IJPSR (2026), Volume 17, Issue 2 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 23 August 2025; received in revised form, 20 September 2025; accepted, 25 September 2025; published 01 February 2026

FORMULATION AND EVALUATION OF COLON SPECIFIC DRUG DELIVERY SYSTEM OF SULFASALAZINE

Sarthak Kamble, Sakshi Girme, Aniruddha Kulkarni *, Apurva Shelar, Satish Mendake and Pawan Rathod

Department of Microbiology, Sinhgad Institute of Pharmaceutical Sciences Lonavala, Pune - 410401, Maharashtra, India.

Keywords:

Microsponge, Colon specific, Sulfasalazine, Systemic delivery

Correspondence to Author:
Aniruddha Kulkarni

Head of Department,
Senior Professor & Researcher,
Department of Microbiology, Sinhgad Institute of Pharmaceutical Sciences Lonavala, Pune - 410401, Maharashtra, India.

E-mail: askulkarni.sips@sinhgad.edu

ABSTRACT: Site-specific drug delivery systems are designed to provide therapeutic drug concentrations at targeted body sites, achieving effective treatment while minimizing impact on non-target tissues. Targeted drug delivery specifically directs drugs into designated biological locations, optimizing therapeutic outcomes and reducing side effects. Among current advances, colon- specific drug delivery systems have gained considerable interest. It promises for both treatment of local diseases and systemic delivery of challenging pharmaceuticals. The oral route remains the widely accepted method for systemic drug administration, constituting about 50% of available drug delivery systems due to advantages like patient acceptance, compliance, and ease of administration. Research over the past decade has focused on developing colon- targeted formulations for conditions such as Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and constipation, as well as the delivery of proteins, peptides, anti-asthmatic, antihypertensive, and antidiabetic drugs. Sulfasalazine, a non-steroidal anti- inflammatory agent commonly used in IBD treatment, is ideal for micro sponges due to its poor water solubility, allowing for controlled and targeted drug release. Micro sponges, which are small, spherical, porous carriers, can encapsulate both hydrophilic and lipophilic drugs, protect active moieties from physicochemical degradation, and enable controlled release. These carriers can be formulated into various dosage forms including gels, creams, lotions, sunscreens, and especially colon-specific tablets. Incorporating sulfasalazine micro sponges in colon-targeted tablets optimizes site-specific drug delivery, enhances controlled drug release, improves patient compliance, and helps prolong dosage intervals, representing a significant advancement in drug delivery technology for the treatment.

INTRODUCTION:

Site Specific Drug Delivery Systems: The drug delivery system to specific site is to provide a therapeutic amount of drug to a proper site in a body so that the desired concentration can achieved promptly and then maintained. Site specific drug delivery system refers to targeting the drug directly into the certain biological location. Targeted drug delivery system implies selective and effective localization of drug into the target at therapeutic concentrations with limited access to non- target sites.

Recently, greater emphasis has been placed on controlling the rate and the site of drug release from oral formulations for the purposes of improving the patient compliance and the treatment efficacy [1]. Benefits of the site-specific drug delivery system was, drug directly reaches at the target site, decrease in dose to be administered, decrease the side effects, improving drug utilization; it is a promising site for the drugs which

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.17(2).703-20

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(2).703-20

are unstable or poorly absorbed at the upper GI tract. It is a challenging task to formulate such kind of the drug delivery system. Oral drug delivery system is the most preferred route being user friendly route of the administration, as non-invasive mode of drug delivery and has good level of patient compliance and flexibility in the formulation. Conventional oral dosage forms provide a specific drug concentration in systemic circulation without offering any control over drug delivery. These systems achieve, as well as, maintain drug concentration within therapeutically effective range needed for the treatment only, when taken several times a day, resulting in significant fluctuation of drug levels in the systemic circulation. For various chronic diseases generally, oral therapy is given as required for long term [2].

Oral Colon Specific Drug Delivery System (CSDDS): Nowadays, there are new developments in the field of colon specific drug delivery system. Colon targeting holds a great potential and still need more innovative work. The oral route of drug administration is the most convenient and important method of administering drugs for the systemic effect. Nearly 50% of the drug delivery systems available in the market for the treatment of disease, are oral drug delivery system and these systems have more advantages due to patient acceptance, patient compliance and ease of administration. During the last decade there has been interest in developing site-specific formulations for targeting drug to the colon. Colonic drug delivery has gained increased importance not just for the delivery of the drugs for the treatment of local diseases associated with the colon such as Crohn's disease, ulcerative colitis, inflammatory bowel disease, irritable bowel syndrome and constipation and also for the systemic delivery of proteins, therapeutic peptides, anti-asthmatic drugs, antihypertensive drugs and antidiabetic agents [3].

There are various methods or techniques through which colon targeting of drug can be achieved, for example, formation of prodrug, coating with pH-sensitive polymers, coating with biodegradable polymers, designing formulations using polysaccharides, timed released systems, pressure-controlled drug delivery systems, osmotic pressure-controlled systems. Coating of the drugs with pH-sensitive polymers provides simple & novel approach for colon-specific drug delivery [4].

Introduction to Microsponge Drug Delivery System: Nowadays there are new developments in the field of drug delivery system. Micro particles and nanoparticles have been increasingly investigated to achieve targeted and sustained release of drugs. Micro sponges are one of the novel drug delivery systems which is gaining popularity now days because of their perceived application in controlled and site-specific drug delivery [5]. In the recent years, a significant stress has been given to the development of micro sponge based novel drug delivery systems, with the objective to modify and control the release behavior of the drugs and also by incorporation into a carrier system, it is possible to vary the therapeutic index and duration of the activity of drugs. Micro sponges are porous microspheres, biologically inert particles that are made of synthetic polymers and the particles serve to protect the entrapped drug compound from physical and environmental degradation. They offer programmable release active drug into the skin in order to reduce systemic exposure and minimize local cutaneous reactions to active [6].

Micro sponge technology has been introduced in topical drug products to facilitate the controlled release of active drug into the skin in order to reduce systemic exposure and minimize local cutaneous reactions to active drugs. Micro sponge drug delivery technology holds a great promise for reaching the goal of controlled and site-specific drug delivery and hence, has attracted wide attention of researchers (Tile MK *et al.,* 2015). The micro sponge technology was discovered by Won in 1987, and the original patents were assigned to Advanced Polymer Systems. Micro sponges are patented polymeric delivery systems, consisting of porous microspheres, like a true sponge. The microsphere consists of a myriad of interconnecting voids within a non-collapsible structure, with a large porous surface [7]. Micro sponge delivery systems are uniform, spherical, porous polymeric microspheres having myriad of interconnected voids of particle size range 5-300μm. Microspheres are average 25 μm in diameter and embedded in the vehicle, act like microscopic sponges and storing the active drug until its release is triggered by

application to the skin surface. Microspores within the spheres comprise a total pore density of approximately 1ml/g and pore length 10ft for extensive drug retention. Micro sponges have capacity to entrap wide range of active ingredients such as emollients, fragrances, essential oils, sunscreens, and anti-infectives, anti-fungal and anti-inflammatory agents etc [8].

In the present study formulation and evaluation of Sulfasalazine micro sponge was carried out. The micro sponge has the ability to include either lipophilic or hydrophilic drugs and release them in a controlled and predictable manner at the target site. Micro sponge enables the insoluble drugs and protects the active moieties from the physicochemical degradation and controlled release. Because of their small size and spherical shape, Micro sponge can be developed as different dosage forms like gel, cream, lotion, sunscreen and tablets. Sulfasalazine micro sponge can be effectively incorporated into Colon specific tablet, especially for colon specific delivery and controlled release drug delivery system. Thus, it improving patient compliance by providing site specific drug delivery system and prolonging dosage intervals. Sulfasalazine is orally used as anti-inflammatory agent and commonly used in the treatment of inflammatory bowel disease. It is an effective non-steroidal anti-inflammatory agent. As the drug entrapped in micro sponge, it should be slightly soluble in water, Sulfasalazine being practically insoluble in water fulfil such criteria and hence it was selected for micro sponge formulation [9].

Preformulation study was carried out to determine the melting point and it was found to be 240-242°C. Solubility studies revealed that the Sulfasalazine is slightly soluble in DMSO, ethanol and methanol. FTIR study confirms no interaction between Sulfasalazine and Eudragit S 100, hence it can be concluded that they can be compatible in the micro sponge formulation. Sulfasalazine micro sponge was prepared using quasi-emulsion solvent diffusion technique. Micro sponge formulation was optimized by using 23 factorial designs with different drug: polymer ratio. Evaluation of microsponge like Particle size analysis, SEM, FT-IR study, XRD analysis was successfully evaluated. Particle size of the micro sponge was found to be 1.256 µm. The Optimized batch was found to be batch F8 on the basis of its entrapment efficiency of 92% and production yield of the same batch was obtained 66% as compared to other batches. The colon specific tablet of Sulfasalazine micro sponge was evaluated for the Weight variation, Thickness, Hardness, Friability, Drug content and In-vitro dissolution Study Compare with marketed formulation [10]. The Controlled release of the formulation was confirmed when it was found that the Sulfasalazine tablet showed 89.50% of drug release as compared with Sulfasalazine micro sponge tablet which showed 81.36 % of drug release after a period of 12 hr. Hence, it can be concluded that the formulation of Sulfasalazine incorporation in micro sponge is very effective and successful technique to control or prolong the drug release.

