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FORMULATION AND EVALUATION OF FAST DISINTEGRATING OMEPRAZOLE TABLET BY DIRECT COMPRESSION METHOD

Darshan Dipak Bhamare*, Dr. Avish D. Maru, Parag D. Kothawade, Dhiraj D. Malunjkar, Kalpesh S. More

At Post Tandulwadi Tal. Satana Dist. Nashik.

***Corresponding Author: Darshan Dipak Bhamare**
At Post Tandulwadi Tal. Satana Dist. Nashik.

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ABSTRACT
Over the last 10 years, the market for fast disintegrating tablets (FDTs) has grown rapidly, and this area is now one of the most rapidly growing areas of the pharmaceutical sector. For several drugs, oral drug administration is still the most prevalent form of administration. Because they are simple to administer and improve patient compliance, fast-disintegrating drug delivery systems have begun to gain recognition and acceptance new methods of delivering drugs. Usually, elderly people struggle to consume traditional dosage forms. Omeprazole quick-dissolving tablets have been developed by rapidly compressing several Superdisintegrants, namely Crospovidone, croscarmellose sodium, and sodium starch glycolate. The manufactured tablets were evaluated based on several variables, including content homogeneity, toughness, softness, soaking time, absorption of water ratio, dissolution time, and in-vitro dissolution. more disintegration time of 10 seconds the disintegration time of the formulation F3 was 10 seconds, which was longer than that of croscarmellose sodium and sodium starch glycolate. Crospovidone has a longer time of disintegration than sodium starch glycolate and croscarmellose sodium.

KEYWORDS: omeprazole, Crospovidone, homogeneity, quick-dissolving.

INTRODUCTION
A fast disintegrating system, sometimes known as a tablet, is a solid dose form that breaks down or dissolves in a matter of seconds. Due to its self-administration of dose form, compactness, and ease of manufacture, the tablet is one of the most often used dose types nowadays one of the most often used dose types nowadays.[1] However, regular tablets are difficult for younger, elderly, and mentally ill individuals to stomach, which causes low compliance from patients. According to the Council for Drug Assessment and Research (CDER), US FDA[2], oral disintegrating tablets (ODTs) are "a solid dosage form containing medicinal substances, which disintegrates rapidly, typically within a matter of seconds, when placed upon the tongue a pharmaceutical dosage form in the form of a solid dosage" Placing it on the tongue, whish instantly breaks down, frequently in a few seconds. Fast-dissolving pills are also known as melt-in-your-mouth pills, Oro dispersible pills, rap melts, porous pills, quick-dissolving pills, etc.[3]

The use of Superdisintegrants, which offer rapid tablet breakdown after placement on the tongue and thereafter release the medication in saliva 5, is a fundamental approach in the development of FDT.[4] Superdisintegrants are used to rapidly break down or disintegrate the fast-dissolving tablets. The formulation is more beneficial for people who are bedridden and who have swallowing issues.[5] The advantages of FDTs include enhanced bioavailability, quick start of action, and superior stability, which popularise these pills as a preferred dose form on the present market. The quickly evaporating solid dose form transforms into a soft paste or liquid for simple ingesting, and it is therefore free from choking hazards10, 11. Numerous improved medication delivery methods have recently been created in order to boost bioavailability, simplicity, and patient compliance. True fast-dissolving tablets are those that are created to dissolve in saliva within a short amount of time. Following benefits are provided by fast dissolving technology.[6]

50–60% of all commercially accessible pharmacological dose forms are oral preparations. Oral administration is considered as the most widely recognised method due to its simplicity, convenience of administration, absence of discomfort, and patient compliance. However, many paediatric and geriatric patients refuse to consume solid medications due to a fear of choking or a swallowing disorder (dysphagia). Additionally, taking oral dosage forms requires drinking water, which is not always available. Fast-dissolving tablets rapidly dissolve when put on the tongue, releasing the medication, which dissolves or diffuses in the mouth.[6] Orally disintegrating

tablets are solid oral formulations that, in accordance with FDA requirements, dissolve quickly in the mouth and have an in vitro disintegration time of less than 30 seconds.[7] Superdisintegrants are needed for making orally disintegrating medicines. These excipients contain cross-linked carboxymethyl cellulose (Croscarmellose®), sodium starch glycolate (Primogel®, Explode®), and crospovidone (Polyplasdone®). When a pill is put on the tongue, these superdisintegrants enable the tablet to disintegrate quickly.[8]

