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Formulation and evaluation of oral fast dissolving film containing glibenclamide

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ABSTRACT

Glibenclamide (GBC) is an oral hypoglycemic drug that stimulates the pancreatic beta cells to secrete insulin and is often used to treat diabetes, including diabetes during pregnancy. In present research work an attempt has been made to prepare mouth dissolving films of Glibenclamide (GBC) were prepared using different polymers like HPMCE5, HPMCE15 by solvent casting method. The fast dissolving oral film evaluated for folding endurance, swelling index, surface pH, in-vitro disintegration time, drug content, drug polymer compatibility (IR Study), and in-vitro drug release. The physical appearance and folding endurance properties were found to be good and electron microscopy shows that films are clear, colorless with smooth surface without any scratches. The surface pH was found to be in the range of 6.35 to 6.75 which is close to salivary pH, which indicates that films may have less potential to irritate the oral mucosa, thereby they are comfortable. The drug content of all the films was in the range of 95 to 99 suggesting that drug was uniformly dispersed throughout all films. The In-vitro disintegration time of films prepared with HPMCE5 &HPMCE15 was in the range of 25 to 35 sec. the Invitro dissolution results showing that FA8 producing 98.59% Hence it can be inferred that the fast dissolving oral film of Glibenclamide may produce the rapid action thereby improving bioavailability and enhance the absorption by avoiding the first pass effect.

Keywords: Glibenclamide, HPMCE5, HPMCE15, Solvent casting method.

INTRODUCTION

The oral route of drug administration is the most important method of administration of drug for systemic effect, despite of tremendous advancement in drug delivery system. Its ease of administration, pain avoidance and various advantages over other routes is the reason that the oral route achieved such recognition. But the most evident drawback of oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patient's incompliance particularly in case of pediatric and geriatric, bedridden, nauseous patients [1].

Orally fast-dissolving film is new drug delivery system forthe oral delivery of the drugs. It was developed on thebasis of technology of the transdermal patch. The deliverysystem consists of a very thin oral strip, which is simplyplaced on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly hydrates andadheres onto the site of application. It then rapidly disintegrates and dissolves to release the medication fororomucosal and Intragastric absorption. TechnologyCatalysts forecasts the market for drug products in oral

Thin film formulations was valued of $500 million in 2007 and could reach $2 billion in 2012. Based on upward global growth trends of the past decade, the fast dissolving dosage market could produce revenues of $13 billion by 2015 [2].

MATERIALS AND METHODS

Glibenclamide drug purchase from yarrow chem products Mumbai and Hydroxyl propyl methylCellulose E5 & E15, Poly ethylene glycol-400, Citric acid were purchased from SD fine chemicals.

Preformulation Studies

Identification Tests

IR Spectroscopy

The FT-IR spectrum of the obtained sample of drug was compared with the standard FT-IR spectra of the pure drug.

Melting Point determination

Melting point determination of the obtained drug sample was done because it is a good first indication of purity of the sample since the presence of relatively small amount of impurity can be detected by a lowering as well as widening in the melting point range.

Compatibility Studies

IR Spectroscopy

FT-IR spectroscopy was carried out to check the compatibility between drug and polymers. The FT-IR spectra of drug with polymers were compared with the standard FT-IR spectrum of the pure drug

Preparation of phosphate buffer

Preparation of 0.2M Potassium Dihydrogen Ortho Phosphate

Dissolve 27.218gof KH2PO4 in distilled water and made up the volume to 1000 ml with distilled water Preparation of 0.2M Sodium Hydroxide: Dissolved NaOH in water to produce a 40 to60 % w/v solution and allowed to stand. Taking precautions to avoid absorption of carbon dioxide siphoned off the clear supernatant liquid dioxide free water a suitable volume of the liquid to contain 8 g of NaOH in 1000 ml.

Preparation of pH 6.8 buffer

Placed 50 ml of 0.2M KH2PO, in a 200 ml volumetric flask and 22.4ml of 0.2M NaOH was added the and made up the volume with distilled water.

λmax determination of drug in buffer solution

10 ug/ml of drug solution was prepared and scanned against pH6.8 buffer as reference solution under wavelength range of 200-400nm by using UV spectrophotometer. A graph was plotted by taking absorbance on Y-axis and wavelength on X-axis. mg/ml.

