

DESIGN AND CHARACTERIZATION OF ORODISPERSIBLE TABLETS OF CALCIUM CHANNEL BLOCKERS

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ABSTRACT

Objective: Using sodium starch glycolate, croscarmellose sodium, kyon T-314, and crospovidone as super disintegrants to increase the disintegration and dissolution rates and assess the tablet's pre- and post-compression parameters was the goal of this study in order to create a fast-dissolving nimodipine tablet. **Methods:** Nimodipine fast-dissolving tablets were made using the direct compression method. The fast dissolving tablet was assessed for weight variation, thickness, hardness, friability, wetting time, water absorption ratio, disintegration time, and dissolution time. Pre-compression parameters included bulk density, tapped density, Hausner's ratio, angle of repose, and Carr's index. The fast-dissolving tablet formulation of nimodipine's drug release has been quantified using the UV-spectrophotometric approach.

Results: Pre and post compression parameter were evaluated. Bulk density ($0.50\text{--}0.56\text{ g/cm}^3$) and Tapped density ($0.60\text{--}0.65\text{ g/cm}^3$). The hardness, friability, wetting time, the water absorption ratio, disintegration and dissolution time were found to be acceptable according to the standard limit and compare to all formulations. All batches of fast dissolving tablet were satisfactory in term of dissolution. The drug release from tablets of nimodipine tablets found to be in the range of 99.36 to 99.90%, DCP4 is best of all formulations with disintegration time 11.18 sec, hardness (3.3 Kg/cm^2) and percentage friability (0.62 %). **Conclusion:** The outcome revealed that, in accordance with standard limits, the dissolution and disintegration of Nimodipine Tablets was deemed acceptable. Super disintegrants can be added to the direct compression approach to significantly increase the rate of disintegration and dissolution of nimodipine.

KEYWORDS: Fast dissolving tablet, Nimodipine, Sodium starch glycolate, Crospovidone.

INTRODUCTION

The most convenient method of administering medication is orally. Tablets are one of the most often used dosage forms due to its ease of production, ease of administration, accuracy in dosing, stability in comparison to other forms, etc.^[1-2] A drug's bioavailability depends on a number of physiological variables as well as disintegration and dissolution. Scientists have been concentrating on the development of orodispersible and rapidly disintegrating tablets (ODTs) in recent years.^[3] ODT is defined as "a solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within seconds to three minutes when placed upon the tongue" by the US Food and Drug Administration. Generally speaking, ODTs disintegrate in around three minutes. Orally disintegrating tablets (ODTs) can have a variety of features, including mechanical strength, taste and mouthfeel, swallowability, drug breakdown in saliva, bioavailability, and stability.^[4-6] ODTs are formulated using a variety of procedures, each with its own unique approach. The creation of quickly disintegrating tablets is achieved by the use of an appropriate superdisintegrant and diluent.^[7-9]

Nimodipine is a calcium channel blocker. The chemical formula is 3-(2-methoxyethyl)-5-propane-2-yl,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate and boiling point is 418.44 and the melting point is 125 C . It is soluble in water and freely soluble in ethyl acetate. Its plasma concentration decline rapidly with a half- life of 1-2 hrs and reported terminal half-life of 9 hrshence, it is most suitable for manufacture of ODT. The aim of present study was to develop fast disintegrating tablet of nimodipine with possible advantages like, quick onset of action due to rapid dissolution and enhanced rapid absorption. Sodium starch glycolate(SSG), Crospovidone, croscarmellose sodium(CCS) and Kyron-T314 were screened in the present study, and the best one was used for further studies. The direct compression technique was adopted for formulating the ODT of nimodipine.^[10-11]

MATERIALS AND METHODS

Materials: Nimodipine, Croscarmellose Sodium, crospovidone, Sodium starch glycolate, Kyron T-314, Microcrystalline cellulose, Mannitol, Aspartame, Avicel ph-102, Talc, Magnesium Stearate.