METHODS AND MATERIALS

Materials

Mannitol, microcrystalline cellulose, croscarmellose sodium, Crospovidone, and sodium starch glycolate Omeprazole, magnesium stearate, and talc flavours Every chemical utilised was of the lab-grade variety Aspartame**.**

Methods

The fundamental methodology used to examine and assess Fast disintegration tablets. The different Superdisintegrants were chosen to be Crospovidone, croscarmellose, and sodium starch glycolate. For this study's formulation of the fast-dissolving Omeprazole tablets using the direct compression method.

Differential Scanning Calorimetry (DSC)

Using DSC, the thermal behaviour of clopidogrel was studied both on its own and in genuine physical combinations with tablet excipients. Weighed samples (3-5 mg) were hermetically sealed in aluminium pans and heated continuously between 25 and 250 °C at a rate of 10 °C/min. Using differential scanning calorimetry (DSC-60, Shimadzu, Japan), sample thermograms were created.[9] TA 50I PC hardware was used for recording. the thermal analysis's data. Shimadzu software tools, as well. The DSC enthalpy and temperature scales are calibrated by using the indium standard. N2 was employed as the purging gas at a flow rate of 30 millilitre/ min.

Fourier transform infrared spectroscopy (FTIR)

The FTIR spectra of TNX, KL, and their binary complexes (Spectrum BX) were captured by a Perkin Elmer FTIR spectrophotometer.[10] Before scanning starting at 4,000 Samples were mixed with spectroscopic grade potassium bromide and compressed using a hydraulic press into discs at 600 cm-1. Spectrum V5.3.1 from Perkin Elmer was used to analyse the data.

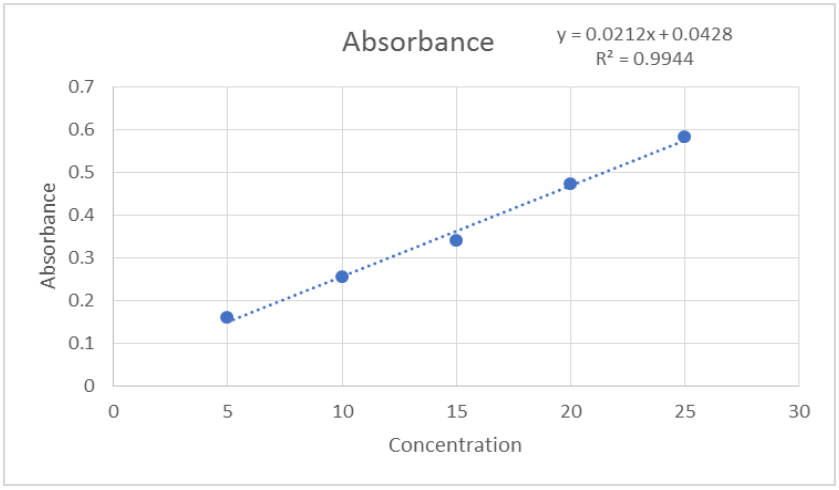
UV Visible Spectroscopy

Determination of λ max in methanol

With the use of a UV-visible spectrometer (UV 3000), the UV spectrum of Omeprazole was discovered. One hundred millilitres of volumetric flask were filled with precisely weighed 10 mg of the medication. 100 micrograms of methanol were used to generate a volume of up to 100 ml for storing purposes, this approach was adopted. To get the concentration of 10 micrograms/ml, aliquots of 1 ml from the stock solution were taken out and brought up to 10 ml in volume with water.[11] The result was scanned from 200 to 400 nm, and the spectra was recorded to determine the maximum wavelength in each solvent.

