Formulation and Development of Nanoparticulate Tablet of Mesalamine

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***Abstract*- The present study focuses on the formulation and development of nanoparticulate tablets of Mesalamine to enhance its therapeutic efficacy and patient compliance in the treatment of ulcerative colitis and Crohn's disease. Mesalamine-loaded chitosan nanoparticles were prepared using the ionotropic gelation technique, optimizing particle size, zeta potential, and entrapment efficiency. The nanoparticles exhibited a mean particle size of 34.2 nm, polydispersibility index (PDI) of 0.534, zeta potential of +28 mV, and entrapment efficiency of 84%, indicating a stable and effective delivery system. The nanoparticulate tablets were formulated with varying ratios of Eudragit RS and Eudragit L as release-controlling polymers and evaluated for pre-compression and post-compression parameters. Results showed excellent flow properties, acceptable hardness, weight variation, friability, and disintegration times within pharmacopeial limits. In-vitro dissolution studies demonstrated sustained drug release over 60 minutes, with formulation F2 showing the most favorable release profile and stability over a 3-month period. The study concludes that the chitosan-based nanoparticulate system is a promising approach for controlled delivery of Mesalamine, improving its bioavailability and reducing gastrointestinal side effects.**

***Index Terms*- Mesalamine, Nanoparticles, Chitosan, Ionotropic Gelation, Nanoparticulate Tablet, Controlled Drug Delivery, Sustained Release, Bioavailability, Eudragit, Ulcerative Colitis.**

I. INTRODUCTION

Nanotechnology, term got from Greek word 'Nano', which implies dwarf, applies guidelines of building, devices, physical and material science and amassing at nuclear and supra-micron level.

Present study reveals procedures for course of action, depiction and use of couple nanoparticulate drug movement structures. Nanoparticles have higher surface-to-volume extent as differentiated and mass material, and along se lines estimation and repeat of association would be diminished therefore growing tolerant consistence. One of most promising techniques to improve bioavailability by oral movement with colloidal bearers is just polymeric nanoparticles.

Oral course gives points of interest of avoiding distress and uneasiness associated with imbuements furthermore wiping out pollutions. For quite a while, examination has been coordinated in scope of progress of oral movement of therapeutic solutions. To comprehend this errand colloidal transporters, for instance, polymeric nanoparticles, is one of best approach proposed to upgrade their oral bioavailability.

II. NEED FOR NANOTECHNOLOGY

At present 95% of all new potential therapeutics has poor pharmacokinetic and biopharmaceutical properties. Along se lines, re is need to make suitable solution movement systems that scatter remedially dynamic medicine molecule just to site of action, without affecting strong organs and tissues, cutting down estimations required for practicality and moreover growing therapeutics records and security profiles of new therapeutics.

Different reasons are,

1) Pharmaceutical
   - Drug precariousness in standard dosage structure
   - Solubility

2) Biopharmaceutical
   - Low digestion
   - High film hopping
   - Biological precariousness

3) Pharmacokinetic/Pharmacodynamic

4) Clinical

To achieve looked for pharmacological response at picked site without undesirable relationship at or site, thusly pharmaceutical have specific movement with minimum side effects and better remedial rundown. Ex: in illness chemotherapy and Enzyme substitution treatment

Ideal Characteristics

- Targeted drug transport structure should be

- Biochemically inactive (non-perilous), non-immunogenic
- Carriers used must be biodegradable (or) immediately wiped out from body with no issue and no conveyor activated parity of wiped out state.
- Arranging of transport structure should be basic (or) sensibly essential regenerative and monetarily astute.

III. INTRODUCTION TO NANOPARTICLES

Nanoparticles are solid colloidal particles which are made out of general, fabricated, or semi built medications. Nanoparticles has size degree from 1 nm to 1000 nm.

Types of Nanoparticles

Classes of nanoparticles recorded underneath are all astoundingly wide and multivaluable, n again, some of their crucial properties and current known uses in Nanomedicines are depicted here.

1. Polymeric nanoparticles
2. Solid lipid nanoparticles
3. Nanocrystal and nanosuspensions
4. Polymeric micelles
5. Liposomes
6. Dendrites.
7. Magnetic NPs
8. Gold Nanoshells
9. Nanowire

1. Solid lipid nanoparticles (SLNs)

SLNs generally include lipids that are in solid stage at room temperature and surfactants for emulsification, mean estimations of which range from 50 nm to 1000 nm for colloid drug movement applications SLNs offer exceptional properties, for instance, minimal size, enormous surface domain,high medicine stacking, participation of stages at interfaces, and are charming for their ability to upgrade execution of pharmaceuticals, neutraceuticals and diverse materials average systems for arranging SLNs join sprinkle drying high shear mixing ultra-sonication and high weight homogenization.