List of Equipments: Tablet compression machine (Rimek, Mini press 10 station rotatory machine, Karnavathi engineering Ltd Gujarat), hardness tester (Pfizer hardness tester, Serve well instruments and equipment pvt), Friability Test apparatus (020334-Veego digital), Tablet Dissolution Test apparatus (220307- Electrolab USP (XXIII)), UV visible spectrophotometer (UV-1700 Shimadzu corporation, Japan), Balance (BT 220 H- Shimadzu Digital Balance, Japan), pH meter (5291679- Hanna Instrument, Italy), Stability Chamber (Thermo Lab, Mumbai), Thickness Tester (Screw Gauge), FT-IR spectrometer (Perkin Elmer Instruments, USA), DSC (DSC60 Shimadzu Corporation, Japan,).

Preparation of Orodispersible Tablets: Each ingredient was passed through 60 mesh sieve separately. The drug and the microcrystalline cellulose was mixed by small portion of both each time and blending it to get uniform mixture kept aside. Then the ingredients are weighed and mixed in geometrical order and tablets were compressed of 8 mm flat round punch to get tablet using Rimek Compression Machine.^[12-14] Croscarmellose sodium, sodium starch glycolate, Crospovidone and kyon-T314 were used in varying concentration as shown in Table-1. Batch (DCP1 to DCP4) contained Nimodipine (15%) crospovidone (3%, 6%, 9%, 12%), Aspartame (6%), D-mannitol (45%, 42%, 39%, 36%), MCC (Avicel PH-102) (27%), Methyl cellulose (1.5%), Talc (1.5%), Mg stearate (1%).^[15-16]

Table 1: Formulation of Nimodipine Fast dissolving Tablets.

Ingredients	Formulation code															
	DCP1	DCP2	DCP3	DCP4	DCC1	DCC2	DCC3	DCC4	DCS1	DCS2	DCS3	DCS4	DCY1	DCY2	DCY3	DCY4
Nimodipine	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
Crospovidone	6	12	18	24	--	--	--	--	--	--	--	--	--	--	--	--
Croscarmellose sodium	--	--	--	--	6	12	18	24	--	--	--	--	--	--	--	--
Sodium starch glycolate	--	--	--	--	--	--	--	--	6	12	18	24	--	--	--	--
Kyron T-314	--	--	--	--	--	--	--	--	--	--	--	--	6	12	18	24
Aspartame	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
D-mannitol	90	84	78	72	90	84	78	72	90	84	78	72	90	84	78	72
MCC(Avicel PH-102	54	54	54	54	54	54	54	54	54	54	54	54	54	54	54	54
Methyl cellulose	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Talc	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Mg stearate	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Total	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200

1) Pre formulation Studies

Determination of λ max for nimodipine, FTIR studies.

2) Pre-compression parameters

Various Pre-compression parameters such as bulk density, tapped density, hausner's ratio, compressibility index, and angle of repose are among the characterization used to assess the quality of mixed blends.^[17-20]

3) Post compression parameters: The tablets were evaluated for various parameters like Hardness, friability, thickness, weight variation.^[17-20]

RESULT AND DISCUSSION

1) Result of Pre formulation Studies

FTIR Studies

The pure drug nimodipine contains 2 carboxylic functions of a ring substitution exhibiting two intense peaks at 3529 cm⁻¹ and 3409 cm⁻¹ supporting the presence of carboxylate moieties. The pyridine N-H which is substituted by ortho methyl group shows a absorption peak at 3313cm⁻¹ hence it is not pyrimidine nucleus, it is a pyridine nucleus. The C-H peaks are seen at 3027 cm⁻¹ due to the presence of aromatic ring system. the aliphatic absorption peak of C-H are seen at 2950 cm⁻¹ to 2915 cm⁻¹, the carboxylate absorption of C=O give a distinct peak at 1751 cm⁻¹ and 1673cm⁻¹ these data's are full agreement with the structure of the drug used is nimodipine during the present research work, No interaction was found after 3 months accelerated studies. The spectra has same absorption and peak as reference pure drug.

