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Original Research Article

Dry Granule Formulation For Ciprofloxacin Hydrochloride Capsule Using Co-Processed *Grewia Mollis* Gum

Nnabuike D. Nnamani[1]*, Adesegun, J. Kashimawo[2], Michael Zar[1]

[1]*Department of Pharmaceutics and Pharmaceutical Technology, College of Pharmacy, Igbinedion University Okada, Edo State, Nigeria.*
[2]*Pharmaceutical and Medicinal Chemistry Department, Niger Delta University, Yenogoa, Bayelsa State, Nigeria.*

ABSRTACT

Co-processing excipients improve functionality, dosage form processing and drug delivery. This research seeks to employ co-processed *grewia* gum in the formulation of ciprofloxacin capsule. *Grewia* gum was extracted from *Grewia* plant stem bark and purified. The gum was analysed for drug interaction using FT-IR and DSC techniques. Eight combinations of *grewia* gum, lactose and microcrystalline cellulose were derived from 2^3 factorial designs and co-processed using the wet agglomeration method. The co-processed excipient was analysed for micromeritic properties, kneaded with ciprofloxacin and granulated. The granules were analysed for densification properties, and filled into size 00 hard gelatin capsule shell. The capsule was analysed for physicochemical properties. The yield of *grewia* gum was 32.87 %. The FT-IR and DSC results showed no new chemical entity. The co-processed powder excipients showed angle of repose, Carr's indices and Hausner ratios less than 29.23, 15.95 and 1.15 degrees respectively, and flow rate greater than 21.19 grams per second. The granules gave yield strength and compactibility ranges of 133.32 to 720.62 and 0.07 to 0.19 respectively. These results value fall within reference indices of good powder flow and granules compaction. Capsules from the nine batches disintegrated within 12.5 minutes and dissolved between 54 and 62 percent drug after 60 minutes in both acidic and basic pH media respectively. The optimal formulation containing 78.3, 17.4 and 4.3 percent lactose, *grewia* gum and avicel respectively showed extended drug release properties. Increasing the concentration of *grewia* gum in co-processed excipient improved flowability and processing efficacy of ciprofloxacin hydrochloride capsules.

Keywords: Kneaded, agglomeration, granulated, compressibility, compactability

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Introduction

Formulation excipients and extensive formulation processes can exert stress conditions such as heat, hydrolysis, and electrostatic charges from mixing, on dosage design, which may affect drug delivery. The effect of these stress conditions on drug can be reduced, by first pre-formulating some excipients to co-excipients before formulating with active ingredient.[1] This procedure can shorten processing time and cost of drug development, and improve drug delivery without significant change to their chemical properties.[2] Co-processed excipients have better processing abilities, improved functionalities and physical properties, such as better flow, binding and blending, than the properties of any of its separate excipient.

*Corresponding author. E mail: Nnamani.didacus@iuokada.edu.ng
Tel: +2348033276431

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[1] Co-processed excipients are produced from extensive coupling techniques like co-milling, melt extrusion, granulation, solvent evaporation, and spray drying, and not through simple physical mixing.[3] Materials with different mechanical properties are combined in proportion to formulate co-excipient with improved properties.

Brittle and plastic excipients, such as cellulose and gum, may be co-processed to produce co-excipients with improved binding and flow properties. Excipients such as calcium chloride and polyvinyl pyrrolidone to improve flow and compressibility; microcrystalline cellulose and colloidal silicon dioxide to improve flow and for direct compression of hygroscopic material; lactose and cellulose to improve compressibility, disintegration and mouth feel; sucrose and dextrin for direct compression have been produced as co-processed excipients.[2,4,5] Co-excipients from standard materials may not require extensive safety testing before use since they are produced from materials that have already been approved for use. Co-excipients from synthetic and natural excipients are gaining interest because of the relative safety of natural excipients and their unique functionalities.[6,7] This study aims to co-process natural *grewia* gum with lactose and microcrystalline cellulose to improve flow, binding and disintegration properties of ciprofloxacin capsule formulation.

