±0.02
4	30	8.06±0.03	48.87±0.05	46.35±0.02	52.67±0.03	54.42±0.03	59.34±0.01	69.41±0.06
5	40	11.41±0.02	66.48±0.04	59.14±0.03	68.77±0.03	63.97±0.03	69.44±0.02	84.19±0.03
6	50	13.67±0.02	75.95±0.06	76.73±0.03	80.91±0.01	71.26±0.01	76.99±0.01	89.61±0.04
7.	60	18.58±0.02	79.37±0.04	81.16±0.01	88.38±0.03	78.96±0.03	89.76±0.03	93.39±0.06

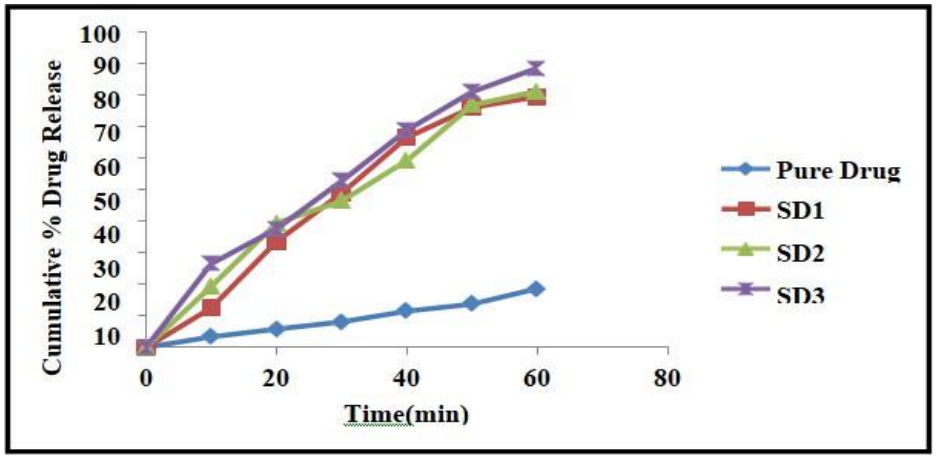

Fig.6: Cumulative drug release profile of pure drug, SD1, SD2 and SD3

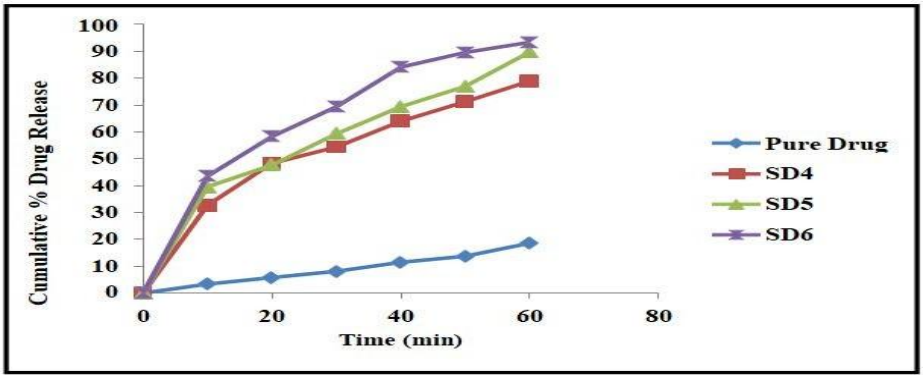

Fig.7: Cumulative drug release profile of pure drug, SD4, SD5 and SD6

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FTIR Spectra of optimized solid dispersion batch (SD6)-