MATERIALS AND METHODS:

Materials:

Drug and Chemicals: The following materials were used of analytical grade or best possible laboratory reagents, supplied by the manufacturer as shown in **Table 1.** The distilled water was used in all experiments [11].

TABLE 1: LIST OF CHEMICALS AND THEIR MANUFACTURERS

Sr. No.	Materials	Manufacturers	Category
1.	Sulfasalazine	Jiuzhou Pharmaceutical, China	Anti-inflammatory
2.	Eudragit S 100	Research Lab fine chem, Mumbai	Polymer
3.	Polyvinyl alcohol	Evonik, Mumbai	Polymer/Stabilizer
4.	Lactose	Research Lab fine chem. Mumbai	Binder
5.	Magnesium Stearate	Research Lab fine chem. Mumbai	Lubricating agent

Instrument:

TABLE 2: LIST OF INSTRUMENTS

Sr. no.	Instruments	Model	Manufacturer
1.	Digital balance	AUX-220	Shimadzu, Japan

2.	Ultra turrax	IKA T 18 basic	IKA, Germany
3.	Hot air oven	PEW-202/PEW-205	Pathak electrical work, Mumbai
4.	UV-vis spectrophotometer	UV-3000	Labindia, India
5.	FTIR Spectrophotometer	V-530 FT/IR-4100	Jasco, Japan
6.	Scanning Electron Microscope	Supra-5	Carlzeiss, Germany
7.	X-Ray Diffraction	Bruker AXD8	Bruker
8.	Particle size analyser	Zetasizer ver.7.12	Malvern Instruments Ltd
9.	pH meter	EQ-610	Equitronic
10.	Magnetic stirrer	IKA ETSD-5	IKATRON
11.	Zeta potential	Zetasizer ver.7.12	Malvern Instruments Ltd
12.	Rotary Tablet machine	Jm-6	Jaguar, Mumbai
13.	Hardness tester	8M	Monsanto
14.	Vernier caliper	VC88	Mitutoyo
15.	Hand operated crimping machine	F1020	Labindia, India
16.	Dissolution apparatus	DS 8000	Labindia, India

Methods:

Selection of Drug and Excipients: Sulfasalazine is an anti-inflammatory drug used in the treatment of inflammatory bowel disease. It belongs to BCS class IV drug and major problem is low solubility and low permeability resulting to poor bioavailability. To solve the problem of poorly water-soluble drug, the microsponge is one of the methods to enhance the bioavailability and absorption of drug. Therefore, microsponges were made to enhance the solubility and bioavailability. The prepared microsponge of sulfasalazine incorporate into colon specific tablet because it should prevent drug release in the stomach and initiate abrupt on set of drug release upon entry in the colon [12]. Taking into all considerations, the drug was selected for research work. The development of microsponge formulation with sulfasalazine was not reported. Polymers occupy a major role in controlled release formulations and drug targeting systems, because this class of materials are seemingly endless diversity in topology and chemistry. In this type of drug delivery formulation Eudragit S 100 play important role in control release formulation. Hence Eudragit S100 was selected. The solubility studies were performed to select the choice of excipients for microsponge preparation. The solubility of drug was determined in various solvent like DMSO, ethanol, methanol, Acetone and distilled water. Similarly, the solubility of Eudragit S100 was determined in above mentioned solvents. Polyvinyl alcohol was selected as it was a good emulsifier and also a good stabilizer [13]. Most of polymers are water soluble. In these studies, we need those polymers which are insoluble in water and Eudragit S100 fulfil these criteria and hence it was selected.

Preformulation Studies: Preformulation studies were designed to study the physicochemical properties of drug, excipients and the best possible formulation. Various parameters were studied like melting point, solubility study, Drug excipient compatibility study and UV spectrometry [14].

Solubility of Sulfasalazine: Solubility of sulfasalazine was determined in distilled water, ethanol, methanol, acetone, and DMSO. The sulfasalazine sample (10mg) was placed in test tube containing of 10ml solvent each and mixed on the vortex for 10 min respectively. Solubility was evaluated visually; if solid particle were still observed, another milliliter of the same solvent was added. This procedure was repeated till solution was achieved [15].

Determination of Melting Point: Melting point of sulfasalazine was determined by capillary method. The capillary tube was sealed at one end by fusion and was filled with sulfasalazine by repeated tapping's. The capillary was tied to the thermometer, placed in Thiele's tube containing paraffin oil and the temperature was noted at which the drug starts melting. The experiment was performed in triplicated and the average value was calculated.

Determination of λ_{max}: The 10 mg of Sulfasalazine was weighed and dissolved in 10 ml Methanol (1mg/ml). The aliquot (1ml) of this solution was withdrawn and volume was made up to 10 ml. Appropriate dilutions were made with Methanol to give concentration of 10 µg/ml [16]. It is scanned in the range from 200-800nm using UV-visible spectrophotometer (V-530 Jasco, Japan) and

the spectrum was recorded using spectra manager software to determine λ_{max}.

Calibration Curve of Sulfasalazine Methanol:
Stock Solution I: Stock solution I was prepared by dissolving 40mg of sulfasalazine in 20 ml Methanol (40µg/ml).

Calibration Curve: A series of working test solutions of concentration ranging from 2- 10ug/ml (Beers-Lambert range for Sulfasalazine) were prepared from stock I. The absorbances of these solutions were measured on UV spectrophotometer (V-530 Jasco, Japan) at λ_{max} 359nm.

Compatibility Study of Drug and Excipient: Fourier Transforms Infrared Analysis: FTIR was done for identification of functional groups present in sulfasalazine, Eudragit S100, PVA and physical mixture of drug and excipient. The FT-IR was scanned on Jasco V-530 FT/IR-4100 spectrometer (Japan) over range of 400-4000 cm^{-1} in dry KBr pellet. Dry KBr (50mg) was finely grounded in mortar and subsequently added, which was then softly mixed in order to avoid of the crystals and compressed into disks using hydraulic press. FTIR was used for determination of functional group in the samples [17].

Partition Coefficient Determination: The partition coefficient is defined as the ratio of unionized drug distributed between the organic and aqueous phase at equilibrium.

Po/w = (Coil/Cwater) equilibrium

Partition coefficient is a measure of drugs lipophilicity and an indication of its ability to cross bio membrane. The partition coefficient of metformin was determined in n-octanol: water system. 10ml of n-octanol and 10ml of distilled water and 10mg of drug are mixed by hand shaking method for 30 min and then each oily layer and aqueous layer was analyzed by UV-spectroscopy at 359nm.

Preparation of Sulfasalazine Microsponge: Micro sponges were prepared by quasi-emulsion solvent diffusion method. It consists of two phases, the internal and the external phase. Polymer and plasticizer were dissolved in a suitable organic solvent to form the internal phase and another was external phase [18]. The drug was added to the internal phase with gradual stirring (1000 rpm). The internal phase was then poured into the external phase containing polyvinyl alcohol (30,000-70,000) solution in water. After 8 h of stirring, the former micro sponges were filtered and dried at 40° for 12 h.

Optimization of Formulation: Drug, Polymer**,** solvent was optimized by using 23 factorial design and was investigated to prepare the microsponge formulation [19].

Characterization of Microsponge: Microsponge formulations were characterized for FTIR, SEM, Particle size, zeta potential, XRD.

Fourier Transforms Infrared Analysis (FT-IR): The FTIR of pure drug and prepared nanosuspension were recorded using Bruker, FTIR-ATR, Alpha -E instrument. About 2-3 mg of sample was placed and scanned through the wave number range of 4000-400cm^{-1} [21].

Determination of Production Yield: The production yield of microsponge can be determined by calculating accurately the initial weight of the raw materials and the last weight of the microsponge obtained [20].

Production Yield = Practical mass / Theoretical mass (polymer + drug) × 100

Determination of Entrapment Efficiency: For the determination of entrapment efficiency (EE), a weighed amount of drug-loaded microsponge (100 mg) was placed in 100 ml phosphate buffer pH 6.8 for 12 h with continuous stirring. The samples were filtered and analyzed at 300 nm against blank on a UV spectrophotometer [22].

% Entrapment = Mass of drug in microsponge Efficiency / Initial mass of the drug × 100

Particle Size Analysis: The particle size of nanosuspension was measured using Malvern Zetasizer. Before running the sample, the nanosuspension was dispersed in distilled water to confirm that light scattering signal (as indicated by particles count per second). The analysis was carried out at room temperature, keeping the angle of detection at 90°C. The average particle size was measured.

Zeta Potential: Zeta potential of prepared nanosuspension was determined by photon correlation spectroscopy using Zetasizer Version [19]. Each measurement was performed in triplicate. The sample were diluted with distilled water to obtained obscuration.