Construction of calibration graph in pH 6.8 buffer

1 to 8 concentrations of drugsolutions were scanned against phosphate buffer as reference solution at 204 nmunder UV spectrophotometer. A graph was plotted by taking absorbance on Y-axisand concentration (mgml) on X-axis. This graph yields standard calibration graph ofdrug solutions.

Table No.1 formulation table

FORMULATION CODE	DRUG (mg/2*2 cm^2)	HPMC E5	HPMC E15	CITRIC ACID(mg)	PEG 400 (ml)	METHANOL	WATER
F1	5	200	-	50	1	QS	QS
F2	5	212.5	-	50	1	QS	QS

F3	5	225.5	-	50	1	QS	QS
F4	5	238	-	50	1	QS	QS
F5	5	250	-	50	1	QS	QS
F6	5	267	-	50	1	QS	QS
F7	5	283.5	-	50	1	QS	QS
F8	5	300	-	50	1	QS	QS
F9	5	-	200	50	1	QS	QS
F10	5	-	212.5	50	1	QS	QS
F11	5	-	225.5	50	1	QS	QS
F12	5	-	238	50	1	QS	QS
F13	5	-	250	50	1	QS	QS
F14	5	-	267	50	1	QS	QS
F15	5	-	283.5	50	1	QS	QS
F16	5	-	300	50	1	QS	QS