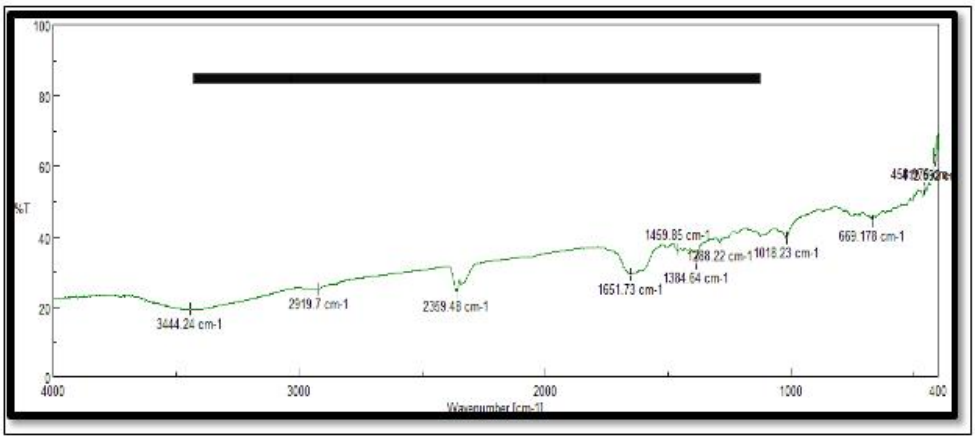

Fig.8:FTIR spectra of batch SD6

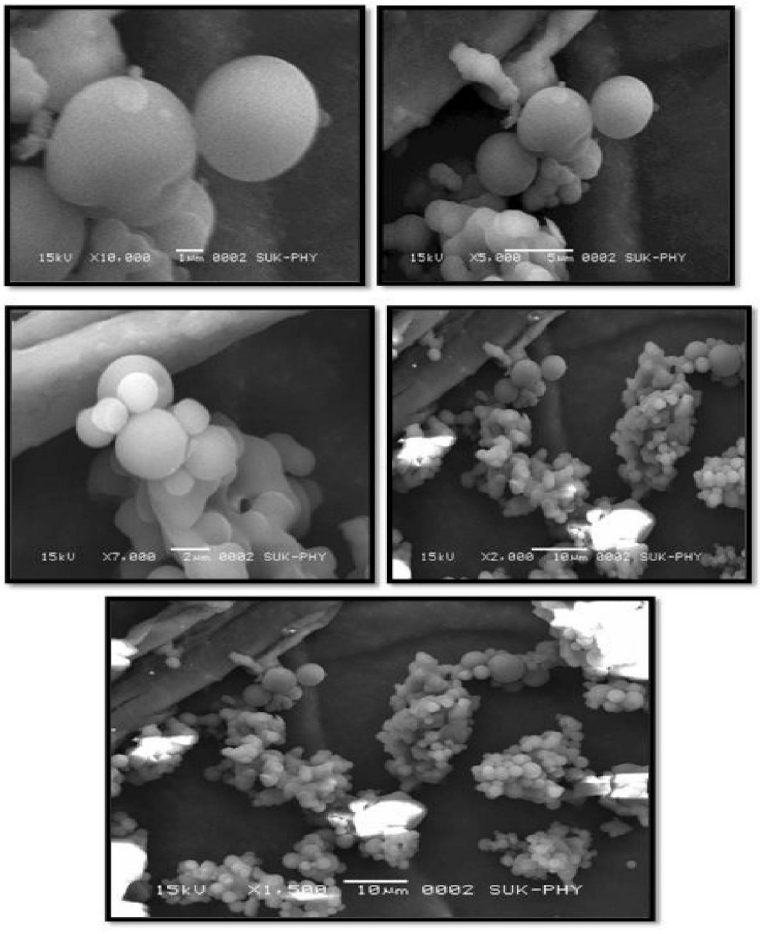

Fig. 10: SEM images of Solid dispersion batch SD6

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Evaluation of Powder Mixture For Core Tablet:

Precompression Evaluation of Immediate Release Core Tablet Blend Table No.9: Pre compression valuation of core tablet blend

Batch Code	Bulk Density* (g/cm^3)	Tapped Density* (g/cm^3)	Angle of Repose*(°)	Bulkiness (cm^3/gm)	Carr's Compressibility Index (%)*	Hausner's ratio*
L1	0.464±0.02	0.586±0.02	25.24±0.14	2.3407	22.4±0.03	1.23±0.01
L2	0.475±0.01	0.567±0.03	29.61±0.15	2.4281	20.5±0.01	1.24±0.01
L3	0.467±0.03	0.597±0.01	26.47±0.13	2.4304	21.6±0.02	1.26±0.03
L4	0.439±0.02	0.549±0.04	29.80±0.15	2.4972	21.7±0.02	1.24±0.05

Postcompression Evaluation of Immediate Release Core Tablets

Table No.10: Post compression evaluation of core tablets

Batch Code	Average Weight (mg)	Thickness (mm)*	Hardness(kg/cm^2)*	Friability (%)*	Disintegration Time(sec)*
L1	99.0	0.302±0.04	3.2±0.02	0.197±0.003	32±0.078
L2	98.3	0.312±0.03	3.5±0.06	0.104±0.007	37±0.240
L3	99.5	0.328±0.03	2.8±0.02	0.132±0.001	34±0.015
L4	98.1	0.311±0.02	3.5±0.04	0.146±0.005	39±0.317