X-Ray Diffraction Analysis: X-ray diffraction analysis of optimized batch was studied by using Bruker AXD8 diffractometer. The diffractogram can be used to confirm the crystalline or amorphous nature of sample. The study was confirmed by powder X-ray diffractometer at continuous scan range of 2θ = 5 - 60; the operating voltage and current were 40 (kV) and 30 (mA) respectively [21].

Scanning Electron Microscopy: The particle morphology was observed using SEMJSM-6360LV. The samples an appropriate amount of powder or a glass slide with a small drop of the nanosuspension, were fixed on an SEM stub using double-sided adhesive tape and coated with Au at 50mA for 6 min through a sputter-coated. A scanning electron microscope with a secondary electron detector was used to obtain digital images of the samples at an accelerating voltages 10kV [21].

Preparation of Colon Specific Tablet: The optimized microsponges were further compressed into core tablets consisting of drug- loaded microsponges containing 300 mg drug and other excipients like lactose and magnesium stearate using the direct compression technique. All tablet constituents were weighed and mixed in a mortar for 15 min. The final powder mix is compressed using round flat punches on a tablet punching machine by applying required compression pressure [22].

TABLE 3: COMPOSITION OF MICROSPONGE COMPRAESSED CORE TABLET

Sr. no.	Ingredient	Quantity	Uses
1	Sulfasalazine Microsponge powder	350 mg	API
2	Lactose	142 mg	Binder
3	Magnesium Stearate	8 mg	Lubricating agent

Evaluation of Colon Specific Tablet:

Thickness: Three tablets were picked from each formulation randomly and thickness was measured by Vernier Callipers scale.

Hardness: The prepared tablets were subjected to hardness test. It was carried out by using hardness tester and expressed in Kg/cm^2 [23].

Friability: Hand operated crimping machine was used for testing the friability. Ten tablets were weighed accurately and placed in the tumbling apparatus that revolves at 25 rpm. After 4 min, the tablets were weighed and the percentage loss in tablet weight was determined [24].

%loss = Initial wt. of tablets – Final wt. of tablets / Initial wt. of tablets × 100

Weight Variation: 20 tablets were selected randomly from the batch and weighted individually to check for weight variation. Weight variation specification as per I.P. is shown in **Table 4** [23].

TABLE 4: WEIGHT VARIATION SPECIFICATION AS PER IP

Average Weight of Tablets	% Deviation
80mg or less	±10
More than 80mg but less than 250	±7.5
250mg or more	±5

Drug Content: Ten tablets were weighed and powdered and 500 mg equivalent weight of sulfasalazine was accurately weighed and transferred into a 100 ml volumetric flask. It was dissolved and made up the volume with phosphate buffer pH 6.8. Subsequently the solution in volumetric flask was filtered and suitable dilutions were made and analyzed at 359 nm using UV-Visible spectrophotometer [23].

***In-vitro* Dissolution Studies:** *In-vitro* dissolution studies were carried out using the USP Type-I tablet dissolution test apparatus. In vitro drug release studies of colon-specific tablet formulations were carried out using USP basket apparatus with stirring rate 50 rpm at 37±0.5°. For the first 1 h, simulated gastric fluid of pH 1.2 was used, followed by a mixture of simulated gastric and intestinal fluid (pH 4.5) for the next 2 h, after which simulated intestinal fluid of pH 6.8 for next 2 h followed by simulated intestinal fluid of pH 7.5 for next 7 h was used. Samples were withdrawn periodically and compensated with an equal amount of fresh dissolution media. The samples were analyzed for the drug content by measuring absorbance at 359 nm using a UV spectrophotometer [23].

Preparation of Buffer Solutions:

pH 1.2 Simulated Gastric Fluid (SGF): NaCl (2.0gm) and purified pepsin (3.2gm, derived from porcine stomach mucosa with an activity of 800 to 2500 units per mg of protein) were dissolved in 7.0 ml of 0.2 M HCl. Sufficient water was added to make up to 1000 ml (pH 1.2).

pH 4.5 Simulated Intestinal Fluid (SIF): SIF pH 4.5 was prepared by mixing SGF pH 1.2 and SIF pH 7.4 in a ratio 39:61 and sufficient water was added to make up to 1000 ml.

pH 6.8 Simulated Intestinal Fluid (SIF): Dissolve 28.80gm of Disodium hydrogen phosphate, 11.45gm of potassium dihydrogen phosphate in sufficient water to produce 1000ml. Adjust pH if necessary.

pH 7.4 Simulated Intestinal Fluid (SIF): Monobasic KH2PO4 (6.8gm) was dissolved into 50 ml of water to this 190.0 ml of 0.2N NaOH and 500 ml water were added. 10.0 gm of pancreatin was added and pH of the resultant solution was adjusted with either 0.2N NaOH or 0.2N HCl solution to 7.5 ± 0.1 and diluted to 1000 ml [25].

Similarity Factor: Similarity factor was calculated by the Two profiles are considered identical when f2=100. An average difference of 10% at all measured time point's results in an f2 value of 50. A public standard of f2 value between 50-100 to indicate similarity between two dissolution profiles. Another way of saying this is that on average if difference at each sampling time is 10% or less then f2 value will be between 50 and 100.

Among several methods investigated for dissolution profile comparison, f2 is the simplest. Moore and Flanner proposed a model independent mathematical approach to compare the dissolution profile using two factors, f1 and f2:

$$f_1 = \left\{ \left[\sum_{t=1}^{n} |R_t - T_t| \right] / \left[\sum_{t=1}^{n} R_t \right] \right\} \times 100$$

And

$$f_2 = 50 \cdot \log \left\{ \left[1 + \frac{1}{n} \sum_{t=1}^{n} (R_t - T_t)^2 \right]^{-0.5} \times 100 \right\}$$

Where Rt is the percentage of dissolved product for a reference batch at time point t, Tt is the percentage of dissolved product for the test batch, n is the number of time points. For each brand, the calculations were made on the mean values for the six vessels. The factor, f1, is the average % difference over all time points in the amount of test brand dissolved as compared to the reference brand. The f1 value is 0 when the test and the reference profiles are identical and increases proportionally with the dissimilarity between the two profiles. The f2 value is between 0 and 100.

RESULT AND DISCUSSION:

Preformulation Studies:

Solubility: Solubility of Sulfasalazine was determined in distilled water, ethanol, methanol, Acetone and DMSO as shown in **Table 5.**

TABLE 5: SOLUBILITY STUDIES OF SULFASALAZINE

Sr. no.	Solvent	Description	Inference
1	Distilled water	Practically insoluble	0.04327 mg/ml
2	Ethanol	Slightly soluble	0.08845 mg/ml
3	Methanol	Slightly soluble	0.09475 mg/ml
4	DMSO	Slightly soluble	0.08301 mg/ml
5	Acetone	Practically insoluble	0.04395 mg/ml

Determination of Melting Point: The melting point Sulfasalazine was found to be in the range of 240-242°C, indicating purity of the drug sample as shown in **Table 6.**

TABLE 6: MELTING POINT OF SULFASALAZINE

Drug	Melting point
Sulfasalazine	240-242°C

Determination of λ_{max}: The λ_{max} of pure Sulfasalazine was found to be 359 nm in Methanol by using UV-visible spectroscopic method as shown in **Fig. 1.**

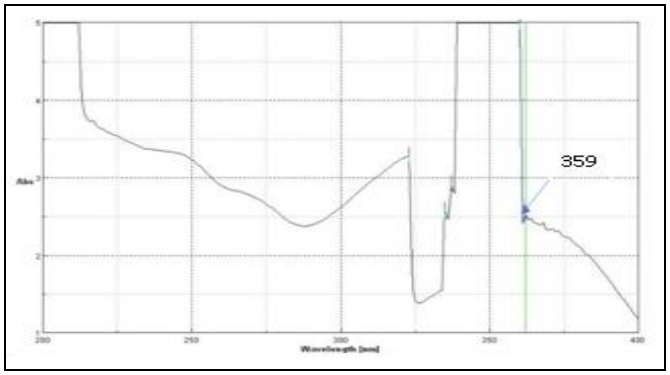


FIG. 1: UV-VISIBLE SPECTRA OF SULFASALAZINE

Determination of Partition Coefficient: It is calculated using following formula:

$$Po/w = (C_{oil/water})\ equilibrium$$

TABLE 7: ABSORBANCE READING OF PARTITION COEFFICIENT

Drug	Absorbance
Sulfasalazine + water	1.4512
Sulfasalazine +Octanol	4.7359

The partition coefficient was found to be 3.26.

Calibration Curve for Sulfasalazine: Pure Sulfasalazine in solution was found to be obey Beer's Lambert's law within concentration range of 2-10 µg/ml in Acetone. The absorbance was measured at 359 nm. The calibration curve of Sulfasalazine was shown in **Fig. 2.** The absorbance readings of different concentrations of Sulfasalazine were mentioned in **Table 8** the correlation coefficient value (R2) for the calibration curve was found to be R2= 0.9948.