Preparation of calibration curve of omeprazole in methanol

Stock solutions of the medication at concentrations ranging from 5 to 30 ug/ml were prepared.[12] Using the appropriate solvent and UV-Visible spectroscopy, the absorbance of the resultant solution was determined at 240 nm.



Preparation of Omeprazole Fast Disintegrating Tablets by Direct Compression

Omeprazole tablets were produced using direct compression. The components for each pill are listed in Table 2. Using sieve #40, the medication, diluents, and Superdisintegrants. In a plastic bag, the ingredients were properly mixed before the weight of mannitol was added. Talc and magnesium stearate were added to the original mixture in a poly bag after being passed through mesh #80. Following mixing, the powder mixture was crushed

into 300 mg tablets employing 8-station rotary punch tableting equipment and 8 mm circular punches (Camacho Machineries, Station, D tooling). The required number of tablets were produced using the same hardness.[13] Compressed pills were evaluated by authorised and unauthorised testing. The pills were kept in light- and moisture-proof containers.

Table 1: Formulations of Omeprazole containing different Superdisintegrants.

Ingredients(mg)	Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Omeprazole	20	20	20	20	20	20	20	20	20
MCC	201	197	193	201	197	193	201	197	193
Crospovidone	4	8	12	-	-	-	-	-	-
Croscarmellosesodium	-	-	-	4	8	12	-	-	-
Sodium starchglycolate	-	-	-	-	-	-	4	8	12
Mannitol	10	10	10	10	10	10	10	10	10
Aspartame	5	5	5	5	5	5	5	5	5
Magnesiumstearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Flavour	qs	qs	qs	qs	qs	qs	qs	qs	qs
Total	250	250	250	250	250	250	250	250	250

Table 2: Standard graph for Omeprazole.

S. No	Concentration (µ/ml)	Absorbance (302 nm)
1	0	0
2	2	0.113
3	4	0.253
4	6	0.338
5	8	0.469
6	10	0.578

Preformulation studies

Table 3: Preformulation studies of API.

Sr. No	Preformulation studies	Omeprazole
1	Bulk density (gm/ml)	0.30
2	Tapped density (gm/ml)	0.43
3	Angle of repose	21.2
4	Carrs index	11.53
5	Hausner ratio	1.13

Table 4: Preformulation studies of blend of all formulation.

Formulation	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Angleof repose(θ)	Carr's Index (%)	*Hauser's* ratio
F1	0.40	0.45	21.5	12	1.13
F2	0.30	0.45	20.1	14.45	1.16
F3	0.30	0.43	19.6	11.53	1.13
F4	0.30	0.41	17.8	11.11	1.12
F5	0.40	0.46	19.2	14	1.16
F6	0.40	0.47	18.4	14.28	1.16
F7	0.30	0.43	18.5	11.53	1.13
F8	0.30	0.41	17.4	11.11	1.12
F9	0.30	0.42	17.8	11.36	1.12

Table 5: Evaluation of tablets.

Formulations	F1	F2	F3	F4	F5	F6	F7	F8	F9
Disintegration time(Sec)	30	40	10	60	50	15	55	52	20
Friability (%)	0.80	0.82	0.79	0.85	0.88	0.83	0.90	0.92	0.85
Thickness (mm)	4.40	4.65	4.45	4.50	4.70	4.65	4.60	4.65	4.45
Hardness (kg/cm^2)	4.0	4.01	4.04	4.0	4.03	4.02	4.03	4.05	4.04
Weight variation(mg)	251	250	253	251	252	251	250	251	252

Drug release study by *in-vitro* drug dissolution

Table 6: Percent Drug release of formulation.