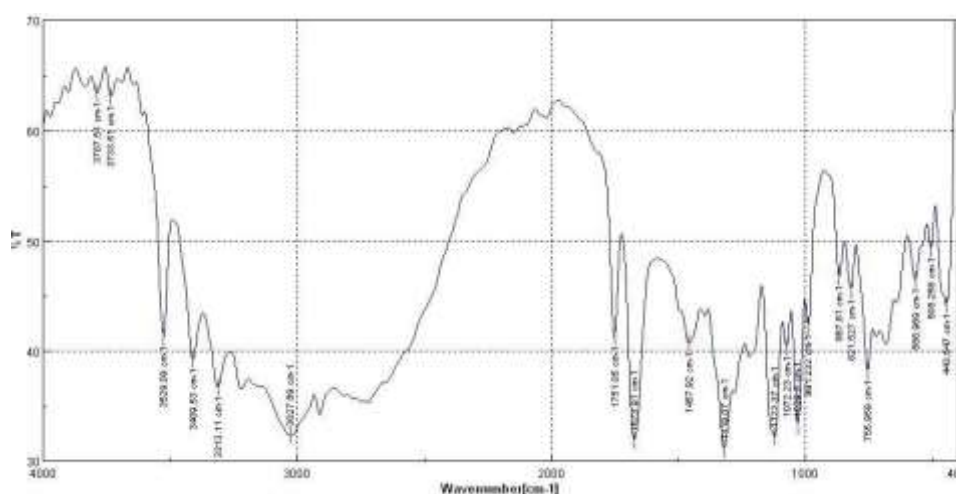


Fig-1: FTIR Spectra Nimodipine.

Analytical method for estimation of nimodipine

Standard calibration curve of nimodipine in acetate buffer pH 4.5: Solution ranging from 2 to 12 $\mu\text{g/ml}$ were prepared using acetate buffer (pH 4.5); separately, absorbance was measured for each solution at λ_{max} of 317nm using Shimadzu UV/visible 1700 spectrophotometer, graph was plotted for absorbance versus concentration of nimodipine.

Procedures

100mg of pure drug transferred into 100 ml of acetate buffer (pH 4.5) in a volumetric flask. Withdrawn 10ml from this solution and diluted to 100 ml it make 100 mcg/ml (stock solution) then concentration made by withdrawing 0.2, 0.4, 0.6, 0.8, 1.0, 1.2 ml from stock solution and diluted to 10 ml it makes solution of concentration 2 $\mu\text{g/ml}$, 4 $\mu\text{g/ml}$, 6 $\mu\text{g/ml}$, 8 $\mu\text{g/ml}$, 10 $\mu\text{g/ml}$, 12 $\mu\text{g/ml}$.

Table 2: Standard calibration curve of Nimodipine in 4.5 pH acetate buffer solution at λ_{max} 317nm.

Sl.No.	Concentration (mcg/ml)	Absorbance
1.	00	0.000
2.	02	0.132
3.	04	0.270
4.	06	0.400
5.	08	0.546
6.	10	0.659
7.	12	0.790

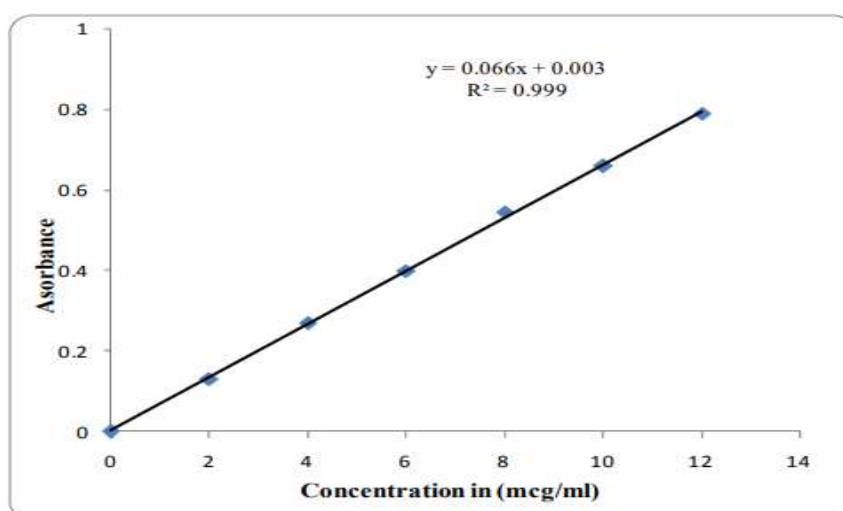


Fig. 2: Standard calibration curve of Nimodipine in 4.5 pH acetate buffersolutionsat λ_{max} 317nm.