TABLE 8: UV-VISIBLE ABSORBANCE READING FOR CALIBRATION CURVE OF SULFASALAZINE

Sr. no.	Concentration (µg/ml)	Absorbance (nm)
1	2	0.2154
2	4	0.4256
3	6	0.6231
4	8	0.8265
5	10	0.9624

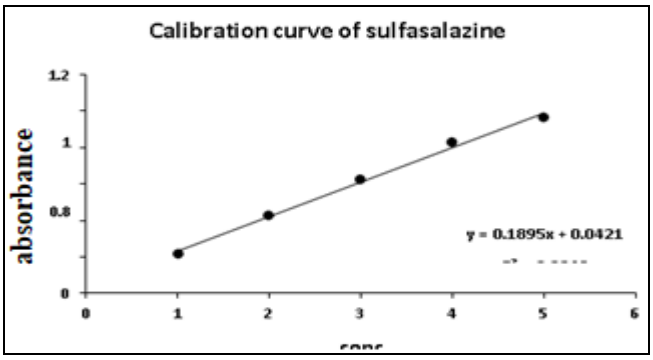


FIG. 2: CALIBRATION CURVE OF SULFASALAZINE

Compatibility Study of Drug and Excipient FTIR: For evaluating the compatibility between drug and excipients FTIR spectra were recorded. FTIR spectra of Sulfasalazine and physical mixture of Sulfasalazine with PVA, Eudragit were observed. The result showed some important functional group in the spectra of drug sample which confirmed that the analyzed sample was Sulfasalazine **Fig. 3** and the peaks of the spectra found are described in the **Table 9.**

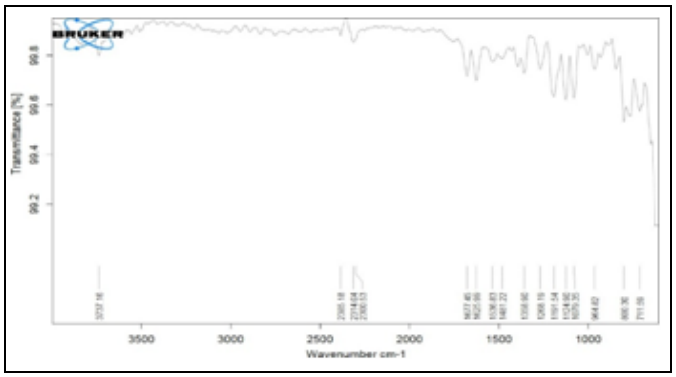
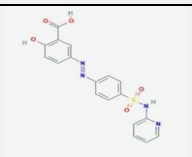


FIG. 3: FTIR SPECTRA OF SULFASALAZINE TABLE

TABLE 9: FTIR INTERPRETATION OF SULFASALAZINE

Sr.	Functional group	Frequency (cm^{-1})	Inf.
1	c-c multiple bonds stretching	1677.45	
2	Carboxylic acid	1358.90	
3	C-N vibrations	1268.19	
4	Sulfonamides sulfur compounds	1191.54	
5	Halogen compounds, C- X stretching vibrations	1124.90	
6	C-H Bending, Alkene disubstituted trans	964.82	Hence functional group are present in structure.
7	Halogen compounds, C- X Stretching vibrations	800.30	

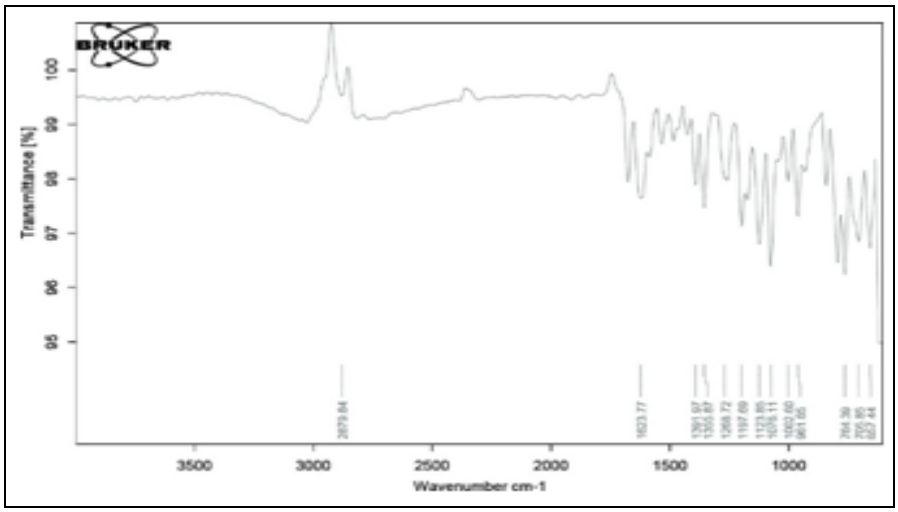


FIG. 4: FTIR SPECTRA OF PHYSICAL MIXTURE OF DRUG AND PVA

The FTIR spectra of PVA and drug **Fig. 4**, and the peak of the spectra found are described in the **Table 10.** From the obtained result it was observed that all functional groups of drugs are present in the physical mixture so it was concluded that PVA is compatible with the drug.

TABLE 10: FTIR INTERPRETATION OF PHYSICAL MIXTURE OF DRUG AND PVA

Sr. no.	Functional group	Frequency (cm^{-1})	Inference
1	C-H stretching, Alkene	2879.84	
2	C-C multiple bonds stretching	1623.77	All functional
3	C-H bending, Alkane	1391.97	group of drug
4	Unsaturated nitrogen compounds	1268.72	and excipients
5	Amines	1123.85	are present
6	Sulfur compounds S=O stretching vibrations	1076.11	
7	Halogen compound C-X stretching vibrations	1002.60	

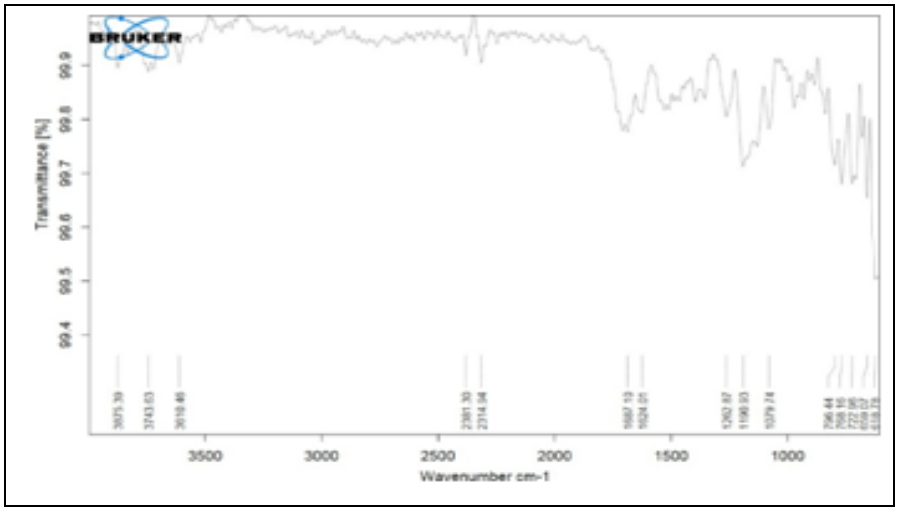


FIG. 5: FTIR SPECTRA OF PHYSICAL MIXTURE OF DRUG AND EUDRAGIT S100

The FTIR spectra of Eudragit S100 and drug **Fig. 5**, and the peak of the spectra found are described in the **Table 11**. From the obtained result it was observed that all functional groups of drug are present in the physical mixture so it was concluded that Eudragit S100 is compatible with the drug.

TABLE 11: FTIR INTERPRETATION OF PHYSICAL MIXTURE DRUG AND EUDRAGIT S100

Sr. no.	Functional group	Frequency cm^{-1}	Inference
1	O-H stretching	3610.46	
2	Carboxylic acids	1687.10	All functional
3	Sulfur compounds, S=O stretching vibrations	1202.87	group of drug
4	Sulfur compounds=S stretching vibrations	1190.93	and excipient are
5	Halogen compounds, C-X stretching vibrations C-CF	1079.74	present
6	Halogen compounds, C-X stretching vibrations, C-Cl	764.44	
7	Halogen compounds, C-X stretching vibrations, C-Cl	722.96	

Optimization of Microsponge Formulation: Microsponge was prepared by quasi emulsion solvent diffusion method. Eudragit S100 is used as polymer and PVA is used as stabilizer and methanol is used as solvent because the **Table 12** Optimization of batch by using design expert 11 software's solubility of drug in methanol showed maximum as compare to other solvent. The 23 factorial design is used for optimization of batch. They are showed as follow **Table 12.**

TABLE 12: OPTIMIZATION OF BATCH BY USING DESIGN EXPERT 11 SOFTWARE

Std	Run	Factor 1	Factor 2	Factor 3	Response 1	Response 2
		A: drug	B: Eudragit S 100	C: methanol	Production yield	Entrapment efficiency
		Mg	Mg	Ml	%	%
8	8	400	400	5	66	92
7	4	300	400	5	53	65
6	2	400	100	5	40	62
5	6	300	100	5	32	60
4	7	400	400	4	60	80
3	5	300	400	4	51	75
2	3	400	100	4	33	61
1	1	300	100	4	30	56

The optimization of 23 full factorial design of microsponge formulation A: drug, B: Eudragit S100, C: methanol was kept as independent variables. Whereas production yield and entrapment efficiency kept as dependant variables. Design expert trial software was used for studying effect of independent variables on responses. Experimental design layout 8 possible combination the main effects (A, B and C) represent the average result changing one factor at a time from its low to high value. The interaction terms show that how the response changes when three factors are simultaneously changed.