time	F1	F2	F3	F4	F5
0	0	0	0	0	0
1	2.295	0.04	7.04	2.47	0.38
2	11.92	12.14	18.93	9.80	9.80
3	19.57	22.96	32.94	19.78	20.84
4	25.93	31.03	42.07	21.69	26.78
5	33.58	42.07	54.38	30.82	40.37
6	39.73	49.92	63.29	37.82	45.89
7	46.31	61.17	72.42	42.07	59.47
8	57.14	69.02	82.61	54.80	64.78
9	66.26	76.03	93.01	62.02	72.42
10	72.63	83.25	99.38	68.17	81.12

time	F6	F7	F8	F9
0	0	0	0	0
1	4.92	4.41	2.52	2.80
2	14.68	5.56	5.34	10.44
3	30.82	12.99	18.93	27.84
4	37.61	18.93	22.54	33.58
5	52.25	20.63	38.25	47.58
6	59.05	22.11	41.64	54.59
7	70.30	27.42	57.14	67.33
8	77.94	31.03	60.53	73.48
9	88.34	35.06	69.66	83.67
10	94.71	38.67	76.03	91.74

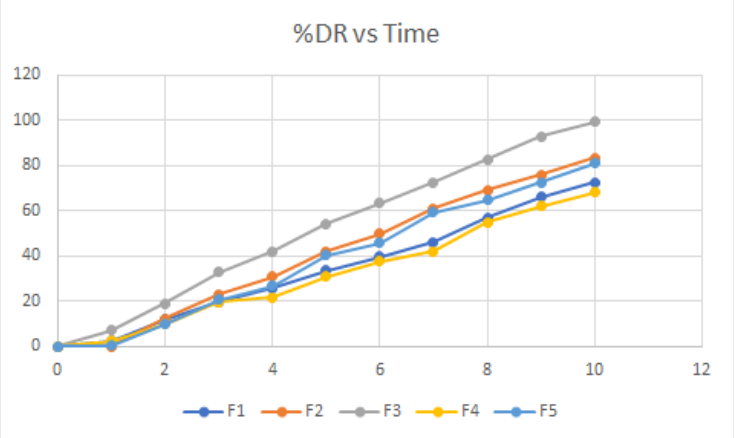


Fig 2: Drug Release of F1 to F5.

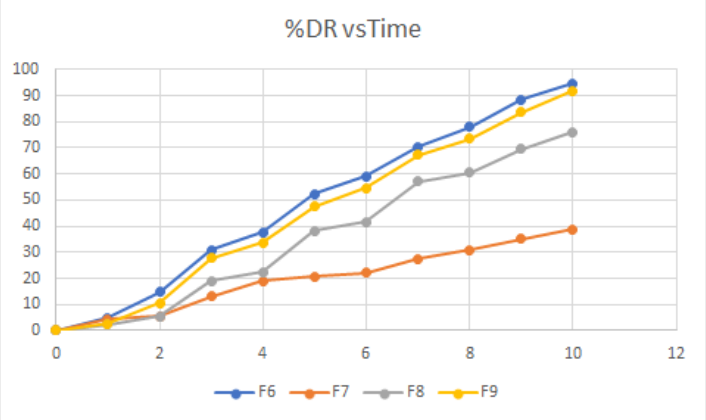


Fig 3: Drug Release of F6 to F9.

RESULT AND DISCUSSION

- **DSC curve of Omeprazole**

The DSC curve of omeprazole gives sharp peak at 160.55^0 C at 11.57min.