RESULT & DISSCUSSION

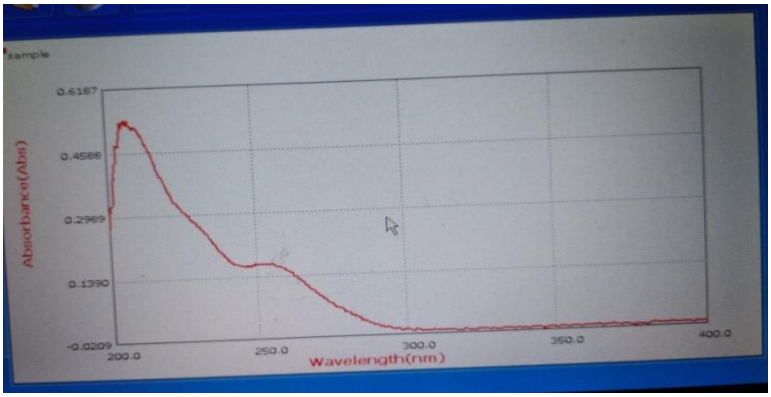

Figure no: 1λmax determination of drug in buffer solution at 204nm

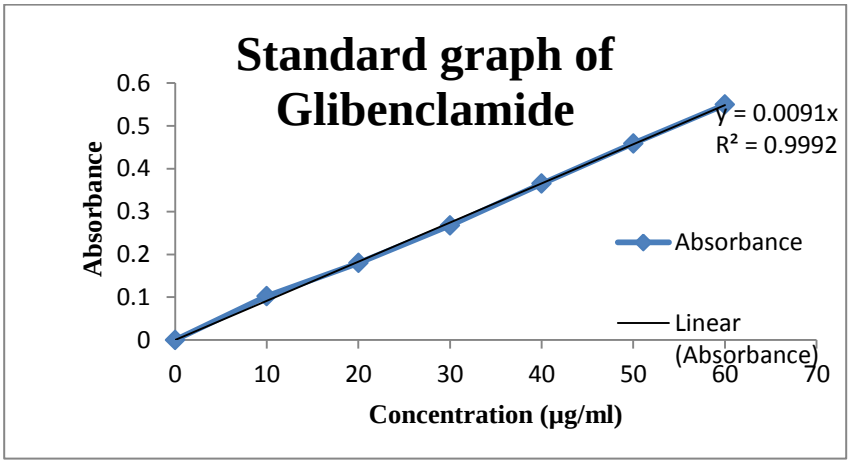

Figure no: 2 Calibration graph of Glibenclamide

Compatibility of IR spectroscopy

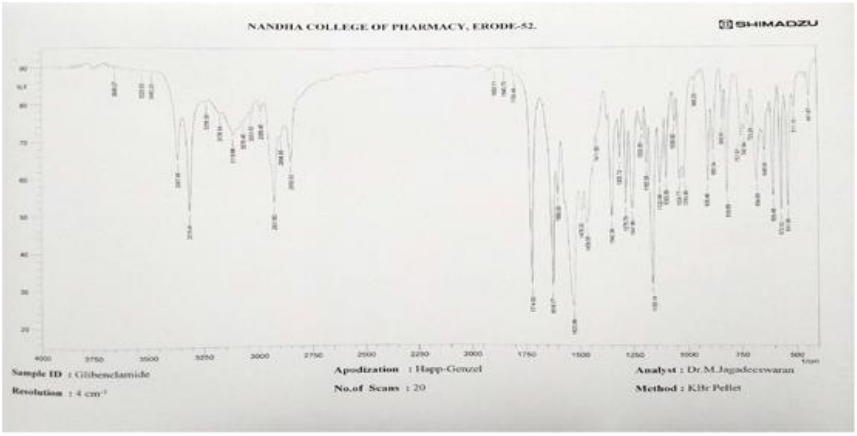

Figure no: 3 IR spectra of glibenclamide

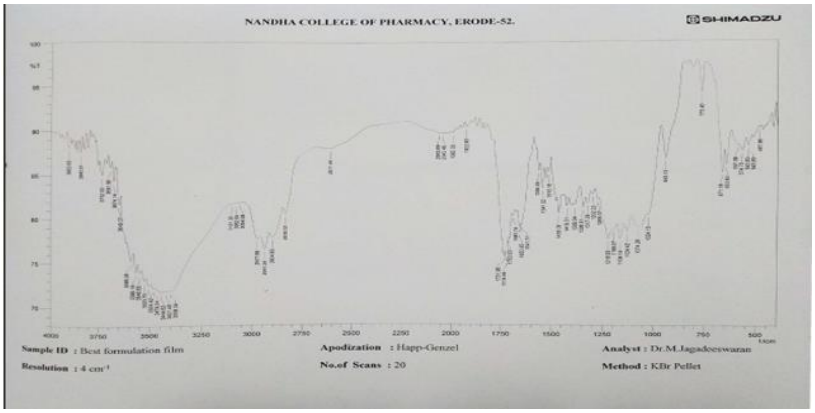

Figure no: 4 IR spectra of glibenclamide+all excipients

Table No 2: FTIR interpretation of Glibenclamide pure drug

Characteristic bands	Reference peak(cm^{-1})	Observed peak(cm^{-1})
CH3-O stretch	2830-2810	2852.52
C=O	1725-1705	1714.60
N-H(secondary amine) Deformation	1650-1550	1616.17
S=O stretch	1358-1336	1342.36
C-Cl stretch	730-580	723.28

Melting point determination

The melting point of the obtained drug sample was found to be 169˚C which is the reported range of 168-174˚C. It complies with USP standards thus indicating the purity of the drug sample.

Table No 3: Physical parameters of all formulations

Physical parameters	Formulation code						
	F2	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
Physical appearance	Transparent	transparent	transparent	transparent	transparent	transparent	Transparent
Thickness uniformity(mm)	0.16	0.19	0.15	0.18	0.13	0.14	0.15
Drug content uniformity (%)	95	97	96	98	97	98	99
Folding endurance	210 ±212	228 ±226	236 ±233	215 ±217	236 ±233	215 ±216	104 ±101
pH	6-7	6-7	6-7	6-7	6-7	6-7	6-7
Disintegration time(sec)	25	20	28	19	20	22	18

Physical parameters	Formulation code						
	F10	**F11**	**F12**	**F13**	**F14**	**F15**	**F16**
Physical appearance	Transparent	transparent	transparent	transparent	transparent	transparent	Transparent
Thickness uniformity(mm)	1	0.13	0.16	0.19	0.16	0.19	1
Drug content uniformity (%)	95	98	95	97	98	98	95
Folding endurance	250 ±253	248 ±244	236 ±237	225 ±228	226 ±223	235 ±238	194 ±200
pH	6-7	6-7	6-7	6-7	6-7	6-7	6-7
Disintegration time(sec)	30	25	38	30	40	33	35