Effect of Formulation Variables on Production Yield: On applying factorial design, the quadric model was suggested by software and found to be significant. The model F-value of 63.93 implies the model is significant.

There is only 0.31% chance that F value this large could occur due to noise. P-value less than 0.0031 indicate model term are significant **Table 13**. In the case AB, AC, BC are significant model terms. R2 value of 0.998 which implied that model was significant.

TABLE 13: RESPONSE 1: PRODUCTION YIELD

Source	Sum of Squares	Def.	Mean Square	F-value	p-value
Model	1310.50	4	327.63	63.93	0.0031
A-drug	136.13	1	136.13	26.56	0.0142
B-Eudragit S 100	1128.12	1	1128.12	220.12	0.0007
C-methanol	36.13	1	36.13	7.05	0.0767
AC	10.13	1	10.13	1.98	0.2545
Residual	15.38	3	5.13		
Cor Total	1325.88	7			

Factor coding is Coded. Sum of squares is Type III – Partial. The production yield of drug was found to be depends upon the microsponge formulation. The combination effect of factor A, B and C can be further interpreted with the help of contour plot and 3D response surface plots **Fig. 6, 7**.

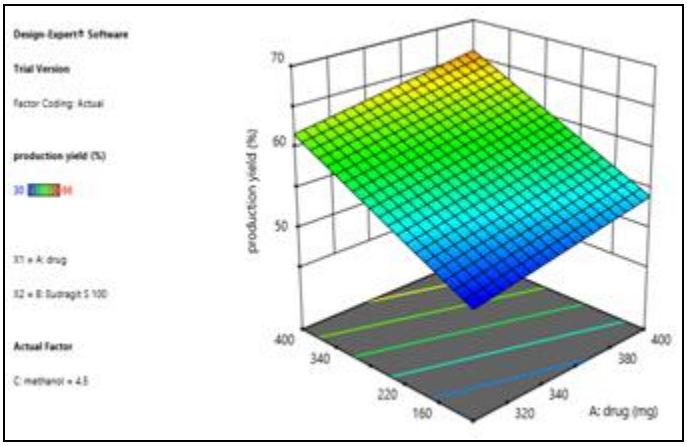


FIG. 6: THREE-DIMENSIONAL 3D RESPONSE SURFACE PLOTS FOR Y1 (%YIELD)

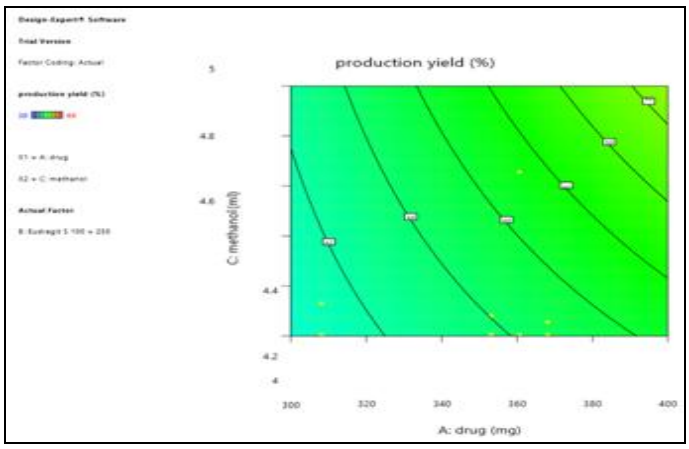


FIG. 7: TWO-DIMENSIONAL CONTOUR PLOT FOR PRODUCTION YIELD

Effect of Formulation Variables on Entrapment Efficiency: On applying factorial design, the quadric model was suggested by software and found to be significant. The model F-value of 9.55 implies the model is significant. There are only 2.70% chance that F value this large could occur due to noise. P-value less than 0.0270 indicate model term are significant **Table 14.** In the case AB, AC, BC are significant model terms. R2 value of 0.9932 which implied that model was significant.

TABLE 14: RESPONSE 2: ENTRAPMENT EFFICIENCY

Source	Sum of Squares	Def.SA	Mean Square	F-value	p-value
Model	934.38	3	311.46	9.55	0.0270
A-drug	190.12	1	190.12	5.83	0.0732
B-Eudragit S 100	666.12	1	666.12	20.42	0.0107
AB	78.13	1	78.13	2.39	0.1967
Residual	130.50	4	32.62		
Cor Total	1064.88	7			

Factor coding is Coded. Sum of squares is Type III – Partial. The entrapment efficiency of drug was found to be depends upon the microsponge formulation. The combination effect of factor A, B and C can be further interpreted with the help of contour plot and 3D response surface plots **Fig. 8, 9.**

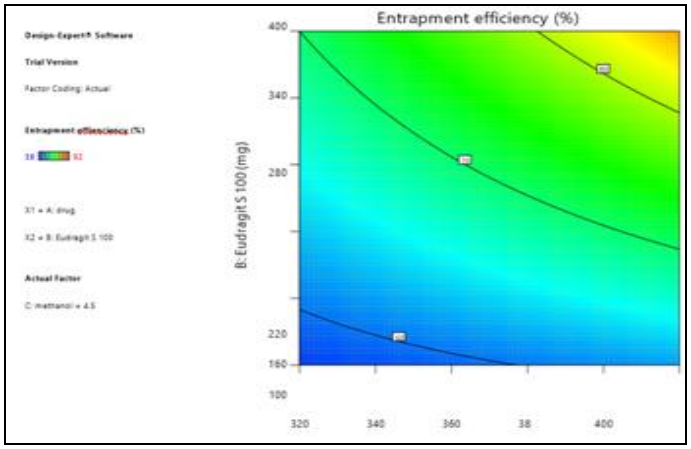


FIG 8: TWO-DIMENSIONAL CONTOUR PLOT FOR ENTRAPMENT EFFICIENCY

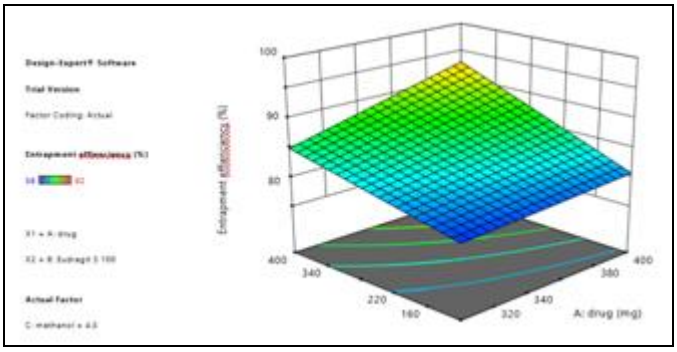


FIG. 9: THREE-DIMENSIONAL 3D RESPONSE SURFACE PLOTS FOR Y2(ENTRAPMENT EFFICIENCY)

Evaluation of Microsponge:

Fourier Transform Infrared Spectroscopy: For the evaluation of compatibility between drug and excipients in the microsponge FTIR spectra of optimized batch F8 was recorded. The result showed some important functional group in the spectra of optimized batch of microsponge. All characteristics peak of pure sulfasalazine were found in the optimized batch. From the result we can find that there was no chemical interaction between drug molecule and excipients and drug was stable in the prepared microsponge. The FTIR spectra of microsponge is shown in **Fig. 10** and the peak explain in **Table 15.**

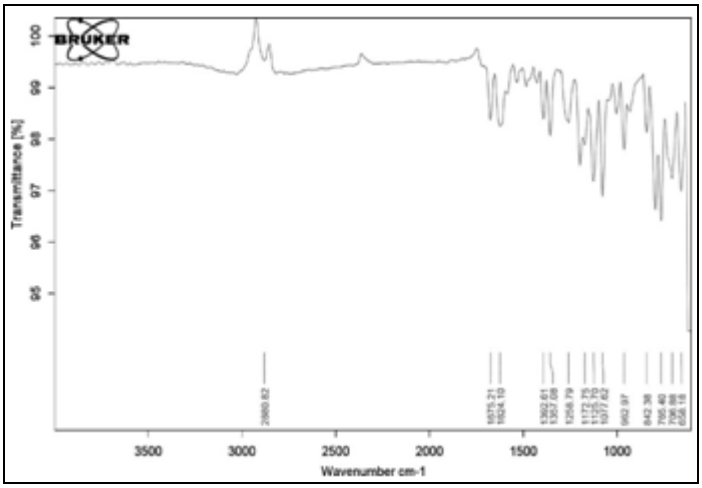


FIG. 10: FTIR SPECTRA OF MICROSPONGE FORMULATION (F8)

TABLE 15: FTIR INTERPRETATION OF MICROSPONGE FORMULATION (F8)

Sr.	Functional group	Frequency (cm^{-1})	Inference
1	C-H stretching, Alkane	2880.82	All functional
2	C-C multiple bonds stretching	1675.21	group of drug

3	C-H bending		1392.61	and excipients
4	Unsaturated	nitrogen compounds	1258.79	are present
5	Amines		1172.75	
6	Sulfur compounds	C=S stretching vibrations	1077.62	
7	Halogen compounds	C-X stretching	824.32	

Determination of Production Yield: As shown in **Table 16** and in **Fig. 11**, the production yield of all batches of microsponges ranged from 30 to 66%. Drug: polymer ratio and solvent concentration were found to affect the production yield significantly.