Grewia gum is a natural polysaccharide gum obtained from the bark of *Grewia mollis*, Juss (Tiliaceae) plant stem.[8] This plant is abundant in the wild and cultivated for food. The *grewia* gum has low aqueous solubility and is used as medicine and as thickener for food (soup).[9]

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Grewia gum mucilage is heat stable and in pharmaceutics, it has been used as an excipient for modified release dosage forms such as sustained release matrix, as aqueous film-coating for tablets, as stabilizer for liquid, suspensions and semi-solid dosages, and as binder in some tablet formulation.[8,10]

Lactose is used as diluent in solid dosage design. It is available as coarse grade (60 to 80 mesh) and a standard grade (80 to 100 mesh). It can be acquired in anhydrous and hydrous forms. Lactose formulations have good release rates whether they are in hydrous or anhydrous form. The anhydrous form absorbs moisture easily, hence the need to store its formulation in moisture-proof containers. Wet lactose granules dry easily, making it a useful excipient in wet granulation. The disintegration time of lactose tablets is not particularly affected by changes in solid compact.[11]

Microcrystalline Cellulose is a non-active pharmaceutical ingredient that comes in different grades and has been used as binders, disintegrants, diluents and other functions in dosage design. Microcrystalline cellulose can be used as binder, diluent or lubricant in direct compression of tablets. It can also be used as binder or disintegrant in sustained release formulation and in wet granulation of tablet and capsule formulations.[12]

Ciprofloxacin hydrochloride is a potent bactericidal agent against most gram +ve and gram -ve bacteria. It is a pale yellow, crystalline and slightly hygroscopic BSC Class IV drug with bitter taste.[13] Because of its poor solubility and poor permeability, improvement of dissolution is key to enhancing bioavailability. Ciprofloxacin hydrochloride is presented in 250 mg, 500 mg, 500 mg ER and 1000 mg ER tablets, capsules or infusions dosages. Research works have been carried out on ciprofloxacin hydrochloride ranging from the formulation of fast dissolving tablet of ciprofloxacin hydrochloride; formulation of oral floating matrix tablets of ciprofloxacin hydrochloride using co-excipients such as HPMC and xanthan gum, sustained release formulation using HPMC and ethyl cellulose, controlled release floating capsule using mannitol and lactose co-excipient or cabapol and HPMC, effervescent ciprofloxacin using crospovidone excipient, ciprofloxacillin hydrochloride inhalation powder using different DPI capsules.[14, 15] This work intends to use dry granulation with co-excipient fast process ciprofloxacin for capsule filling.

Materials and Methods

Materials

Ciprofloxacin hydrochloride (Godavari Drugs Limited, Telangana, India), microcrystalline cellulose Avicel PH-102 (Salt Minerals GmbH, Korbach, Germany), lactose (Sigma Chemicals, St. Louis, USA), starch (potatoes) and magnesium stearate (A.H.A. International Co. Ltd, China) were gifted by Ulticare-lyka Pharmaceutical. Inner stem bark of *Grewia mollis* shrub was obtained from Montane Nigeria Institute of Forestry, Jos in April 2019, identified by Mr T.I Adeleke of Dept of Pharmacognosy, University of Lagos, and authenticated by Forestry Institute of Nigeria (FRIN) Herbarium, Ibadan, with voucher number FHI 112884.

Table 1: Formula for Co-processing *Grewia* Gum

Material / Co-pe	(g)							
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Lactose	95.0	95.0	95.0	95.0	90.0	90.0	90.0	90.0
Grewia	20.0	20.0	5.0	5.0	5.0	20.0	5.0	20.0
Avicel	10.0	5.0	1.0	5.0	5.0	5.0	10.0	10.0
Total	125.0	120.0	110.0	105.0	100.0	115.0	105.0	120.0

Key: Co-pre = co-processed excipient

Extraction, purification and yield of grewia gum

Adopting the method of Nep and Conway[8], the inner stem bark of *Grewia mollis* plant was chopped into small pieces with a knife and dried in an oven. The dried bark was pulverized using an electric kitchen blender (Eurosonic, China). The pulverized powder was weighed, and then dispersed in 1% sodium metabisulphite solution and left for 48h. The dispersion was sieved through a muslin bag to remove impurities. The filtrate was treated with 0.1N NaOH and centrifuged for 10 min at 3000 rpm. The supernatant was treated with acidified ethanol containing 0.1N HCl. The supernatant was continually treated with ethanol as the resultant precipitate was collected by sieving through muslin bag. The precipitate was air-dried and the dried product milled. The dried powder was passed through a 710 µm mesh size sieve (Endecotts Ltd., England), weighed and stored in an air-tight container. The yield of *grewia* gum from the weight of the *grewia* gum obtained from the pulverized bark.