Invitro dissolution study

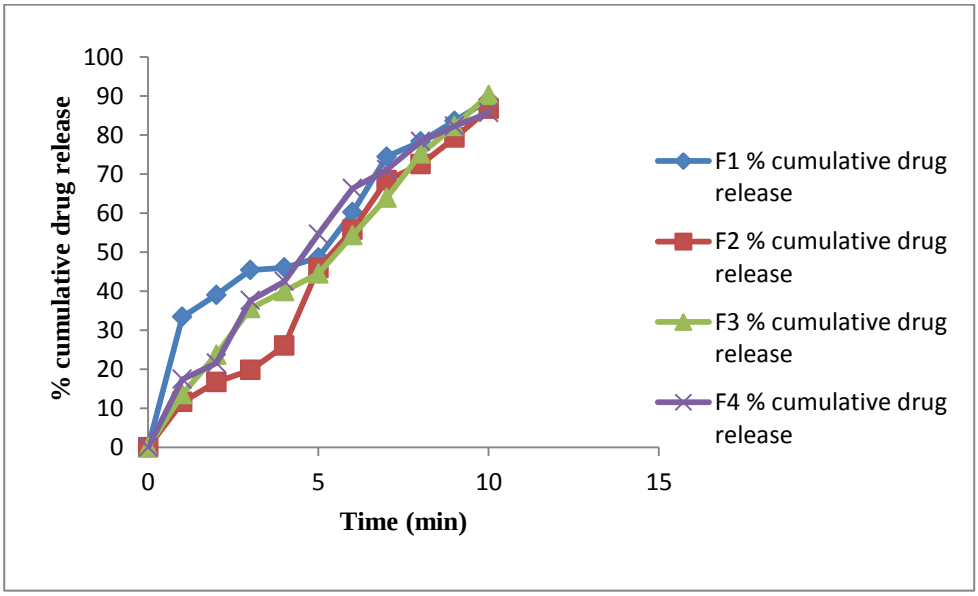

Figure No 5: *In-vitro* dissolution profile of F1-F4 formulations

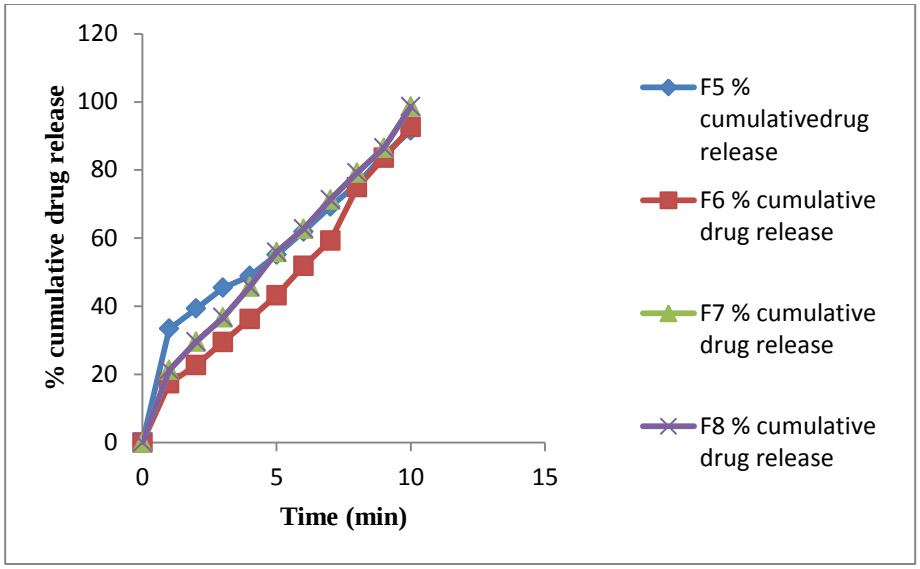

Figure No 6: *In-vitro* dissolution profile of F5-F8 formulations

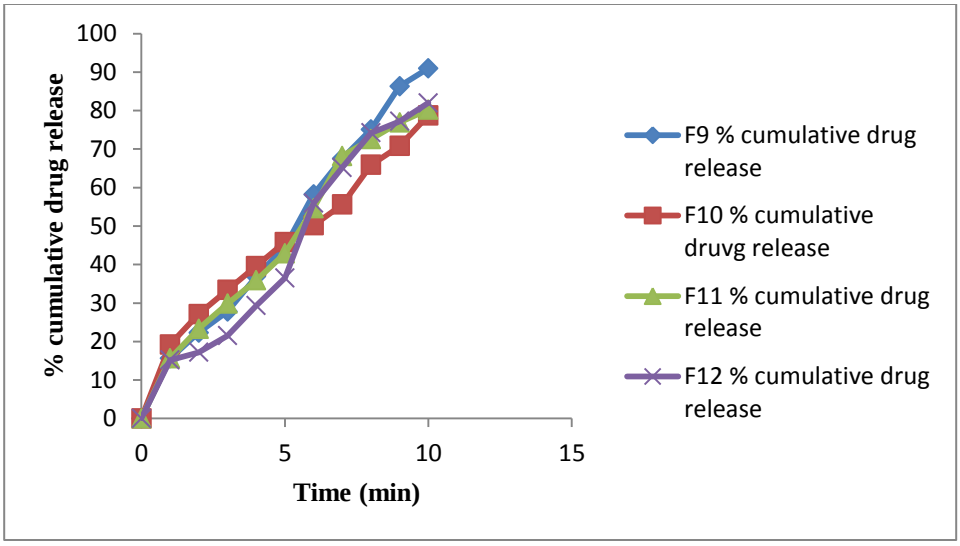