In the case of drug: polymer ratio (F1) production yield was very low i.e. 30 % while for drug: polymer ratio (F8) production yield was 66%. It reproduced that higher the drug: Polymer ratio, higher the productions yield.

TABLE 16: PRODUCTION YIELD OF MICROSPONGE

Sr. no.	Formulation	Production yield (%)
1	F1	30
2	F2	33
3	F3	51
4	F4	60
5	F5	32
6	F6	40
7	F7	53
8	F8	66

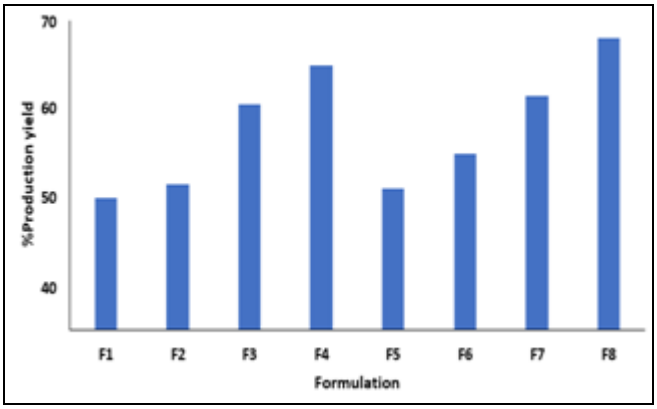


FIG. 11: PRODUCTION YIELD OF MICROSONGE

Determination of Entrapment Efficiency (%): As shown in **Table 17**, the % entrapment efficiency was found to be 92%. It was observed that the entrapment efficiency was affected by drug: polymer ratio.

Lower entrapment efficiency was observed in formulation with large differences in drug polymer ratio as shown in **Fig. 12**.

Entrapment efficiency can be improved by increase in polymer fraction as more particles can entrapped more drug.

TABLE 17: % ENTRAPMENT EFFICIENCY OF MICROSPONGE

Sr. no.	Formulation	% entrapment efficiency
1	F1	56
2	F2	61
3	F3	75
4	F4	80
5	F5	60
6	F6	62
7	F7	65
8	F8	92

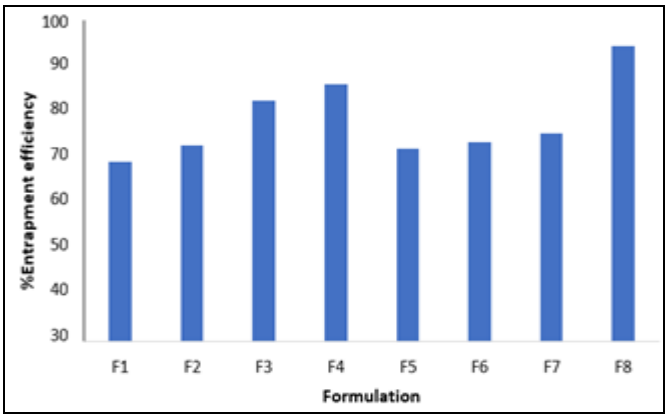


FIG. 12: %ENTRAPMENT EFFICIENCY OF MICROSPONGE

Particle size: The particle size was determined by using Zetasizer ver.7.12 (Malvern instruments ltd). The mean particle size of microsponge was 1.256 µm as shown in **Fig. 13.** Polydispersity index (PDI) was found to be 0.977 for F8 formulation.

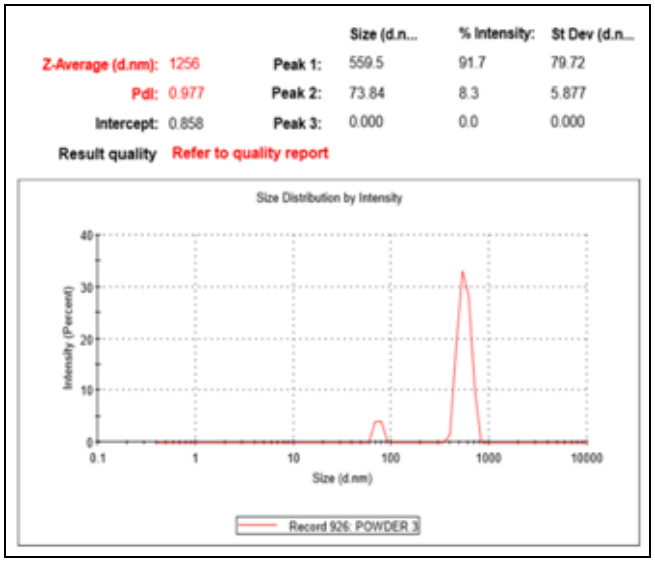


FIG. 13: PARTICLE SIZE OF MICROSPONGE

Zeta Potential: Zeta potential of microsponge F8 was found to be -26.1 as shown in **Fig. 14.** It helps to check the stability of formulation.

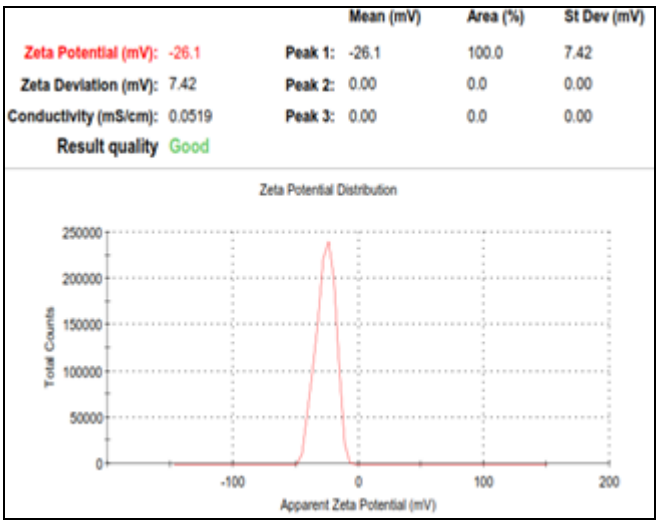


FIG. 14: ZETA POTENTIAL OF MICROSPONGE

SEM: The drug shows irregular larger crystal with wide particle size in **Fig. 15**. While the Microsponge show spherical and porous structure with regular particle size in **Fig. 16.** From the **Fig. 15** and **Fig. 16** comparison of Sem for drug and microsponge shows that the shape of the particle changes to crystal to amorphous nature.

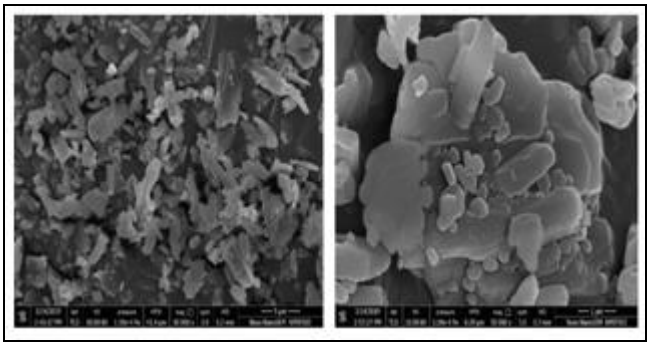


FIG. 15: SEM OF DRUG

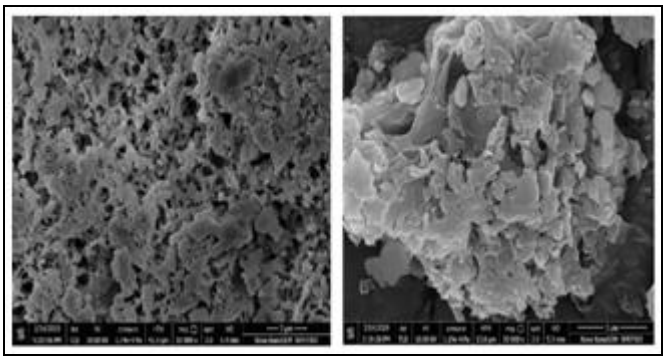


FIG. 16: SEM OF MICROSPONGE

XRD: X-ray diffraction was studied to confirm the physical state of sulfasalazine.

The diffractogram of sulfasalazine shows sharp and multiple distinctive diffraction peaks indicating the crystalline nature of sulfasalazine. The analysis of microsponge (F8) still shows clear peaks but with lower intensity.