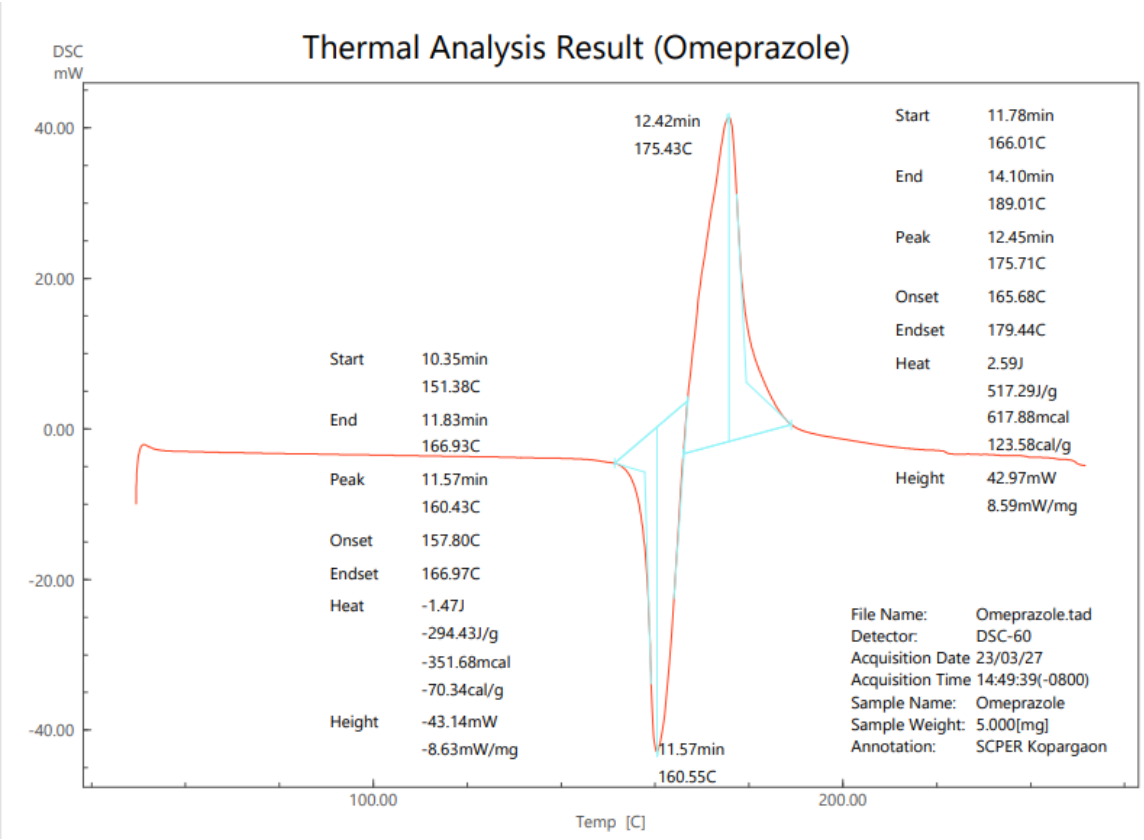


Fig. 1: DSC Curve of Omeprazole.