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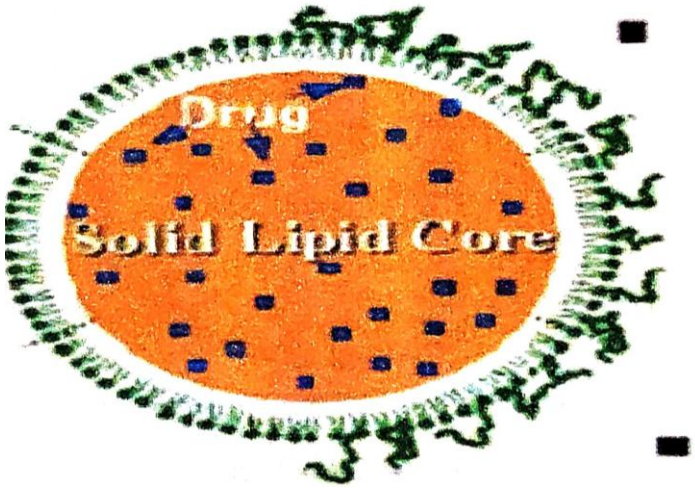


Figure 1: Solid Lipid Nanoparticles

2. Liposomes

Liposomes are vesicular structures with liquid focus included by hydrophobic lipid bilayer, made by removal of phospholipids. Phospholipids are GRAS (all around saw as shielded) fixings, in this way minimizing potential for disagreeable effects. Solutes, for instance, drugs, in focus can't experience hydrophobic bilayer however hydrophobic particles can be ingested into bilayer, enabling liposome to pass on both hydrophilic and hydrophobic iotas.

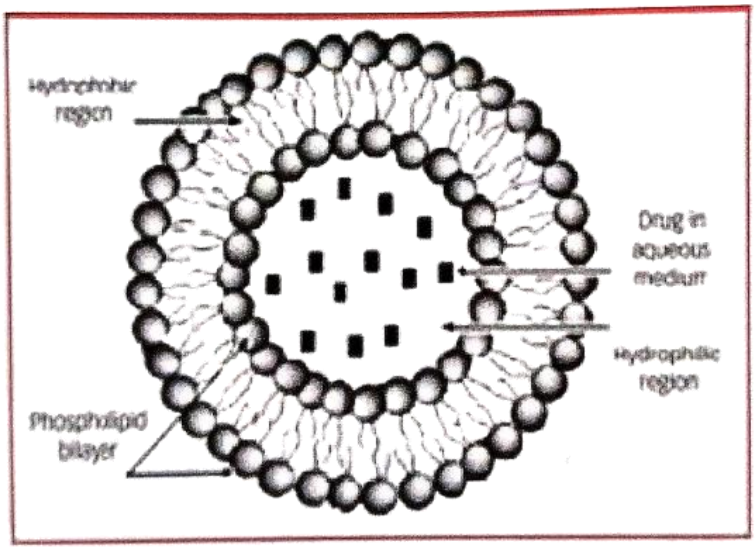


Figure 2: Liposomes

3. Nanostructured lipid carriers (NLC)

Nanostructured Lipid Carriers are delivered from mix of strong and fluid lipids, yet particles are in strong state at body temperature. Lipids are flexible particles that may shape diversely organized strong networks, for example, nanostructured lipid transporters (NLC) and lipid medication conjugate nanoparticles (LDC) that have been made to enhance medication stacking limit. NLC creation depends on hardened emulsion (scattered stage) innovations. NLC can introduce deficient stacking limit because of medication ejection after polymorphic move amid capacity, especially if lipid network comprises of comparable particles.

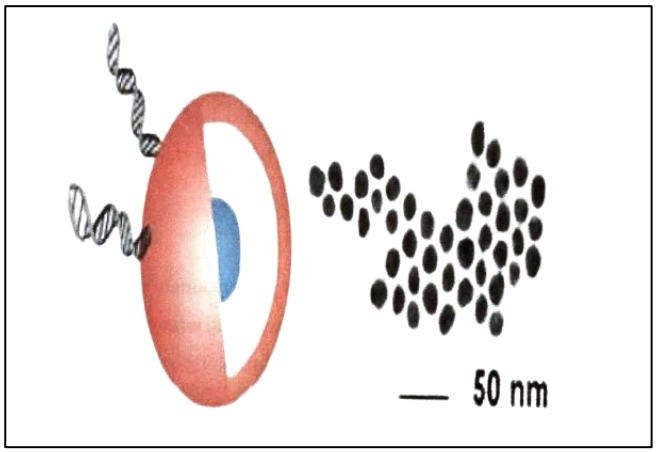


Figure 3: Nanostructured Lipid Carriers

Significant application regions in pharmaceutics are topical medication conveyance, oral and parenteral (subcutaneous or intramuscular and intravenous) course. LDC nanoparticles have demonstrated especially valuable for focusing on water-solvent medication organization. They additionally have applications in beauty care products, nourishment and horticultural items. These have been used in conveyance of calming mixes, corrective arrangement, and topical cortico treatment furthermore build bioavailability and medication stacking limit.