A decrease in the intensity of the strongest peak which indicates the reduction in crystallinity. The diffraction patterns of sulfasalazine and Microsponge (F8) shown in **Fig. 17** and **Fig. 18.**

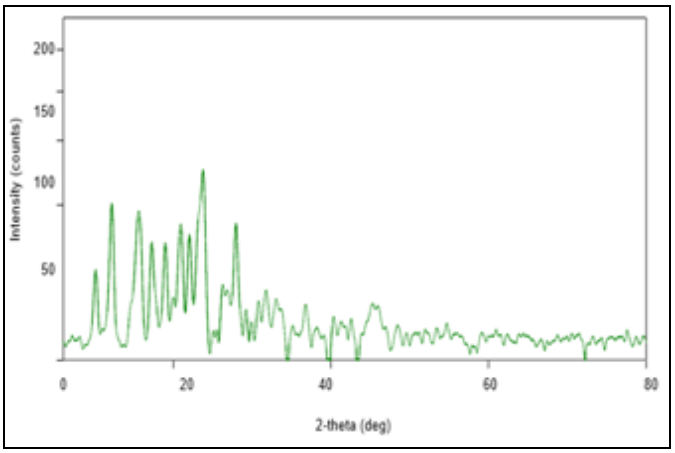


FIG. 17: DIFFRACTOGRAM OF SULFASALAZINE

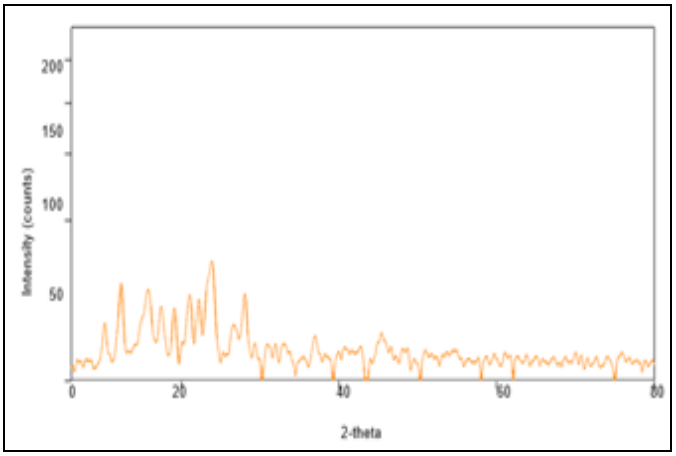


FIG. 18: DIFFRACTOGRAM OF MICROSPONGE

Evaluation of Colon Specific Tablet:

Weight Variation: In weight variation test, the Indian Pharmacopoeia limit for percentage deviation for tablets weighing above 250 is ±5%.

The average percentage deviation of all tablet formulations was found to be within the above limit, hence colon-specific tablet formulation of sulfasalazine microsponge were found to comply with the specification specified in IP for weight variation test.

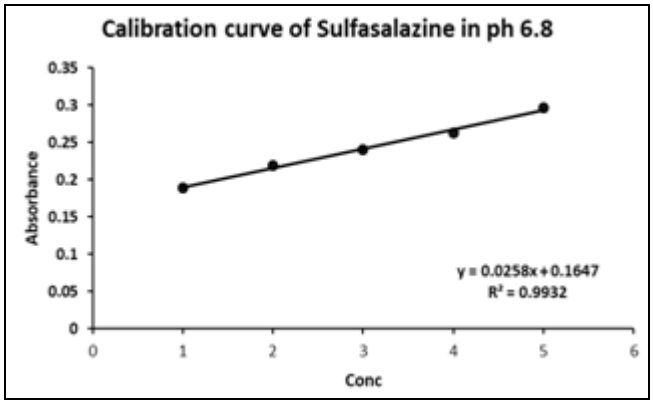


FIG. 19: CALIBRATION CURVE OF SULFASALAZINE IN PHOSPHATE BUFFER 6.8

Thickness: The thickness of colon-specific tablet formulation of sulfasalazine microsponge was found to be 3.8mm.

Hardness: The hardness of colon-specific tablet formulation of sulfasalazine microsponge was found to be 4.6 kg/cm2.

Friability: The friability of colon-specific tablet formulation of sulfasalazine microsponge was found to be 0.4% which was less than the standard limit.

Drug Content: The Drug content of colon-specific tablet formulation of sulfasalazine microsponge was found to be 92%.

***In-vitro* Dissolution Study:**

Calibration Curve of Sulfasalazine in Phosphate Buffer 6.8: Calibration curve of Sulfasalazine was carried out in phosphate buffer (pH 6.8). Sulfasalazine solution was found to be obey Beer's Lambert's law with in concentration range of 2-10 µg/ml in phosphate buffer (pH 6.8).

The absorbance was measured at 359 nm. The calibration curve of Sulfasalazine was shown in **Fig. 19.** The absorbance readings of different concentrations of Sulfasalazine were mentioned in **Table 18.** The correlation coefficient value (R2) for the calibration curve was found to be R2=0.9932.

TABLE 18: UV ABSORBANCE READING FOR CALIBRATION CURVE OF SULFASALAZINE IN PHOSPHATE BUFFER 6.8

Sr. no.	Concentration (µg/ml)	Absorbance (nm)
1	2	0.1898
2	4	0.2196
3	6	0.2405
4	8	0.2633
5	10	0.2969

In-vitro dissolution profile of sulfasalazine tablet and Sulfasalazine microsponge tablet, the cumulative amount of drug release was found to be 89.50% and 81.36% after a period of 12 hr for sulfasalazine tablet and microsponge tablet respectively as shown in **Table 19** and **Fig. 20**

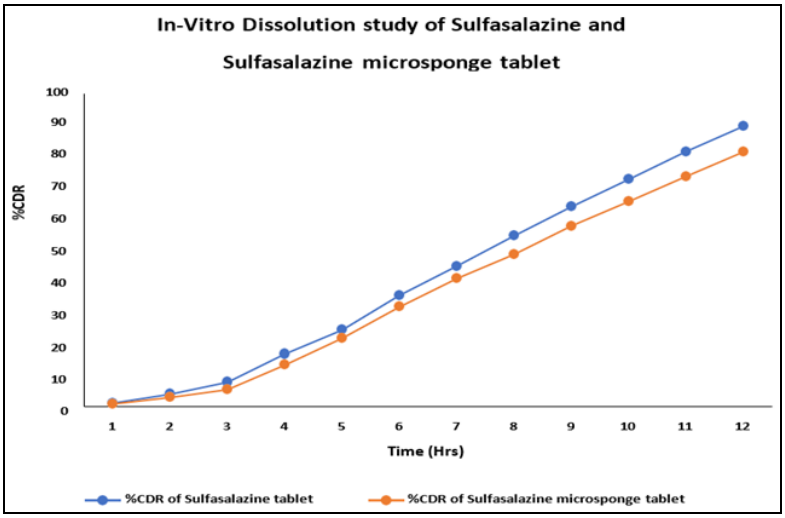


FIG. 20: GRAPH SHOWING COMPARISON BETWEEN %CDR IN SULFASALAZINE TABLET AND SULFASALAZINE MICROSPONGE TABLET

TABLE 19: *IN-VITRO* DRUG RELEASE OF SULFASALAZINE TABLET AND SULFASALAZINE MICROSPONGE TABLET

Time (Hrs.)	% CDR	
	Sulfasalazine tablet	Sulfasalazine Microsponge tablet
1	1.09	0.84
2	3.89	2.87
3	7.72	5.44
4	16.79	13.27
5	24.44	21.83
6	35.52	31.79
7	44.88	40.87
8	54.52	48.62
9	63.79	57.70
10	72.53	65.54
11	81.47	73.53
12	89.50	81.36