2) Result of Pre-compression parameters

Table 3i: Pre-compression parameters.

Formulation code	Bulk density (g/cc)	Tapped density (g/cc)	Angle of repose (degree)	Carr's index (%)	Hausner's Ratio
DCP1	0.53 ± 0.002	0.64 ± 0.01	28.32 ± 1.52	17.18 ± 1.0	1.20 ± 0.02
DCP2	0.52 ± 0.005	0.62 ± 0.01	29.08 ± 1.20	16.12 ± 1.52	1.19 ± 0.04
DCP3	0.55 ± 0.003	0.66 ± 0.02	30.21 ± 1.70	16.66 ± 1.20	1.20 ± 0.03
DCP4	0.54 ± 0.008	0.60 ± 0.03	24.52 ± 0.88	11.1 ± 1.31	1.11 ± 0.03
DCC1	0.51 ± 0.007	0.63 ± 0.02	28.43 ± 1.46	19.04 ± 1.13	1.23 ± 0.06
DCC2	0.50 ± 0.009	0.61 ± 0.02	30.38 ± 1.31	18.03 ± 0.93	1.22 ± 0.07
DCC3	0.53 ± 0.002	0.63 ± 0.31	31.03 ± 1.40	15.87 ± 1.42	1.18 ± 0.11
DCC4	0.54 ± 0.005	0.65 ± 0.02	28.10 ± 1.13	16.92 ± 1.10	1.20 ± 0.09
DCS1	0.52 ± 0.004	0.62 ± 0.01	26.28 ± 1.26	16.12 ± 0.80	1.19 ± 0.04
DCS2	0.50 ± 0.003	0.61 ± 0.01	28.53 ± 1.20	18.03 ± 0.90	1.22 ± 0.02
DCS3	0.56 ± 0.002	0.66 ± 0.02	29.39 ± 1.27	15.15 ± 1.55	1.17 ± 0.7
DCS4	0.55 ± 0.005	0.65 ± 0.01	30.18 ± 1.32	15.38 ± 1.36	1.18 ± 0.11
DCY1	0.52 ± 0.006	0.63 ± 0.02	29.21 ± 1.10	17.46 ± 1.10	1.21 ± 0.03
DCY2	0.53 ± 0.005	0.64 ± 0.01	28.74 ± 1.41	17.18 ± 1.51	1.20 ± 0.08
DCY3	0.50 ± 0.006	0.61 ± 0.02	28.91 ± 1.34	18.03 ± 1.67	1.22 ± 0.12
DCY4	0.53 ± 0.008	0.62 ± 0.02	29.51 ± 1.42	14.51 ± 0.85	1.16 ± 0.04

\pm SD, n=3

Bulk density

Bulk density and tapped density for the blend was performed. The bulk density and tapped density for the entire formulation blend is, Bulk density (0.50 - 0.56 g/cm³) and Tapped density (0.60 - 0.65 g/cm³) as shown in table-3.

Angle of Repose

The data obtained from angle of repose for all the formulations were found to be in the range of 24.52 - 31.18 . All the formulations prepared by the four methods showed the angle of repose less than 30° , which reveals good flow property as shown in table-3.

Hausner Ratio

Hausner ratio of entire formulation showed between 1.11 to 1.23 indicates better flow properties as shown in table-3.

Carr's Index

The results of compressibility index (%) for the entire formulation blend ranged from 11.1 - 19.04 %. The directly compressible granulations had shown excellent compressibility index values up to 15 % result in good to excellent flow properties as shown in table-3.

3) Result of post compression parameter for tablets prepared by direct compression.

Table 4: Post-compression parameters.