4. Fullerenes

Fullerene is any molecule made thoroughly out of carbon, in sort of void circle, ellipsoid, or tube. Roundabout fullerenes are moreover called buck balls, and round and empty ones are called carbon nanotubes or buck tubes. Fullerenes are similar in structure to graphite, which is made out of stacked grapheme sheets of associated hexagonal rings, additionally y may in like manner contain pentagonal (or from time to time heptagonal) rings to give perhaps penetrable iotas. Buckyballclusters or buck balls made out of under 300 carbon particles are conventionally known as endohedral fullerenes

and join most typical fullerene, buckminsterfullerene, C60.

5. Nanoshells

Nanoshells are in like manner scandalous as focus shells, nanoshells are round focuses of particular compound (concentric particles) enveloped by shell or outside covering of shaky layer of another material, which is couple of 1-20 nm nanometers thick Nanoshell particles are exceptionally reasonable materials show balanced and upgraded properties than fused from semiconductors (dielectric materials, for instance, silica and polystyrene), metals and encasings. Regularly dielectric materials, for instance, silica and polystyrene are typically used as focus in light of way that y are astoundingly unfaltering.

6. Quantum touches (QD)

Quantum touches are semiconductor nanocrystals and focus shell nanocrystals containing interface between unmistakable semiconductor materials. Size of quantum spots can be industriously tuned from 2 to 10 nm, which, after polymer exemplification, generally augmentations to 5-20 nm in broadness. Particles more diminutive than 5 nm are instantly cleared by renal filtration. Semiconductor nanocrystals have stand-out and enthralling optical properties; get chance to be fundamental mechanical assembly in biomedical investigation, especially for multiplexed, quantitative and whole deal fluorescence imaging and acknowledgment.

7. Superparamagnetic Nanoparticles

Super paramagnetic particles are those that are pulled into appealing field yet don't hold waiting fascination after field is cleared. Nanoparticles of iron oxide with separations crosswise over in 5-100 nm span have been used for specific appealing bio separations.

Method of Preparation of Nanoparticles

- Diverse frameworks are according to accompanying:
- Emulsion Polymerization
- Desolvation framework
- High Pressure Homogenization
- Controlled Gellification Method
- Controlled Nanoprecipitation without Surfactants
- Solvent Evaporation Method
- Solvent Emulsification or Solvent Diffusion framework
- Supercritical Fluid Extraction
- Melt Emulsification and Homogenization following Spray drying of nanodispersions.

Drug Loading

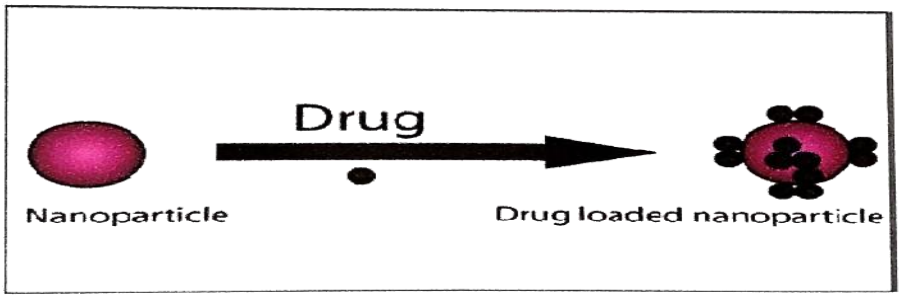


Figure 4: Drug Loading

In perfect world, fruitful nanoparticulate framework ought to have high medication stacking limit accordingly decrease amount of lattice materials for organization.

Advantages of Nanoparticles

- Fairly simple planning.
- Targeted and drug conveyance.
- Due to their little size Nanoparticles infiltrate little fine and are taken up by cell which takes into consideration productive medication collection at target destinations in body.

IV. LITERATURE SURVEY

Nagarajana E. et al (2015), had created of new conveyance frameworks for controlled arrival of medications is one of most imaginative fields of exploration in pharmaceutical sciences. Nanoparticles exceptionally intended to discharge drug in region of target destinations. Point of this

study was to plan and assess Lansoprazole nanoparticles to enhance helpful viability of Lansoprazole by stacking in nanoparticle drug conveyance framework. Lansoprazole stacked chitosan nanoparticles were readied by ionotropic gelation system. Figured nanoparticles were assessed for outer morphological characters, determination of molecule size investigation, zeta potential, medication content, ensnarement productivity and in-vitro discharge ponders. Study exhibited effective arrangement of managed discharge polymeric nanoparticles of Lansoprazole