**All values are expressed mean±SD(n=3)*

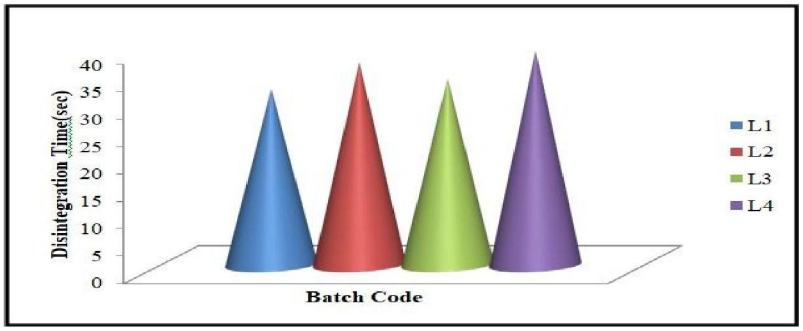

Fig.11: Comparative graph of disintegration times of core tablets L1-L4

In-vitro drug release study of immediate release core tablets-

Table No.11: Cumulative Drug Release data of immediate release core tablets

Sr. No	Time(min)	% Cumulative drug release*			
		L1	L2	L3	L4
1	0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
1	5	25.21±0.12	23.63±0.13	29.73±0.13	25.35±0.13
2	10	43.44±0.15	42.19±0.15	43.57±0.12	48.49±0.12
3	15	79.56±0.14	77.61±0.12	67.50±0.12	75.27±0.15

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4	20	86.81±0.12	85.96±0.13	78.48±0.13	81.61±0.13
5	25	95.67±0.12	88.49±0.12	89.18±0.14	87.69±0.13
6	30	98.58±0.13	92.34±0.12	95.73±0.15	90.88±0.12

**All values are expressed as mean±SD(n=3)*

Fig.12: Cumulative % drug release profile of immediate release core tablets

Evaluation of Press Coating Material Used For Direct Compression: Precompression Evaluation of Press Coating Material

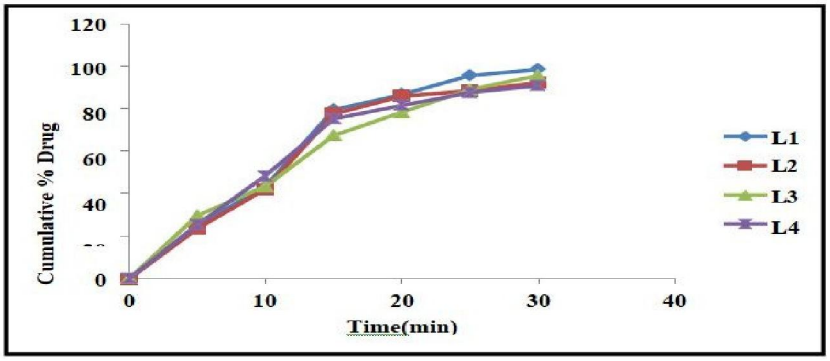

Table No. 12: Precompression Evaluation of Press Coating Material Used for Direct Compression.

Batch Code	Bulk Density (g/cm^3)*	Tapped Density (g/cm^3)*	Angle of repose(°)*	Bulkiness (cm^3/gm)	Compressibility index (%)*	Hausner's ratio*
PCT1	0.4166±0.02	0.4545±0.01	20.55±0.12	2.4003	8.3388±0.02	1.24±0.02
PCT2	0.4166±0.03	0.4652±0.02	19.77±0.13	2.4065	5.3564±0.03	1.23±0.02
PCT3	0.4628±0.01	0.4545±0.01	18.26±0.12	2.4006	12.4973±0.02	1.25±0.03
PCT4	0.4089±0.02	0.4347±0.03	21.79±0.15	2.50	11.9912±0.03	1.24±0.02
PCT5	0.4166±0.03	0.4543±0.03	19.34±0.12	2.4003	4.6657±0.02	1.22±0.03

**All values are expressed as mean±SD(n=3)*

The bulkiness of all the batches were in the range of 2.4003 to2.50 cm^3/gm. The batch PCT2 has lowest Carr's indexx of 4.6657% batch PCT3 has highest Carr's index of 12.4973%. From all the above results we can conclude that batch PCT2 and PCT3 have excellent compressible characteristics.