Formulation code	Hardness (Kg/cm ²)	Friability (%)	Thickness (mm)	Weight variation (mg)
DCP1	3.22 ± 0.08	0.54 ± 0.10	4.61 ± 0.13	199.69 ± 1.8
DCP2	3.23 ± 0.12	0.54 ± 0.04	4.72 ± 0.16	200.44 ± 0.5
DCP3	3.34 ± 0.13	0.57 ± 0.05	4.70 ± 0.10	200.69 ± 1.7
DCP4	3.30 ± 0.12	0.62 ± 0.30	4.75 ± 0.17	199.14 ± 1.0
DCC1	2.90 ± 0.19	0.64 ± 0.12	4.80 ± 0.15	199.75 ± 0.7
DCC2	3.17 ± 0.17	0.59 ± 0.02	4.63 ± 0.09	200.43 ± 1.9
DCC3	3.20 ± 0.16	0.60 ± 0.02	4.59 ± 0.20	198.33 ± 1.1
DCC4	2.91 ± 0.18	0.64 ± 0.12	4.73 ± 0.12	200.14 ± 1.5
DCS1	2.95 ± 0.18	0.70 ± 0.15	4.69 ± 0.14	199.82 ± 1.9
DCS2	3.01 ± 0.17	0.61 ± 0.03	4.71 ± 0.21	199.86 ± 0.9
DCS3	3.20 ± 0.11	0.59 ± 0.03	4.58 ± 0.21	199.08 ± 1.11
DCS4	3.30 ± 0.14	0.61 ± 0.05	4.69 ± 0.08	200.86 ± 1.2
DCY1	2.87 ± 0.14	0.67 ± 0.07	4.76 ± 0.07	199.69 ± 1.3
DCY2	2.63 ± 0.07	0.62 ± 0.07	4.68 ± 0.14	200.42 ± 1.9
DCY3	2.34 ± 0.09	0.63 ± 0.09	4.72 ± 0.09	199.97 ± 2.0
DCY4	2.44 ± 0.11	0.62 ± 0.11	4.79 ± 0.18	200.02 ± 1.6

± SD, n=3

Hardness

The hardness of the tablets prepared by all four methods was maintained within the range of 2.34 kg/cm² to 3.34 kg/cm². The mean hardness test results are tabulated in Table 4.

Friability test

The friability was found in all designed formulations in the range 0.54 to 0.70% to be well within the approved range (<1%). The friability study results were tabulated in Table 4.

Weight Variation

The weight variation was found in all designed formulations in the range 199.14 to 200.86 mg. The mean weight variation test results are tabulated in Table 4.

Thickness

The mean thickness was almost uniform in all the formulations and values ranged from 4.61 ± 0.13 mm to 4.80 ± 0.15 mm. The results of thickness for tablets were shown in Table 4.

Table 5: showing results of Disintegration time, Wetting time, Water absorption ratio and Drug Content.

Formulation code	Disintegration time (sec)	Wetting time (sec)	Water absorption ratio	Drug Content (%)
DCP1	22.90 ± 1.2	38.16 ± 2.2	88.39 ± 1.3	99.90 ± 1.8
DCP2	18.06 ± 1.5	23.16 ± 1.3	85.63 ± 1.1	99.2 ± 0.4
DCP3	13.46 ± 1.3	17.41 ± 1.2	83.44 ± 1.4	99.92 ± 1.2
DCP4	11.83 ± 1.4	13.36 ± 1.4	78.61 ± 1.5	100.17 ± 0.9
DCC1	24.21 ± 1.1	45.93 ± 1.6	76.24 ± 1.9	99.38 ± 1.3
DCC2	21.14 ± 0.4	41.28 ± 1.2	78.31 ± 1.0	99.82 ± 1.9
DCC3	19.21 ± 0.8	25.31 ± 1.6	80.11 ± 1.8	99.90 ± 1.8
DCC4	13.64 ± 1.1	14.67 ± 2.2	77.54 ± 1.4	99.82 ± 1.1
DCS1	28.91 ± 1.6	47.96 ± 1.3	72.41 ± 1.3	100.65 ± 0.5
DCS2	25.41 ± 1.2	33.52 ± 2.2	75.47 ± 1.7	99.20 ± 0.5
DCS3	16.62 ± 0.6	18.26 ± 0.8	74.82 ± 1.1	100.08 ± 0.8
DCS4	19.36 ± 1.3	22.36 ± 1.9	70.23 ± 2.0	100.08 ± 0.5
DCY1	32.49 ± 1.5	46.37 ± 1.8	80.45 ± 1.9	99.73 ± 0.7
DCY2	27.23 ± 0.8	40.47 ± 1.7	82.97 ± 0.8	99.82 ± 1.7
DCY3	22.53 ± 1.3	28.64 ± 1.5	84.03 ± 0.8	99.47 ± 0.9
DCY4	16.19 ± 0.7	18.5 ± 1.1	87.75 ± 1.2	99.55 ± 1.0

± SD, n=3

***in-vitro* disintegration time**

The developed formulation's disintegration time is displayed in Table 5. The amount of time needed for total disintegration is used to calculate the *in-vitro* disintegration time. All of the formulations showed rapid disintegration within a few minutes. Table 5 contains a tabulation of the *in-vitro* disintegration data.