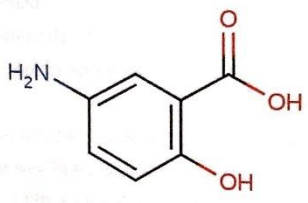
Shumaia P. et al (2014), had enhanced dissolvability and disintegration rate of dexamethasone utilizing its SLNPs with stearic corrosive as strong lipid and stabilizer. SLNPs are readied by hot homogeniza-tion strategy at distinctive proportion of medication, lipid, surfactant and stabilizer and assigned as DNPI to DNP6. Thus, this discovering demonstrates that dexamethasone SLNPs arranged by hot homogenization strategy can be utilized to improve disintegration rate and to show novel application to this medication conveyance framework

Gupta K. et al (2014), had figured and assessed Artemisinin HCI nanoparticles. Artemisinin is sesquiterpene lactone substance remove from Artemisia annua (sweet wormwood), is ineffectively dissolvable in water and quick acting blood schizonticide viable in treating intense assault of jungle fever (counting chloroquine safe and cerebral intestinal sickness). Results demonstrated that nanoparticles can be promising medication conveyance framework for supported arrival of Artemisinin HCL.

Priyanka P. and Manisha B. (2014), had improve and assess doxorubicin stacked shower dried chitosan Nano carriers as managed discharge. Chitosan nanoparticles were readied by utilizing ionotropic gelation strategy. Splash drying turns out to be great strategy to enhance dependability of colloidal nanoparticles. Taking into account in-vitro discharge study details show biphasic example described by starting burst discharge took after by slower and managed discharge.

Amolkumar L. et al (2013), had create and plan supported discharge Glipizide stacked nanoparticles and assess it. Emulsification-dissolvable vanishing system was utilized to create nanoparticles with 32 full factorial configuration. Medication and polymer was broken up in methanol/dichloromethane blended solvents. High weight homogenizer was utilized to diminish particles size in nano level. improved nanoparticles detailing were considered for FT-IR, molecule size, zeta potential, exemplification proficiency, XRD, in vitro discharge study and in vivo assessment and so on supported discharge naoparticles diminished blood glucose level up to 130 mg/dL in seven days study period. Maintained discharge nanoparticles of glipizide might oversee sort II diabetes mellitus with lessened dosage recurrence, diminished reactions and enhance persistent consistence

Drug Profile:

Mesalamine	Mesalamine is an anti-inflammatory drug given orally and topically (rectal route) for the treatment of ulcerative colitis and Crohn's disease. Mesalamine is also known as mesalazine or 5- aminosalicylic acid (5-ASA). Chemically, mesalamine is 5-amino-2-hydroxybenzoic acid.
Structure:	 Figure 5: Structure of Mesalamine
CAS Number	89-57-6
Specifications:	USP, Ph. Eur.
Molecular Formula	C7H7NO
Molecular Weight	153.14 g/mol
Physicochemical Properties	White or light grey or light pink powder or crystals, odorless or with a slight characteristic odour.
LogP	1.2
Melting point	283°C

Solubility	Slightly soluble in water (0.84 g/L. at 20°C); very slightly soluble in dehydrated alcohol, in acetone, and in methyl alcohol; practically insoluble in butyl alcohol, chloroform, dichloromethane, ether, ethyl acetate, n-hexane and propanol; soluble in dilute hydrochloric acid and dilute alkali hydroxides.
Half-life	The mean elimination half-life was 5h for 5-ASA and 6h for Nacetyl-5-ASA following the initial dose and at steady state; it was 7h for both 5-ASA and N-acetyl-5-ASA respectively.
Side Effects	Diarrhea, headache, nausea, vomiting, or loss of appetite may occur. If any of these effects persist, contact physician or pharmacist promptly. A very serious allergic reaction is unlikely, but seeks immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

V. MATERIAL AND METHODOLOGY

Method of preparation of Nanoparticle

1. Preparation of mesalamine loaded chitosan nanoparticles

Chitosan nanoparticles were prepared via the ionotropic gelation technique. Chitosan was first dissolved in 1 ml of 2.0% (v/v) acetic acid and 2 ml of deionized water and solution was prepared at various concentrations (0.1-0.3 g/100ml). These mixtures were stirred at room temperature for 15 minutes. Mesalamine drug was then dissolved in 2 ml of deionized water and 1 ml of 10% (v/v) HCl. Each solution was then sonicated for 6 min to obtain a homogenous suspension. Finally, solutions of mesalarmine were added to the chitosan solution and pH of the resulting solution was then adjusted by NaOH and acetic acid solutions. Chitosan nanoparticles loaded with mesalamine were fabricated through the drop wise addition of TPP solution (0.5 g/100ml) containing Tween (1%, to private aggregation), to 5ml of the final solution under magnetic stirring (400 rpm), resulting in a colloidal solution. The colloidal solution stirred for 30 min to obtain a cross-linked chitosan solution, containing micro and nanoparticles that are formed by means of electrostatic interaction between the positively charged chitosan chains and TPP as a cross-linker. The mesalamine loaded chitosan nanoparticles were separated from the suspension by placing the colloidal solution into microtubes and centrifuging for 5 min (5000 rpm). In this stage, the micro particles separated from nanoparticles. The supernatant was collected and transferred to another microtube and centrifuged for 30 min (15000 rpm), resulting in the formation of white precipitates. Then the precipitate was dispersed via ultra-sonication in 1 ml of deionized water and filtered through a microfilter (450 nm). The resulting solution contained chitosan nanoparticles.