Compatibility behaviour and thermal interaction of grewia gum and ciprofloxacin

Fourier Transform Infrared (FTIR) Spectrum: A 2 mg sample of *Grewia* gum was weighed and made up to 2000 mg with Kbr. The mixture was blended, pulverized and dried at 110 ºC for 2 hours in a hot air oven. The dried mixture was compressed to 80 mg pellet using 13 mm diameter die and 8 tons of pressure for 3 min. FT-IR spectrum was recorded using Kbr disc on a Schimandzu FTIR 8400S Fourier transmission Infrared Spectrophotometer. All the readings were taken at the scan range of 4000 – 650/cm with a resolution of 4/cm and 16/cm. The readings were recorded for analysis. FTIR is used for quality control and product identification.

Differential Scanning Calorimetry (DSC) analysis: Adapting the method of Talik *et al.*[16], DSC analysis was conducted using 5.2 mg sample of *grewia* gum, 1:1 regenerated *grewia* gum dispersion in ciprofloxacin and pure ciprofloxacin. A sample is placed inside the curvet of PerkinElmer Differential Scanning Calorimeter (Model DSC 800, PerkinElmer Private Limited, India) set at left and right limits of 60.0 and 300.6 ºC respectively.

Preparation of co-excipient

Using *grewia* gum, lactose and microcrystalline cellulose as variant excipients in 2^3 factorial design, 8 model co-processed excipients (a-h) were formulated as expressed in Table 1. A 74 g of lactose, 60 g each of *grewia* gum and 60 g microcrystalline cellulose were separately weighed, passed through 1.7 mm stainless steel sieve and kept in clean dry containers. For a model co-processed excipient, mucilage was prepared by heating 10 % $^{w}/_{v}$ *grewia* gum aqueous dispersion for 30 min at 103 ºC. The mucilage was allowed to cool to 45ºC and blended with lactose and Avicel®. The wet mass was dried in a hot air oven set at 103ºC for 30 min to get co-processed excipient. The co-processed excipient was milled through mesh no 22, lubricated with magnesium stearate and stored for powder analysis and capsule filling.

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Evaluation of co-excipient powder

Flow rate: A 25 g co-excipient powder was poured into a 1.1 cm diameter base-sealed funnel mounted at 30 cm from the base. The base of the funnel was opened and the time taken for the powder to flow completely was recorded. The experiment was performed in triplicate and the average flow rate in g/sec was calculated from Equation 1.

Flow rate = $\frac{weight\ of\ powder}{time\ of\ flow}$ …… equation 1

Angle of repose (Ɵ)*:* A 25 g co-excipient powder was poured into an open ended cylinder place on a piece of paper on a flat table. The open ended cylinder was raised up and removed gently allowing the flow of powder. The radius of the base (r), height (h) and slope of the heap formed was measured, recorded and used to calculate angle of repose using equation 2.

$\Theta = \tan^{-1}\frac{h}{r}$ ----------equation 2

Densification properties (Carr's index and Hausner ratio): A 25 g of co-excipient powder was poured into a measuring cylinder, tapped lightly three times, and the volume occupied was recorded as bulk volume (bv) and used to calculate bulk density (equation 3). The cylinder was tapped on a tabletop until a fixed volume, called tapped volume (tv) was observed. The tapped volume was recorded and used to calculate tapped density (equation 4). Carr's index and Hausner ratio were then calculated using equations 5 and 6.