The *in-vitro* disintegration time were found to be in the range of 11.83 to 32.49 sec fulfilling the official requirements.

Wetting time

Wetting time is closely related to the inner structure of the tablet. The results of wetting time are shown in Table.5. The wetting time of prepared nimodipine tablets were found to be in the range of 13.36 to 47.96 sec.

Water absorption ratio

The prepared for mulations shows water absorption ratio in the range 70.23 to 88.39% formulations containing only 3% of super disintegrants shows lower water absorption ratio when compared to formulations 12% of super disintegrants, the water absorption ratio also

decreases due to less swelling property. The values of water absorption ratio shown in Table 5.

Drug Content

The drug content uniformity was performed for all the formulations and results are tabulated in Table 5. The percentage drug content of the tablets was found to be between 98.76 ± 0.9 to $100.65 \pm 0.5\%$ of nimodipine.

In-vitro dissolution studies

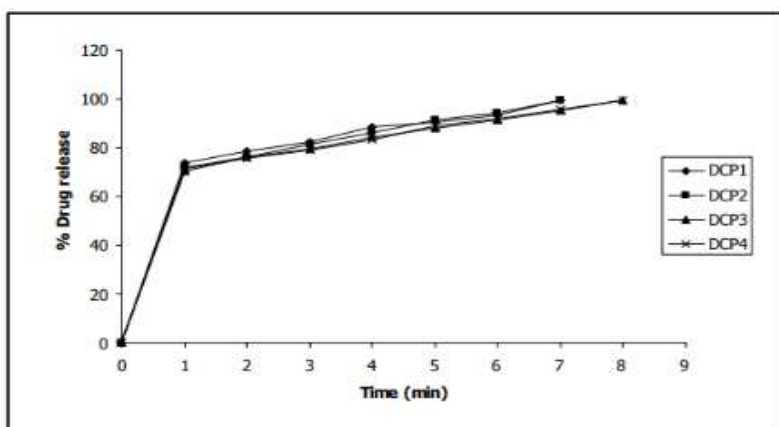
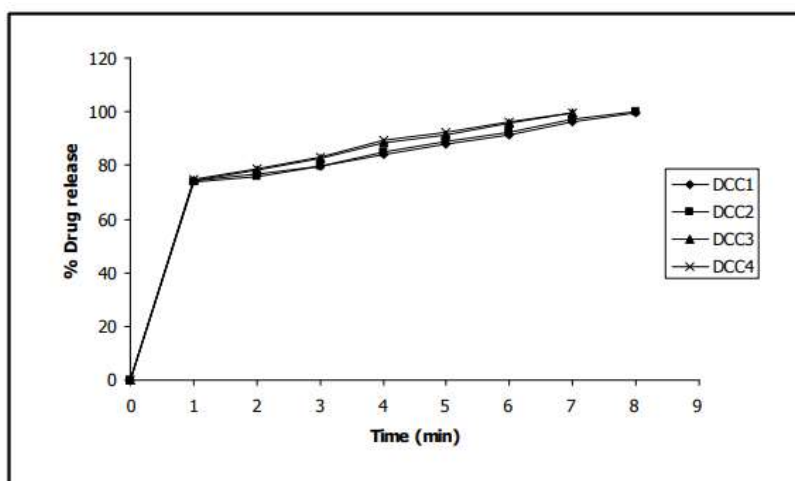
Dissolution rate was studied by using USP type-II apparatus (USPXXIID is solution Test Apparatus at 50rpm) using 900ml of acetate buffer pH(4.5) as dissolution medium. Temperature of the dissolution medium was maintained at $37 \pm 0.5^\circ\text{C}$, aliquot to of dissolution medium was withdrawn at every 1 min. interval and filtered. The absorbance of filtered solution was measured by UV spectrophotometric method at 317 nm and concentration of the drug was determined from standard calibration curve.