2. Formulation of Mesalamine Nanoparticulate Tablet

Mesalamimne, Chitosan, Ethylcellulose, Dextrose and Lactose were taken in required quantities mixed and granulating agent (Starch past) was added and passed through #40 sieves, then lubricant magnesium stearate and tale was added then compressed into tablets by rotary tablet punching machine. Then film coating is done by 6% w/v solution of Cellulose acetate Phthalate in isopropyl alcohol using 2% tween-80 as plasticizer in coating pan. The weight of tablet was kept constant for all formulations.

Table no. 01: Formulations

Sr. no	Ingredient	F-1	F-2	F-3	F-4	F-5	F-6
1.	Mesalamine	250	250	250	250	250	250
2.	Eudragite RS	25	50	75	-	-	-
3.	Eudragite L	-	-	-	25	50	75
4.	Lactose	75	50	25	-	-	-
5.	Dextrose	-	-	-	75	50	25
6.	Talc	5	5	5	5	5	5
7.	Magnesium Stearate	5	5	5	5	5	5
8.	Starch past	QS	QS	QS	QS	QS	QS

VI. RESULTS

- **Preformulation Study**

1) Physico-chemical Characterization of Mesalamine

Organoleptic properties of Mesalamine

Appearance and pH: Solid

Colour: off-white

2) Solubility

Table no. 02: Solubility study of Mesalamine

Medium	Solubility of Mesalamine
Water	Sparingly
0.1N HCI	Soluble
pH4.5 Acetate buffer	Soluble
pH6.8 Phosphate buffer	Soluble
pH7.4 Phosphate buffer	Soluble

3) Melting point

Table no.3: Melting point of Mesalamine

Sr. No.	Sample	Melting point	Reported
1	Mesalamine	283-285 °C	283°C

4) UV Spectroscopic Study

1) Determination of wavelength of maximum absorption

Discussion: The standard solutions containing Mesalamine 1 µg/ml was scanned in UV range 200-400 nm using water as blank. The wavelength corresponding to maximum absorbance in water was found to be 210nm