Figure No 7: *In-vitro* dissolution profile of F9-F12 formulations

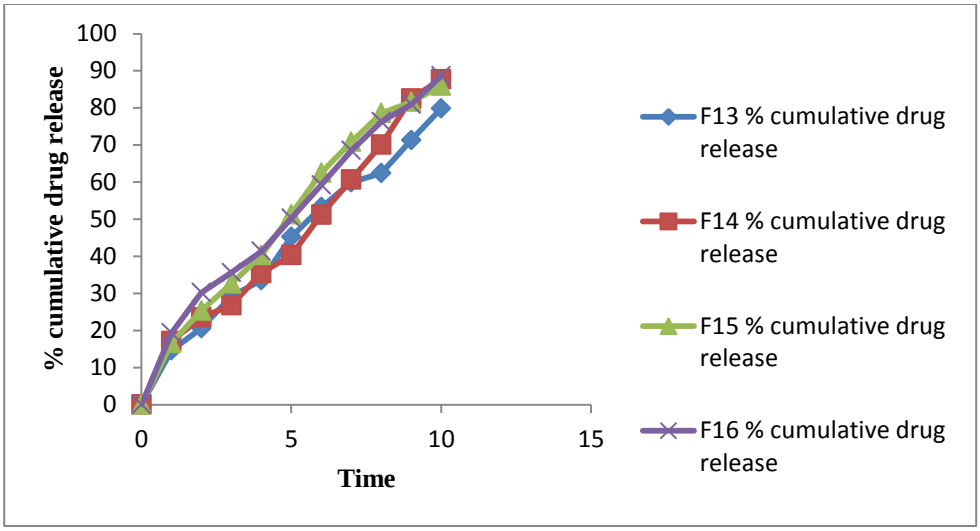

Figure No 8: *In-vitro* dissolution profile of F13-F16 formulations

Percentage of drug release 3D graph by using Factorial design software 11.0 version