Bulk density = $\frac{Weight\ of\ Powder}{Bulk\ Volume}$ ----------equation 3

Tapped density = $\frac{Weight\ of\ powder}{Tapped\ Volume}$---------- equation 4

Carr's index = $\frac{(tapped\ density - bulk\ density)}{tapped\ density}$ x 100 ----------equation 5

Hausner's ratio = $\frac{tapped\ density}{bulk\ density}$----------equation 6

Preparation of ciprofloxacin granules

Twenty five gram (25.0 g) ciprofloxacin hydrochloride, in Table 2, was mixed in a mortar with 10 g of already co-processed lactose, *grewia* gum and avicel, wetted with 3 ml co-solvent of ethanol and water (2:1) and kneaded to a wet coherent mass. The wet mass was passed through mesh no. 22 and dried in a hot air oven at 103 ºC for 25 min to get dried ciprofloxacin granules. The granules were passed through 1.7 mm stainless steel sieve to remove residual lumps. Batches A-H were prepared and all analysed for micromeritic properties and consolidation behavior

Evaluation of Granules

Compaction Characteristic: The Cohesiveness and compressibility behaviour of granules was obtained using Sato *et al.*[17] Kawakita densification parameters. A 25 g of granules was gently poured into a 50 ml measuring cylinder and its volume (V_o) recorded. The cylinder was gently tapped 100 times on a wooden horizontal surface and the resultant volume (V_N) recorded. Tapping continued with the granule volume recorded after every 100 taps for a 1000 taps. The data obtained were fitted in the Kawakita equation 7 and a plot of N/C against N with a slope of (1/a) and intercept of ($^1/_b$).

$\frac{C}{N} = {}^N/_a + {}^1/_{ab}$----------equation 7

Where N = number of taps, C = degree of granule volume reduction (V_o-V_N/V_o), a and b are constants, where a = compactibility of granules (maximum degree of compression) and $^1/_b$ = cohesiveness of granule (yield strength or pressure needed for the powder to reach half of the maximum volume reduction).

Consolidation index (C) *and rate of consolidation* (K): These were determined using Neumann *et al* method and its equation 8.

Log $\frac{Tapped\ density - bulk\ density}{Tapped\ density}$ = K Log N + C---------- equation 8

Graph of Log $\frac{Tapped\ density - bulk\ density}{Tapped\ density}$ against log N was plotted to get K slope and C intercept.

Filling of ciprofloxacin granules into hard gelatin capsules

A 350 mg ciprofloxacin granules was filled into an opened size 00 hard gelatin capsule shell, covered, sealed tight, stored in a dry bottle container, and appropriately labelled.

Evaluation of ciprofloxacin capsules

Disintegration time test: The disintegration time test for 6 randomly selected capsules from a batch was determined using disintegration tester (DT) (MK4, Manesty Machine Limited, England) operated at 30 cycle/ mm in a disintegration medium of 1000 ml of 0.1 N HCl at a temperature of 37 ℃. Each of the capsules were placed in one of the six-opened cylindrical transparent tubes of the basket-rack assembly of the tester, operated and observed over 30 minutes. The test was done in triplicate, and the average disintegration time of the capsules of each particular batch was observed and recorded.

Dissolution rate test: Using the basket method, a capsule was placed in a basket immersed in 900 ml of 0.1N HCl dissolution fluid maintained at 37 ± 2℃ and operated for 2 h at 50 rpm, and the dissolution medium was replaced with phosphate buffer solution of pH 6.8 for the remaining 6 h. At 15, 30, 45, 60, 90, 120, 150 and 180 minutes intervals, 5 ml samples of the leaching fluid were withdrawn with a pipette fitted with cotton wool filter, and replaced with 5 ml dissolution fluid. The withdrawn fluid was diluted 1:100, and the absorbance determined with UV- spectrophotometer (Model 23D, Uniscope, England) at a wavelength (λmax) of 277 nm. The test was repeated in triplicates for each batch. The concentration of drug release was calculated from the absorbance using the standard calibration of the pure ciprofloxacin powder. The percentage ciprofloxacin released from the formulation concentration was calculated.

Statistical analysis

Statistic means and standard deviation were applied to evaluate the final capsule weight and disintegration time's conformity to pharmaceutical pharmacopeia specifications.

Results and Discussion

Properties of grewia gum

***Yield*:** The yield of *grewia* gum from pulverized inner stem of *Gewia millis* was 32.87 %. This yield conforms to the expected yield of *grewia* gum by Nep and Conway[8].

Compatibility and interaction with ciprofloxacin: The compatibility and interaction of *grewia*-gum and ciprofloxacin results from FT-IR spectra taken at 600 – 3500 / cm wavelength and DSC thermographs taken at 60 – 300ºC of grweia gum, ciprofloxacin and dispersion of ciprofloxacin in *grewia* gum are presented in figure 1 and figure 2 respectively.