The dissolution of nimodipine from the tablets is shown in (Fig.3-6) and (Table-6) shows the $t_{50\%}$ and $t_{90\%}$ of the release profiles. That $t_{50\%}$ and $t_{90\%}$ values decreased with increase in the concentration of croscarmellose sodium, crospovidone and kyon T-314. However, $t_{50\%}$ and $t_{90\%}$ values increased with increase in concentration of sodium starch glycolate. The rapid increase in dissolution of nimodipine with the increase in croscarmellose sodium may be due to rapid swelling and disintegrating tablets rapidly into apparently primary particles. While tablets formulated with sodium starch glycolate, disintegrate by rapid uptake of water, followed by rapid and enormous swelling into primary particle but more slowly due to the formation of a viscous gel layer by sodium starch glycolate. Crospovidone and croscarmellose sodium containing tablets rapidly exhibits high capillary activity and pronounced hydration with a little tendency to gel formation and disintegrates the tablets rapidly but into larger masses of aggregated particles. Thus difference in the size distribution generated with different super disintegrants might have contributed to difference in the $t_{50\%}$ and $t_{90\%}$ values with the same amount of superdisintegrants in the tablets.

Although, disintegration times are lesser in crospovidone and croscarmellose sodium containing tablets, comparatively higher $t_{50\%}$ and $t_{90\%}$ values are observed in croscarmellose sodium containing tablets.

Table.6: Release profile of Nimodipine fast dissolving tablets.

Formulation Code	T50 (min)	T90 (min)
DCP1	0.4 ± 1.4	4.3 ± 0.9
DCP2	0.41 ± 1.0	4.43 ± 1.2
DCP3	0.42 ± 0.9	5.35 ± 1.3
DCP4	0.42 ± 1.9	5.24 ± 0.6
DCC1	0.40 ± 1.7	5.58 ± 1.6
DCC2	0.40 ± 1.6	5.25 ± 0.4
DCC3	0.40 ± 1.5	4.25 ± 0.8
DCC4	0.40 ± 1.3	4.50 ± 1.5
DCS1	0.41 ± 0.8	6.58 ± 1.7
DCS2	0.42 ± 1.0	6.35 ± 1.9
DCS3	0.41 ± 1.1	4.50 ± 1.3
DCS4	0.42 ± 1.2	6.30 ± 0.4
DCY1	0.41 ± 0.4	6.39 ± 0.9
DCY2	0.41 ± 0.6	6.30 ± 1.5
DCY3	0.41 ± 0.9	5.0 ± 1.6
DCY4	0.41 ± 0.7	4.56 ± 0.5

**Fig.3: Release profile of formulation containing crospovidone (DCP1-DCP4).****Fig.4: Release profile of formulation containing croscarmellose sodium (DCC1-DCC4).**

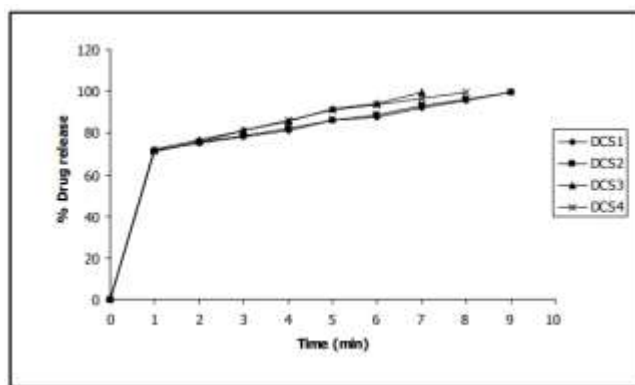


Fig.5: Release profile of formulation containing Sodium Starch Glycolate(DCS1-DCS4).