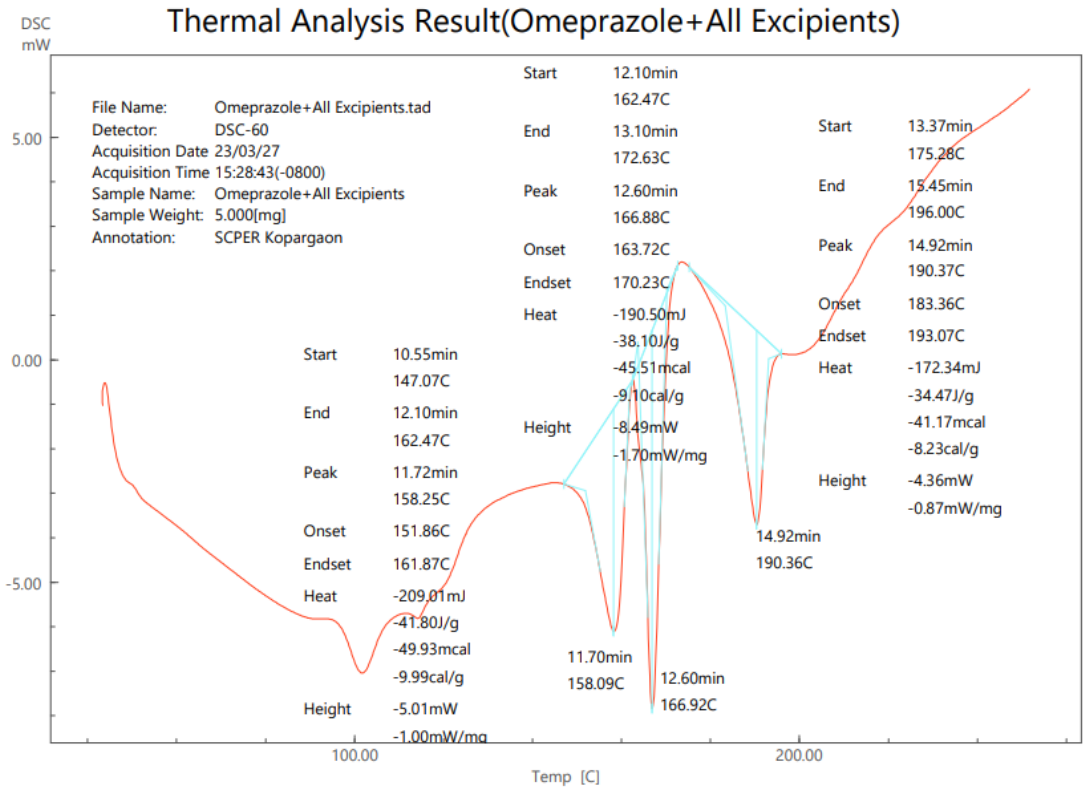


Fig. 1: DSC Curve of Omeprazole+ Excipient.

- **FTIR**

Fourier transform infrared spectroscopy (FTIR)