2) Determination of linearity and range

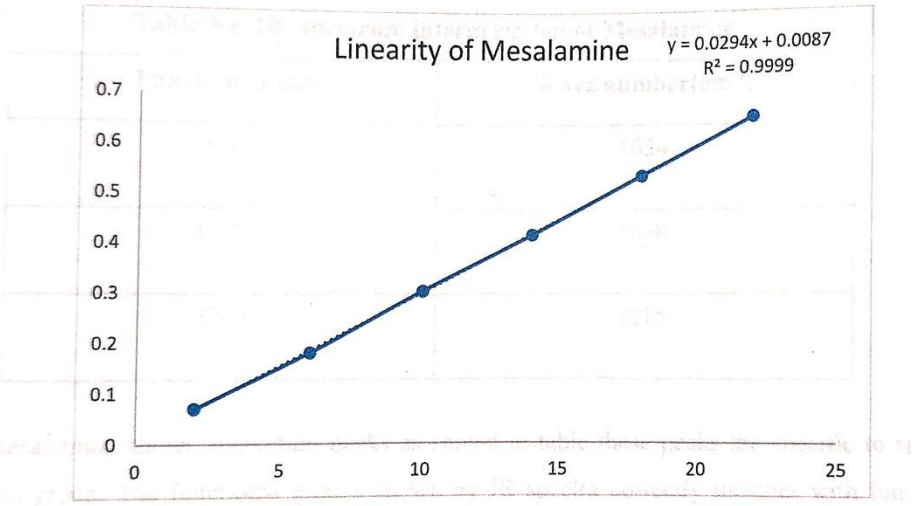


Figure No.6: Calibration curve of Mesalamine

3) FT-IR spectroscopy study

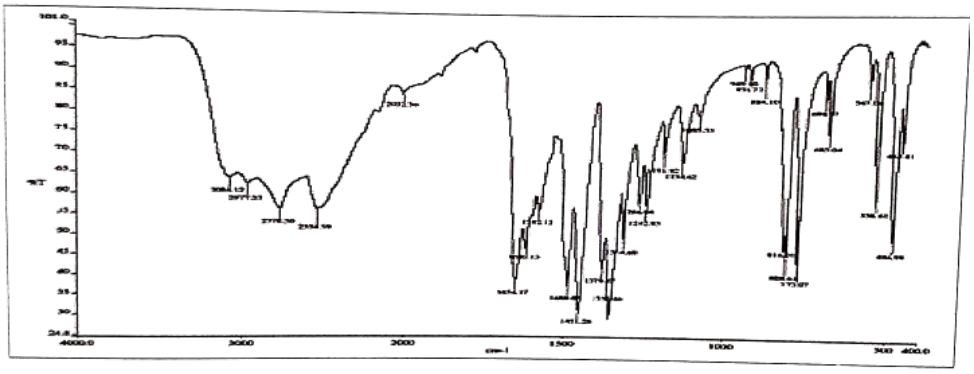


Fig no. 7 : FTIR Spectra of Mesalamine

4) DSC Studies

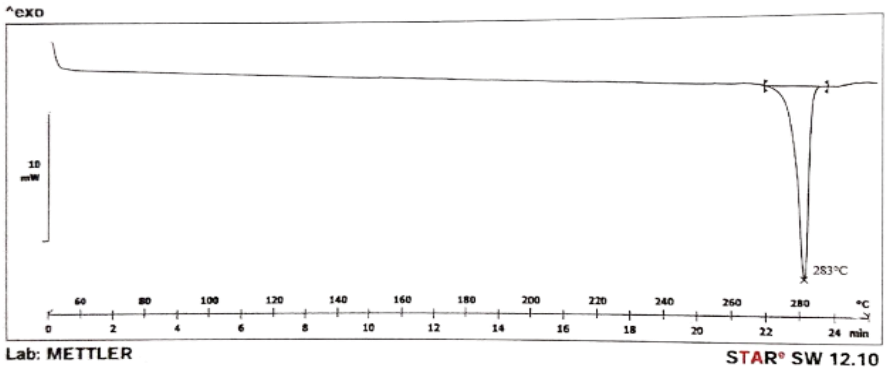


Figure no.8: Spectrum of DSC of Mesalamine

Characterization of Herbal nano particle

1. Particle size & polydispersibility index

The particle size & polydispersibility index of nanoparticles were determined. The nanoparticles particle size was determined to be between a range of 1-100nm. PDI is a measure of distribution of the particles in the sample. The observed particle size was 34.2 nm and polydispersibility index was 0.534.

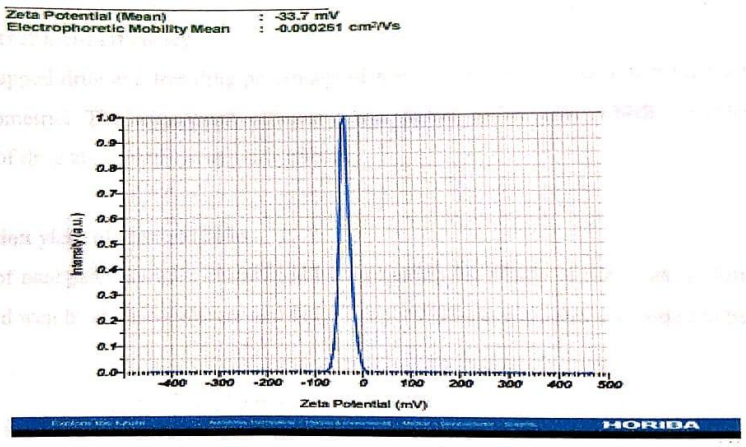


Fig. no 09. Zeta potential

2. Scanning electron microscopy

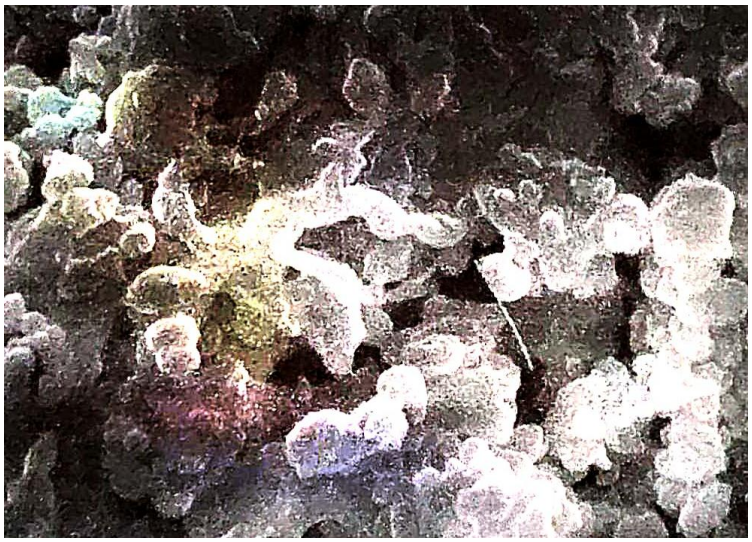


Figure No.10: Scanning electron microscopy of nanoparticle

3. Drug entrapment efficiency

Percent entrapped drug and free drug percentage of nanogel dispersion was determined using the UV spectrophotometric. The entrapment efficiency was found to be 84% which provides optimum availability of drug at site without any side effects.

4. Production yield of nanoparticles

Table 04. Production yield of nanoparticle formulation.