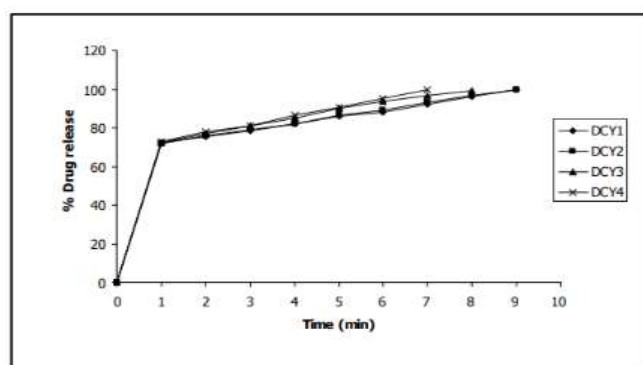


Fig.6: Release profile of formulation containing Kyron T-314 (DCY1-DCY4).

Results of stability studies

Table 7: Result for 40°C/ 75% RH) for 3 months.

Sl. No.	Formulation code	Month	Hardness Kg/cm ²	Friability %	Disintegration time (second)	Percentage Drug release
1	DCP4	1 st	3.3	0.62	11.83	98.69
		2 nd	3.4	0.64	12.01	98.38
		3 rd	3.4	0.66	12.05	97.82
2	DCC4	1 st	3.2	0.59	15.15	98.93
		2 nd	3.3	0.61	15.18	98.45
		3 rd	3.4	0.64	16.02	97.61
3	DCS3	1 st	3.3	0.61	15.38	99.26
		2 nd	3.3	0.62	16.05	98.45
		3 rd	3.4	0.65	17.34	98.06
4	DCC3	1 st	3.2	0.60	15.87	98.74
		2 nd	3.3	0.63	17.25	98.53
		3 rd	3.3	0.66	18.75	97.45

The Table 7 shows the parameters of the tablets after stability study. Four formulations as DCP4, DCC4, DCS3, DCC3 formulations were subjected to short term stability study by storing the formulations at 40°C/75% RH upto three month. The formulations contains

different superdisintegrants as DCP4 contains Crospovidone. DCC4 contains Croscarmellose sodium, DCS3 contains Sodium Starch Glycolate and DCC3 contains Croscarmellose sodium.

After three month the tablets were again analyzed for the hardness, friability, drug content uniformity and disintegration time. There is increase in hardness is observed in all formulations as DCP (3.3-3.4 Kg/cm²), DCC4(3.2-3.4 Kg/cm²), DCS3(3.3-3.4) and DCC3(3.2-3.3). Percentage Friability values are also seen to be increases as DCP4(0.62-0.66), DCC4(0.59-0.64), DCS3(0.61-0.65), DCC3(0.60-0.66). Increase in the disintegration time was observed as DCP4(11.83-12.05), DCC4(15.15-16.02), DCS3(15.38-17.34) DCC3(15.87-18.75). The percentage drug releases is observed to be decreasing as DCP4 (98.69-97.82), DCC4(98.93-97.61), DCS3(99.26-98.06) and DCC3(98.74-97.45). From the above all stability studies we can state that DCP4 is best preparation among all of preparations because after three month it releases 97.82% of drug in 12.05 sec.

CONCLUSION

Prepared tablets were found to be good and free from chipping and capping. The low values of the standard deviation of average weight of the prepared tablets indicate weight uniformity within the batches prepared.

The hardness of the tablets prepared was found to be 3.2 to 3.4 Kg/ cm². The friability values of the prepared tablets were found to be less than 1%. FTIR spectroscopy studies indicated that the drug is compatible with all the excipients used. Based on the in-vitro disintegration time, formulation DCP4 (12% crospovidone), DCC4 (9% sodium starch glycolate), DCS3 (12% sodium starch glycolate), DCC3 (9% Croscarmellose) were found to be promising and showed a disintegration time of 11-17 sec, and friability percentage ranges 0.59-0.66, which facilitate the faster dispersion in the mouth. The drug content of tablets was uniform in all the formulations and was between 98.76 to 100.65%.

The drug release from fast dissolving tablets of nimodipine tablets found to be in the range of 99.36 to 99.90%. The stability study shows that no significant changes in tablets after three month study.

The in-vitro disintegration time of nimodipine tablets prepared were found to be in the

range of 11.18 (DCP4) -18.75.49 (DCC3) see to fulfilling the official requirements.

By the above study we can state the DCP4 is best formulation among all with disintegration time 11.83 sec, hardness (3.3Kg/cm²) and percentage friability (0.62%).

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