Post compression evaluation of press-coated tablets-

Table No.13: Post compression Evaluation of press-coated tablets

Batch Code	Average weight(mg)	Thickness(mm)*	Hardness(kg/cm^2)*	Friability(%)*
PCT1	499.16	0.403±0.11	10.50±1.22	0.691±0.25
PCT2	495.67	0.402±0.10	10.64±1.31	0.644±0.14
PCT3	498.38	0.410±0.10	10.75±1.21	0.701±0.15
PCT4	499.30	0.401±0.10	10.45±1.25	0.645±0.24
PCT5	497.25	0.411±0.13	10.62±0.21	0.712±0.25

**All values are expressed as mean±SD(n=3)*

FTIR Spectra of Physical mixture of tablet composition-

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Fig.13:FTIR Spectra of physical mixture of tablet composition Table 14: FTIR Interpretation of physical mixture of tablet composition

In-vitro drug release study of Press-coated tablets-

Table No.15: Cumulative% Drug Release Data of Press-coated tablets

Sr. No.	Time(min)	% Cumulative drug release*				
		PCT1	PCT2	PCT3	PCT4	PCT5
1	0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
2	60	4.95±0.14	2.37±0.26	1.04±0.12	1.06±0.16	3.57±0.24
3	120	6.28±0.25	4.61±0.36	2.24±0.15	3.20±0.14	9.20±0.16
4	180	78.27±0.12	7.54±0.14	6.31±0.14	6.73±0.13	11.45±0.12
5	240	86.91±0.12	9.06±0.16	10.99±0.12	8.25±0.15	13.67±0.13
6	300	-	61.49±0.19	11.97±0.25	10.26±0.24	15.81±0.24
7	360	-	95.60±0.13	13.85±0.15	11.84±p0.12	89.45±0.13
8	420	-	-	83.04±0.14	13.26±0.13	-
9	480	-	-	90.48±0.16	79.28±0.13	-
10	510	-	-	-	83.86±0.12	-

**All values are expressed as mean±SD(n=3)*

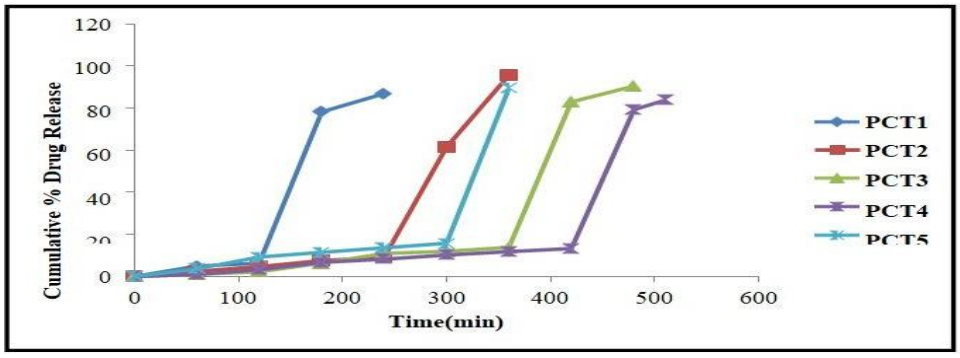

Fig.14: Cumulative % drug release profile of Press-coated tablet batches Table

II. CONCLUSION

The present study successfully developed Ibuprofen solid dispersions using β-cyclodextrin and Plasdone K30 to improve the drug's solubility and dissolution rate. Characterization studies including FTIR, DSC, PXRD, and SEM confirmed successful formulation without significant drug–excipient incompatibility. The optimized solid dispersion (SD6) showed enhanced saturation solubility, high drug content, and approximately 93% drug release within 60 minutes compared with the pure drug. This optimized formulation was successfully incorporated into immediate-release core tablets and further developed into press-coated pulsatile tablets. The optimized press-coated formulation provided an appropriate lag time followed by rapid drug release, making it suitable for chronotherapeutic treatment of inflammatory diseases such as rheumatoid arthritis. Overall, the developed formulation demonstrated improved physicochemical properties and drug release characteristics. The study suggests that solid dispersion combined with press-coating is a promising approach for enhancing Ibuprofen therapy and patient compliance.

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