Formulation	Production yield (%)
ETN	74.10

5. Stability of nanoparticles

Table 05. Stability of nanoparticles.

Storage time	"0" Month	"1" Month	"2" Month	"3" Month
Particle size (nm)	34.1	34.2	34.2	34.2
polydispersibility index	0.533	0.534	0.534	0.534
Zeta potential (mV)	+28	+28	+28	+28
Entrapment efficiency (%)	84.1	84	84	84

Pre compression parameters-:

1. Angle of Repose

Table 06. Pre compression evaluation parameters- Bulk density

Batch	Angle of Repose			Mean	S.D (+-)	Angle of repose
	01	02	03			
F1	28.1	28.4	27.5	28	0.45825757	Excellent
F2	29.05	29.05	28.99	29.03	0.45825757	Excellent
F3	30.2	31.6	31.5	31.1	0.78102497	Good
F4	29.2	29.2	27.4	28.6	1.03923048	Excellent
F5	30.5	30.66	29.6	30.253333	0.57143095	Excellent
F6	29.05	28.16	29.98	29.063333	0.91007326	Excellent

S.D. n=3

2. Bulk density

Table 07. Pre compression evaluation parameters- Bulk density

Batch	Mass of powder M (gm)	Bulk volume	Tapped volume of powder Vt			Tapped density Dt			Mean Dt	S.D. ±
			Vt1	Vt2	Vt3	Dt1	Dt2	Dt3		
F1	25.004	68	65	55	55	0.38467692	0.45461818	0.45461818	0.431304429	0.0403806
F2	25.005	68	60	59	59	0.41675	0.42381356	0.42381356	0.42145904	0.00407815
F3	25.002	68	65	59	54	0.38464615	0.42376271	0.463	0.423802955	0.03917694
F4	25.001	68	61	60	55	0.40985246	0.41668333	0.45456364	0.427033143	0.0240855
F5	25.002	68	63	53	54	0.39685714	0.47173585	0.463	0.443864331	0.04094308
F6	25.004	68	65	56	58	0.38467692	0.4465	0.43110345	0.420760124	0.03218325

Batch	Mass of powder M (gm)	Bulk volume of powder V0			Bulk density Db			Mean Db	S.D. ±
		V01	V02	V03	Db1	Db2	Db3		
F1	25.006	68	67	67	0.36773529	0.37322388	0.37322388	0.37139435	0.00316884
F2	25.004	69	68	66	0.36237681	0.36770588	0.37884848	0.36964373	0.00840508
F3	25.001	66	63	68	0.37880303	0.39684127	0.36766176	0.38110202	0.01472498
F4	25.005	64	65	67	0.39070313	0.38469231	0.37320896	0.38286813	0.0088886
F5	25.002	68	66	68	0.36767647	0.37881818	0.36767647	0.37139037	0.00643267
F6	25.004	67	65	64	0.37319403	0.38467692	0.3906875	0.38285282	0.00888824

±S.D. n=3

3. Tapped density (TD):

Table 08. Pre compression evaluation parameters- Tapped Density.

±S.D. n=3

4. Carr's Index:

Table 09. Pre compression evaluation parameters-Carr's Index

Batch	Tapped Density (Dt)	Bulk Density (Db)	Carr's Index	Flow Character
			100 x (Dt)-(Db)/(Dt)	
F1	0.43	0.37	13.95349	Good
F2	0.42	0.36	14.28571	Good
F3	0.42	0.38	9.52381	Excellent
F4	0.42	0.38	9.52381	Excellent
F5	0.44	0.37	15.90909	Good
F6	0.42	0.38	9.52381	Excellent

5. Hausner's ratio-

Table 10. Pre compression evaluation parameters- Hausner's ratio

Batch	**Tapped Density (Dt)**	**Bulk Density (Db)**	**Hausner Ratio**	**Flow Character**
F1	0.43	0.37	1.16216216	Excellent
F2	0.42	0.36	1.16666667	Excellent
F3	0.42	0.38	1.10526316	Excellent
F4	0.42	0.38	1.10526316	Excellent
F5	0.44	0.37	1.18918919	Excellent
F6	0.42	0.38	1.10526316	Excellent

Evaluation of Tablets (Post compression parameters)

1. Organoleptic properties

All batches (F1-F6) were assessed for organoleptic properties like color, odor, and taste and found to be acceptable in all aspect.

General appearance: The formulated tablets were assessed for its general appearance and observations were made for shape, colour and texture.

a. Shape-oval

b. Colour-off-white

From the results obtained it was found that F1-F6 formulations has hardness, weight variation & friability within IP limit.

2. Weight Variation

Table 11. Weight variation test-F1-F6

Sr. No.	Parameter	F1	F2	F3	F4	F5	F6
1	Weight variation (%)	4.54	4.53	4.52	4.55	4.55	4.56

3. Thickness

Table 12. Tablet parameters (Batch F1-F6) - Thickness.