The 1080.9 and 1025.0 cm $^{-1}$ stretch of grewa gum FT-IR spectrum is typical of gums consisting mainly of polysaccharide. The FT-IR spectra of pure ciprofloxacin and ciprofloxacin-grewa gum dispersion in figure 1 expressed C=C aromatic stretching at 1621.4 and 1617.7 cm^{-1}, C=O

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carboxylic acid stretching at 1871.1 and 1897.2 cm^{-1}, C=H stretching at 2117.1 and 2121.9 cm^{-1}, N=H aromatic stretching at 2683.7 and 2480.95 cm^{-1}, and OH hydrogen bonding at 3324.8 and 3336.0 cm^{-1} respectively. This indicates that the functional groups of ciprofloxacin were not altered and no new functional group formed in the ciprofloxacin dispersion with grewa gum. This is consistent with ciprofloxacin FT-IR spectra interpretation that have little or no interaction nor chemical change.[18]

The DSC thermal analysis curve enthalpy in figure 2 showed endothermic peaks at 87.2, 89.8 and 89.8 ºC for grewa gum, ciprofloxacin and ciprofloxacin-grewa dispersion, indicating water loss for the polymers, and melting points of undissolved ciprofloxacin for both ciprofloxacin and ciprofloxacin-grewa gum dispersion. This is an indication that the nature of the interaction between ciprofloxacin and *grewia* gum may be simple hydrogen bonding or weak van der waals interaction and not complex chemical reaction, and is in conformity with DSC interpretation of Fathy *et al*.[19].

Properties of co-excipients

The micromeritic properties of co-excipients a-h are presented in Table 3 with ranges of angle of repose (25.13-29.23º), Carr's indices (7.02-15.95), Hausner ratios (1.07-1.15) and flow rates (19.23-21.19), and the flow rates (19.23-21.19 g / s) of a>b>f>e>h>c>d>g, Carr's index of g<f<a<b<e<c<h<d, Hausner ratio of g<f<a<b<e<c<h=d, and angle of repose of d<g<e<f<a<c<h<b.

With flow rate >19.23 g / s and ranges of angle of repose < 31 º, Carr's indices < 16 % and Hausner ratios < 1.18, the co-processed excipients powders can be said to be free flowing in line with results of powder behaviour interpretation of research work by Castellanos[20].

Table 2: Formula for producing 100 ciprofloxacin 250 mg capsules

	(g)							
Material/ Batches	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Ciprofloxacin	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0
Lactose	7.6	7.9	8.6	9.1	9.0	7.8	8.6	7.5
Grewia	1.6	1.7	0.5	0.5	0.5	1.7	0.5	1.7
Avicel	0.8	0.4	0.9	0.5	0.5	0.4	1.0	0.8
Magnesium stearate	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total	35.1	35.1	35.1	35.1	35.1	35.1	35.1	35.1

NB: Each capsule weighs 350 mg and contains 250 mg ciprofloxacin hydrochloride

Properties of granules

The compactibility, compression and consolidation behaviours of the granules are presented in Table 3, Figure 3 and Figure 4 respectively. Formulation D with 95.0 % lactose, 4.8 % *grewia* gum and 4.8 % avicel showed greater yield strength than Formulation H with 75.0 % lactose (75.0 %), 16.5 % *grewia* gum and 8.3 % avicel. This means that spatial constraints to powder rearrangement and resistance to compaction reduced with increase in *grewia* gum concentration. High yield strength and compactibility are indicative of elastic behaviour, while materials with low yield strength is attributed to quick fragmentation, plasticity and elasticity. Excessive elasticity may result in compact tablets that cap, laminate and or that are too hard with hindered disintegration. It may be that *grewia* gum and avicel lowered the yield strength of lactose in the co-excipient and would improve disintegration properties during compression. These observations and inference conforms to studies by Sato *et al*.[17] on densification behaviour of powders.