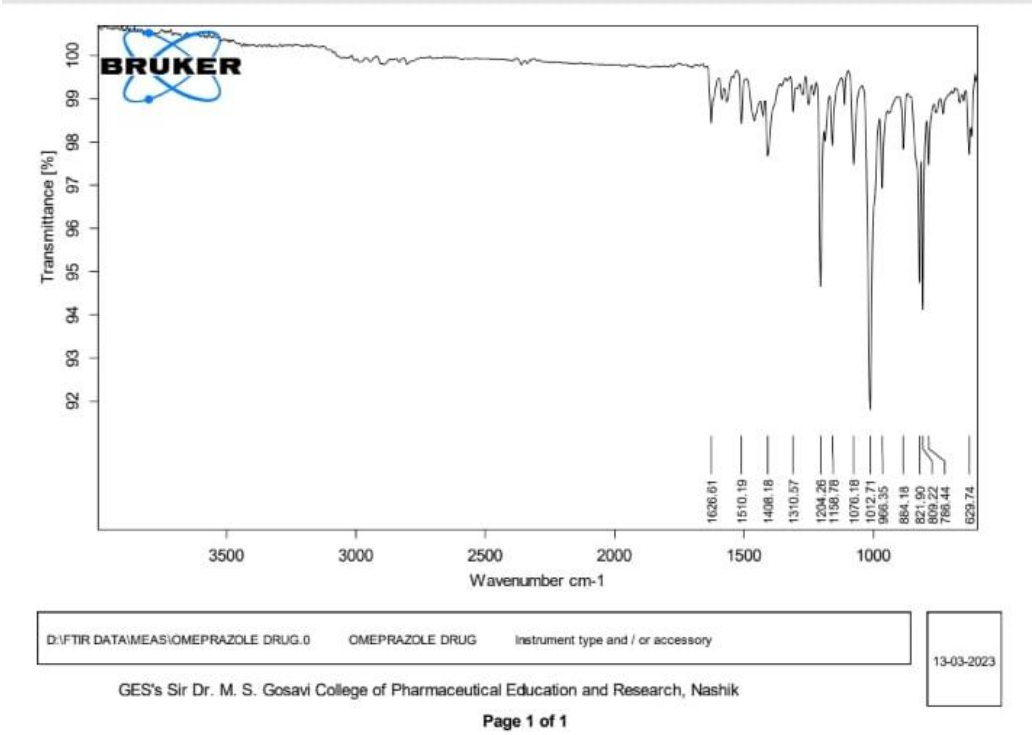


Fig 3: FTIR of pure Omeprazole

- **Drug- Excipient Interaction Study FTIR**

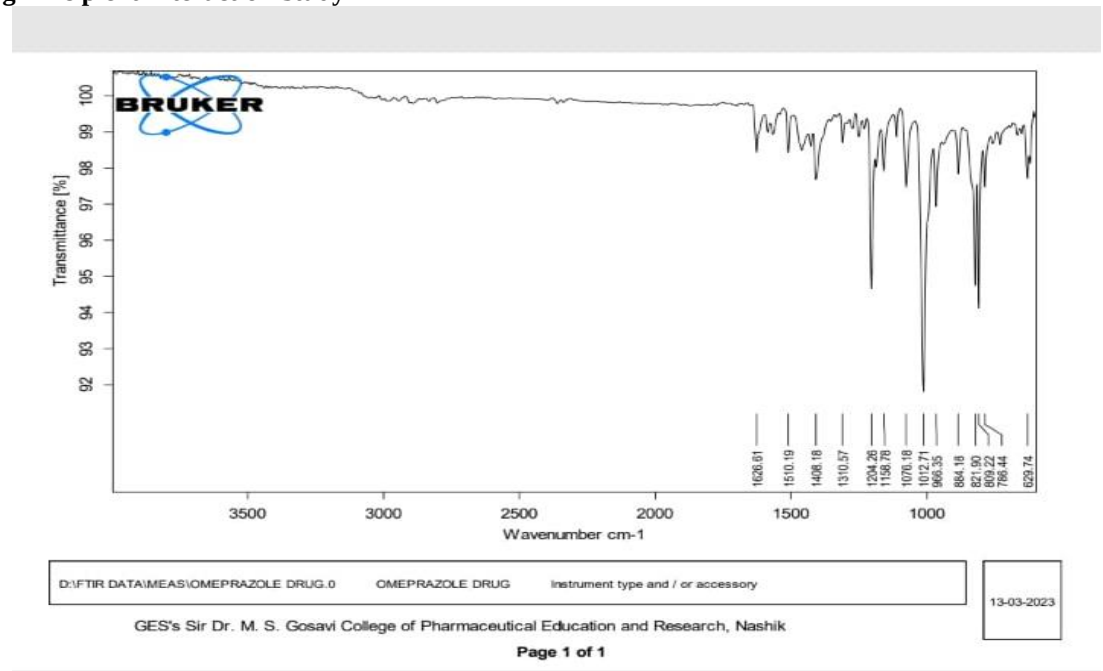


Fig 4: FTIR spectrum of omeprazole + All Excipient physical mixture.

FTIR Interpretation

SR. No	Frequency	IR Range	Functional group
1	1012.71	1000-1100	S=0
2	1204.26	1200- 1350	C-N
3	809.22	910- 665	N-H

SUMMARY AND CONCLUSION

Several Superdisintegrants, including Sodium Starch Glycolate, Croscarmellose Sodium, Crospovidone were used to generate the summary and conclusion. Precompression settings were evaluated for each formulation mix and found to be suitable14. Evaluations were performed on the manufactured tablets for a variety

of parameters, including homogeneity of content, hardness, friability, wetting time, water absorption ratio, disintegration time, and in-vitro dissolution. The outcomes demonstrated that the tablets met the required standards. All formulations decomposed in less than a minute, according to disintegration studies. The formulation F3 shown more disintegration time of 10 seconds. More disintegration time was displayed by crospovidone than by sodium starch glycolate and croscarmellose sodium. When used at the same weight by weight % concentration, These Superdisintegrants representing each of the three major classes of Superdisintegrants in the current investigation showed differences in their capacity to break down a model tablet into its constituent particles15. In conclusion, it may be said that the study's goal has been accomplished. Due to its shorter disintegration time and good% drug release when compared to other formulations, the formula used for the F3 formulation gives better drug release and more disintegration time.

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