	Thickness in mm, n=3				S.D.
	1	2	3	Mean	±
F1	0.2	0.2	0.3	0.23333333	0.05773503
F2	0.3	0.3	0.4	0.33333333	0.05773503
F3	0.4	0.5	0.4	0.43333333	0.05773503
F4	0.5	0.5	0.4	0.46666667	0.05773503
F5	0.5	0.4	0.5	0.46666667	0.05773503
F6	0.6	0.5	0.6	0.56666667	0.05773503

4. Hardness test

Table 13 : Tablet parameters (Batch F1-F6) - Hardness test.

Batch	Hardness in kp n=3				S.D. ±
	1	2	3	Mean	
F1	5.2	5.2	5.3	5.23333333	0.05773503
F2	5.3	5.3	5.4	5.23333333	0.05773503
F3	5.4	5.5	5.4	5.43333333	0.05773503
F4	5.5	5.5	5.4	5.46666667	0.05773503
F5	5.5	5.4	5.5	5.46666667	0.05773503

F6	5.6	5.5	5.6	5.56666667	0.05773503

+S.D. n=3

5. Friability test:

Table 14. Tablet parameters (Batch F1-F6) - Friability test.

Batch	Weight Of Tablets Before Test	Weight Of Tablets After Test	Friability %
	(W1)	(W2)	%Friability = [(W1-W2)/W1] × 100
F1	4.54	4.53	0.220264
F2	4.53	4.52	0.220751
F3	4.55	4.53	0.43956
F4	4.54	4.53	0.220264
F5	4.54	4.53	0.220264
F6	4.55	4.54	0.21978

6. Disintegration time

Table 15. Tablet parameters (Batch F1-F6) - Disintegration time**.**

Batch	Disintegration Time (min)
F1	13.43
F2	14.20
F3	12.55
F4	11.17
F5	12.19
F6	13.42

7. Dissolution Study

Table 16. Tablet parameters (Batch F1-F6)-Dissolution study

Time	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
10	12.22	36.24	28.08	28.18	8.49	19.29
15	27.18	43.56	32.69	36.99	19.57	26.12
30	48.55	57.34	65.58	68.51	48.21	43.51
45	69.33	82.00	70.65	75.26	65.54	60.35
60	77.82	86.12	85.17	73.57	78.68	75.88

8. Stability Study

Table 17. Dissolution Study Data of stability study

Time in Min	Initial	First month
0	0	0
10	36.24	36.22
15	43.56	43.57
30	57.34	57.35
45	82.00	82.11
60	86.12	86.12

9. Cumulative drug release

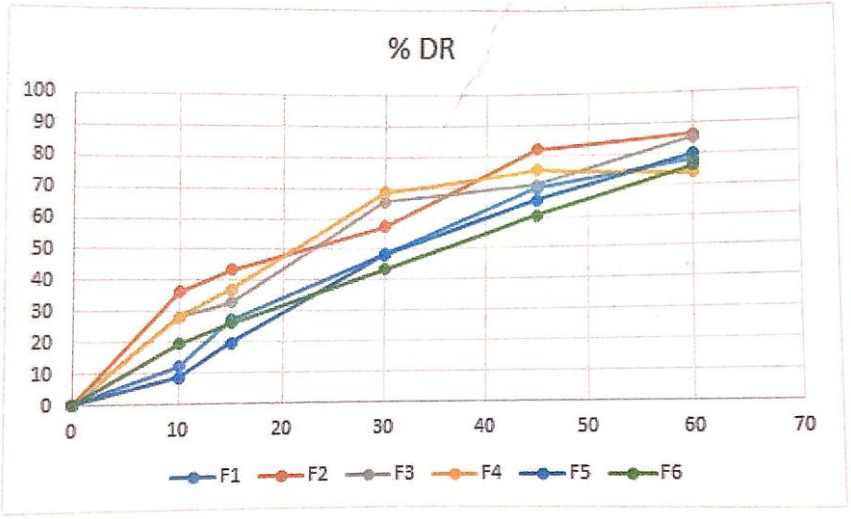


Figure 11-% Cumulative drug release (F1-F6)

VII. CONCLUSION

The study successfully developed and evaluated Mesalamine-loaded chitosan nanoparticles using the ionotropic gelation method, followed by their formulation into nanoparticulate tablets. The nanoparticles exhibited desirable characteristics, including optimal particle size, zeta potential, and high entrapment efficiency. Among the six formulations, F2 demonstrated the most favorable performance in terms of sustained drug release, physical stability, and tablet parameters. The incorporation of Eudragit polymers effectively controlled drug release, indicating the potential of this approach in improving the therapeutic efficacy and patient compliance of Mesalamine. Overall, the nanoparticulate drug delivery system offers a promising strategy for site-specific and sustained release of Mesalamine in the treatment of inflammatory bowel diseases.

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IX. CONFLICT OF INTEREST

All author have declared no conflict of interest.

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