Properties of capsules

The physicochemical properties of capsules showing varied capsule weight of 350.05 – 350.35 and disintegration time of 7.5-29.5 is presented in Table 3. The dissolution profile of the capsules are presented in the dissolution rate graph in Figure 5. At disintegration time range of 8.1-12.5 min, the effect of co-excipients is fairly minimal on the hard gelatin capsule. The formulations with higher proportions of avicel having slightly higher disintegration time. This may be attributed to the modified release effect of microcrystalline cellulose at higher concentration as reported by researchers such as Chaerunisea *et al.*[21]. Formulations C, D and G with relatively low proportions of *grewia* gum showed the fast onset of dissolution. This conforms reports of researchers such as Nep *et al.*[8] and Ogaji *et al.*[10] on delayed release properties of *grewia* gum.

Conclusion

Co-processing of *grewia* gum with lactose and microcrystalline cellulose improved the flowability and processing efficacy of ciprofloxacin hydrochloride formulation. The ciprofloxacin hydrochloride capsules formulated with this co-processed excipient showed fast onset of release and varied prolonged release. Co-processing *grewia* gum with lactose and microcrystalline cellulose may be used to improve processing efficacy and modify drug release.

Conflict of Interest

The authors declare no conflict of interest.

Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

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Table 3: Properties of Co-Processed Excipients, Granules, and Capsules

	Excipients			Granules			Capsules	
	Angle of repose (^{O})	Carr's Index (%)	Hausner ratio (ratio)	Flow rate (g/min)	Yield strength (1/b)	Compactability (a) (ratio)	Weight (mg)	Disintegration time (min)
A	27.75	10.34	1.11	21.19	720.62	0.13	350.05 ± 0.03	10.6 ± 0.35
B	29.23	11.76	1.13	21.19	658.68	0.15	350.15 ± 0.03	8.1 ± 0.35
C	28.34	13.33	1.15	20.16	680.45	0.15	350.10 ± 0.03	12.5 ± 0.35
D	25.13	15.95	1.17	20.03	770.21	0.19	350.15 ± 0.02	9.0 ± 0.71
E	26.28	12.28	1.14	20.78	133.32	0.13	350.25 ± 0.03	9.4 ± 0.71
F	27.41	8.77	1.09	20.83	320.28	0.09	350.15 ± 0.02	8.2 ± 0.35
G	26.57	7.02	1.07	19.23	626.61	0.07	350.15 ± 0.02	13.3 ±1.06
H	28.39	15.49	1.17	20.45	138.92	0.11	350.35 ± 0.02	11.8 ± 0.35

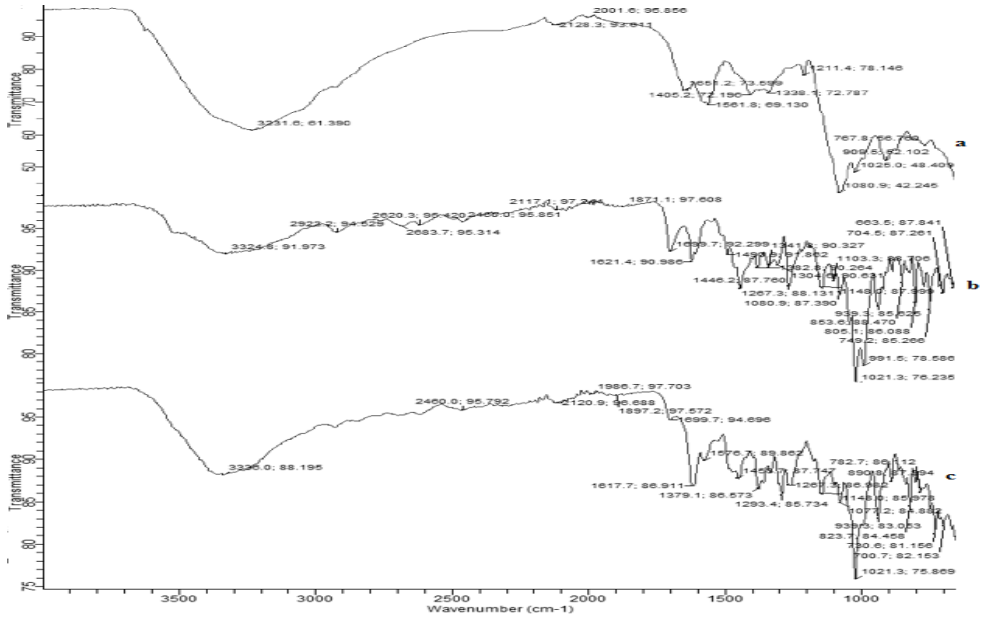

Figure 1: FT-IR Spectra of (a) *Grewia* Gum, (b) Ciprofloxacin and (c) *Grewia*-Ciprofloxacin Powder