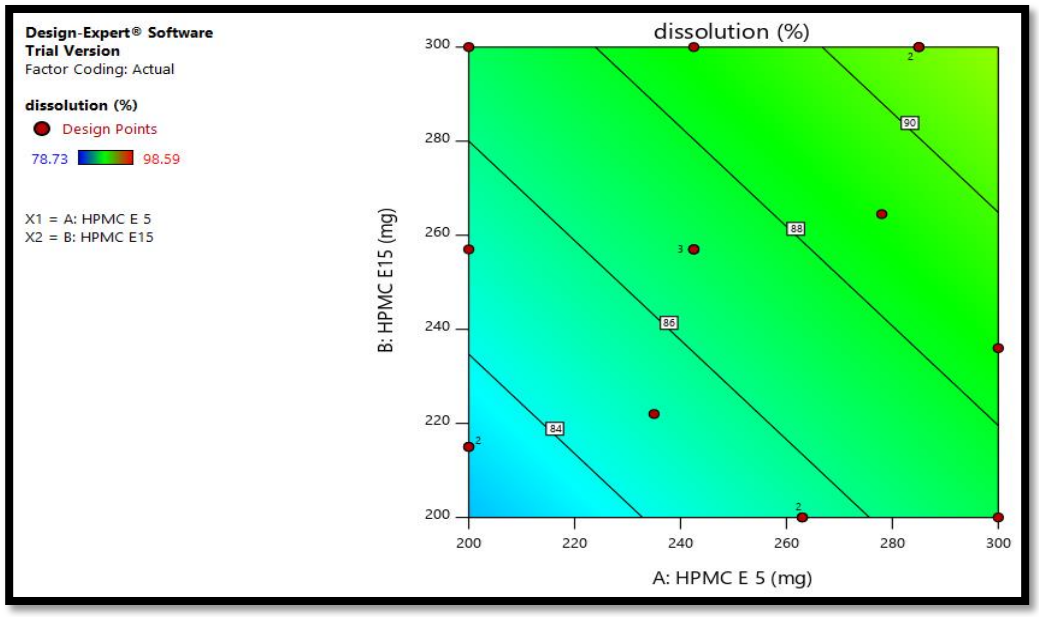

Figure No 9: Drug release (%)

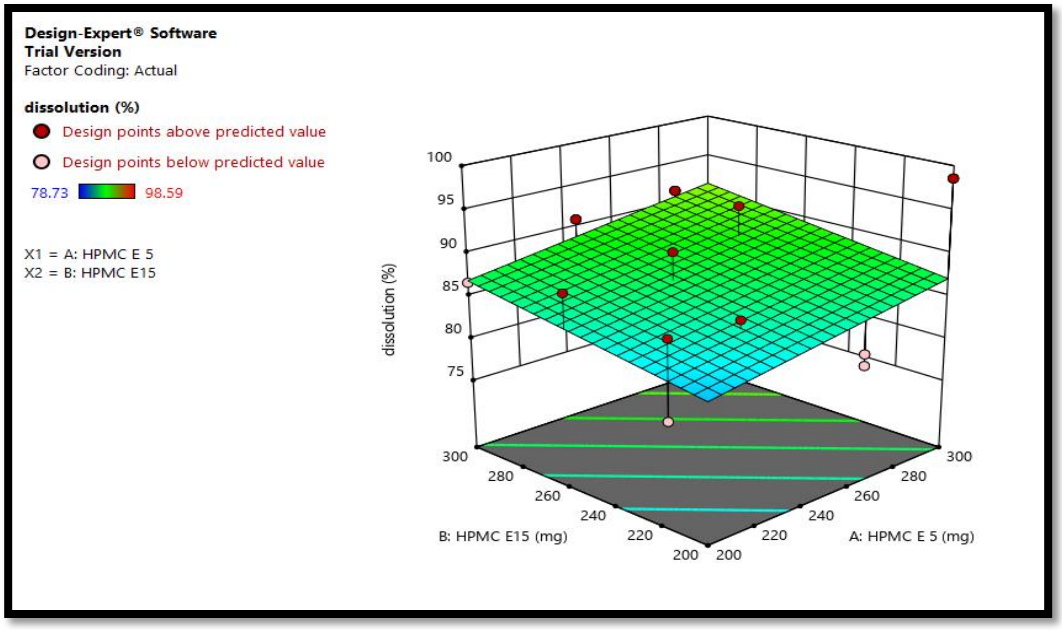

Figure No 10: Drug release (%)

CONCLUSION

In present study Glibenclamide, fast dissolving film for buccal drug delivery prepared and evaluated. In the beginning, blank polymeric fast dissolving film was prepared using HPMC E-15 HPMC E-5. PVP K-30. The concentration of polymer was varied and the best were chosen for further work. The prepared fast dissolving film was evaluated for a number of parameters like physical appearance and surface texture, weight uniformity, the thickness of fast dissolving film, folding endurance, surface pH, in-vitro residence time, drug excipients interaction studies, drug uniformity and *in-vitro* drug release.

The*In-vitro* drug release study shown F8 formulation drug realese 98.59% in 10 mins.

An accelerated stability study on optimized formulation was performed. The formulation was found to be stable; there was no change in the drug content, disintegration time, and *in-vitro* drug release pattern.

In conclusion, it can be stated that the objective of the study has been achieved. From the above study the formula used for F8 formulation was concluded as an optimized formulation due to its good % drug release when compared with other formulation

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