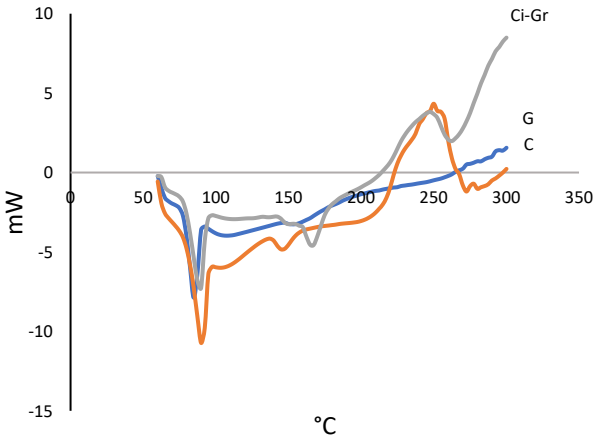

Figure 3: Plot of Compression Behavior of Ciprofloxacin Granules

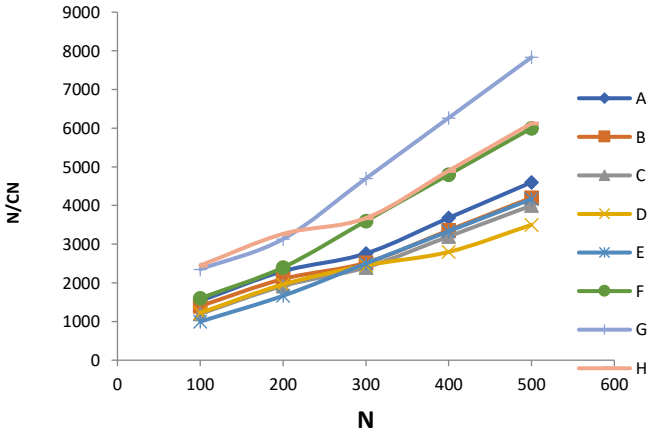

Figure 2: DSC Thermogram of (Gr) *Grewia* Gum, (Ci) Ciprofloxacin and (Ci-Gr) Ciprofloxacin-Grewa Powders

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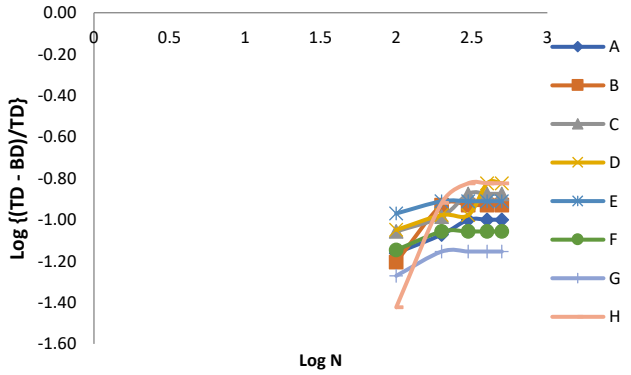

Figure 4: Plots of the Consolidation Behaviour of Ciprofloxacin Granules

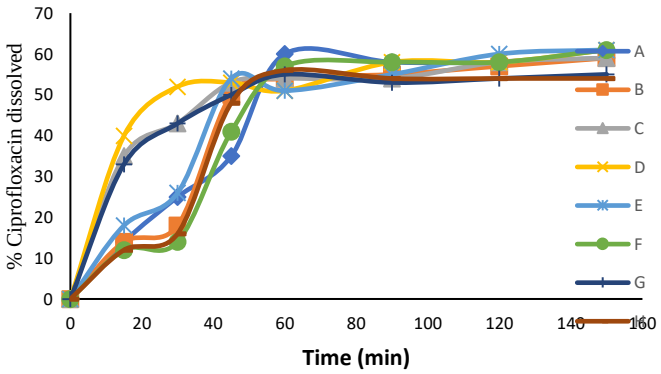

Figure 5: Dissolution Rate Profile of Ciprofloxacin Capsule

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