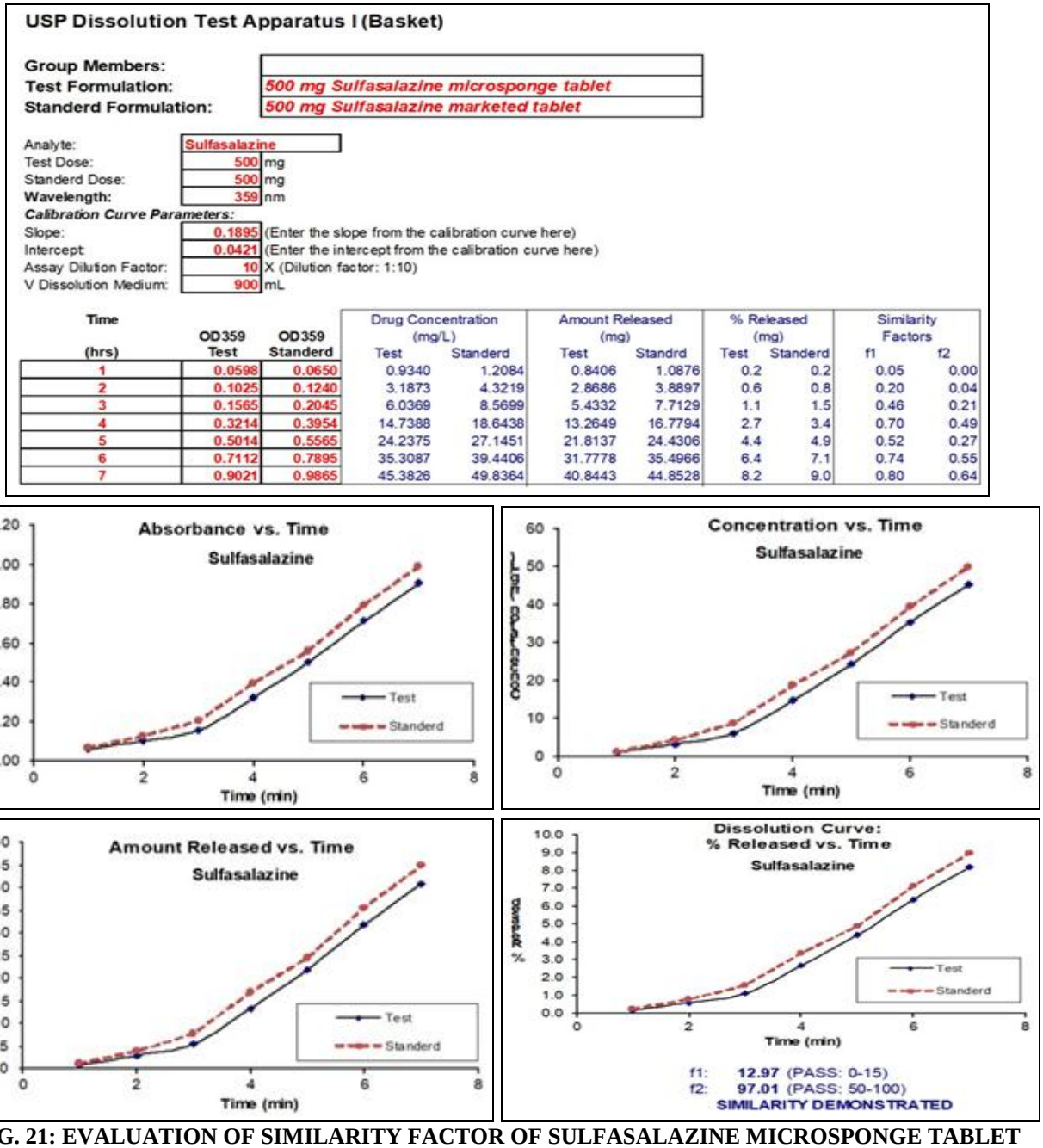


FIG. 21: EVALUATION OF SIMILARITY FACTOR OF SULFASALAZINE MICROSPONGE TABLET

CONCLUSION: In the present study formulation and evaluation of Sulfasalazine microsponge was carried out. The microsponge has the ability to include either lipophilic or hydrophilic drugs and release them in a controlled and predictable manner at the target site. Microsponge enables the insoluble drugs and protects the active moieties from the physicochemical degradation and controlled release. Because of their small size and spherical shape, Microsponge can be developed as different dosage forms like gel, cream, lotion, sunscreen and tablets. Sulfasalazine microsponge can be effectively incorporated into Colon specific tablet, especially for colon specific delivery and controlled release drug delivery system. Thus, it improving patient compliance by providing site specific drug delivery system and prolonging dosage intervals. Sulfasalazine is orally used as anti-inflammatory agent and commonly used in the treatment of inflammatory bowel disease. It is an effective non-steroidal anti-inflammatory agent. As the drug entrapped in microsponge, it should be slightly soluble in water, Sulfasalazine being Practically insoluble in water fulfil such criteria and hence it was selected for microsponge formulation.

Preformulation study was carried out to determine the melting point and it was found to be 240-242°C. Solubility studies revealed that the sulfasalazine is slightly soluble in DMSO, ethanol and methanol. FTIR study confirms no interaction between Sulfasalazine and Eudragit S 100, hence it can be concluded that they can be compatible in the microsponge formulation. Sulfasalazine microsponge was prepared using quasi-emulsion solvent diffusion technique. Microsponge formulation was optimized by using 23 factorial designs with different drug: polymer ratio. Evaluation of microsponge like Particle size analysis, SEM, FT-IR study, XRD analysis was successfully evaluated.

Particle size of the microsponge was found to be 1.256 µm. The Optimized batch was found to be batch F8 on the basis of its entrapment efficiency of 92% and production yield of the same batch was obtained 66% as compared to other batches. The colon specific tablet of sulfasalazine microsponge was evaluated for the Weight variation, Thickness, Hardness, Friability, Drug content and *in-vitro* dissolution study compare with marketed formulation. The Controlled release of the formulation was confirmed when it was found that the Sulfasalazine tablet showed 89.50% of drug release as compared with Sulfasalazine microsponge tablet which showed 81.36% of drug release after a period of 12 hr. Hence, it can be concluded that the formulation of Sulfasalazine incorporation in microsponge is very effective and successful technique to control or prolong the drug release.

ACKNOWLEDGMENTS: Authors are grateful to Prof. M. N. Navale, Founder President, STES, Pune and Rukhsana Pinjari. Principal, Sinhgad Institute of Pharmaceutical Sciences, Lonavala for providing the essential infrastructural facility, cooperation and support in the completion of this study.

CONFLICTS OF INTEREST: Nil

REFERENCES:

1. Rana RS, Ale Y, Pant P, Kukreti N and Jakhmola V: Advancements in formulations and technologies for colon-targeted drug delivery. Journal of Applied Pharmaceutical Research 2025; 13(2): 55-72.
2. Li X: Development of multifunctional drug delivery systems for locoregional therapy. The University of Western Ontario (Canada) 2021.
3. Salunke PA, Wagh RS, Patil SS and Barhate SD: An overview: site specific drug delivery system. Indo American Journal of Pharmaceutical Sciences 2016; 3(1): 57-72.
4. Yeung C, Mccoubrey LE and Basit AW: Advances in colon-targeted drug technologies. Current Opinion in Gastroenterology 2025; 41(1): 9-15.
5. Vitthal P and Anuradha S: A review on microsponges drug delivery system. IJRAR-International Journal of Research and Analytical Reviews (IJRAR), E-ISSN. 2020: 2348-1269.
6. Sahoo S, Patel S, Desai S and Patel T: A comprehensive review on microsponge.
7. Kaur M, Rani R, Singh AP and Singh AP: Microsponge: A Review. Journal of Drug Delivery & Therapeutics 2024; 14(9).
8. Naga Jyothi K and Kumar PD: Formulation and evaluation of microsponges loaded with anti-inflammatory drug sulfasalazine. Int J Adv Pharm Sci 2022.
9. Development of sulfasalazine-loaded nanosponges in hydrogel for enhanced topical psoriasis management. J Neonatal Surg 2025.
10. Kumar S, Nair AB, Kadian V, Dalal P, Jangir BL, Aldhubiab B, Almuqbil RM, Alnaim AS, Alwadei N and Rao R: Development and evaluation of hydrogel-based sulfasalazine-loaded nanosponges for enhanced topical psoriasis therapy. Pharmaceuticals 2025; 18(3): 391. doi:10.3390/ph18030391
11. Mathew M and Patil A: G. H. Development and Characterization of Sulfasalazine Cubosomes for Potential

Transdermal Drug Delivery. Pharm Nanotechnol 2025; 13(2): 320-327.
12. Rehman MU, Aziz UR, Rahman, Islam Z, Khan N, Nazir A and Saeed A: Fabrication of sulfasalazine-loaded solid lipid nanoparticles through solvent emulsification diffusion technique: pharmaceutical and stability studies. Indus J Biosci Res 2025; 3(1): 647-656.
13. Janakidevi S and Ramanamurthy KV: Development of colon-targeted microsponges for the treatment of inflammatory bowel disease. Indian J Pharm Sci 2018; 80(4): 604-609. doi:10.4172/pharmaceutical-sciences.1000399
14. Patra CN, Priya R, Swain S, Jena GK, Panigrahi KC and Ghose D: Pharmaceutical significance of Eudragit: A review. Future J Pharm Sci 2017; 3(1): 33-45. doi: 10.1016/j.fjps.2017.02.001
15. Terse P and Mallya R: Formulation and evaluation of celecoxib-loaded colon targeted microsponges. Asian J Res Pharm Sci 2020; 10(2): 73-78. doi:10.5958/2231-5659.2020.00014.4
16. Abdollahi S, Raissi H and Farzad F: Examine stability of polyvinyl alcohol-stabilized nanosuspensions to overcome the challenge of poor drug solubility utilizing molecular dynamic simulation. Sci Rep 2024; 14: 17386. doi:10.1038/s41598-024-68362-2
17. Savadi P, Casale A, Roggia M and Conte G: Unveiling the role of poly (vinyl alcohol) in the production of mucus-penetrating PLGA nanoparticles. Int J Pharm 2025; 673: 122014. doi: 10.1016/j.ijpharm.2025.122014
18. Miki A, Hara K, Shibata T, Morioka T, Kobayashi A, Yoshimura N, Yamazoe E, Ito T and Tahara K: Development of a solid dispersion system for polyvinyl alcohol nanofibers embedded with silicon dioxide particles via emulsion electrospinning for improved solubility of poorly water-soluble drugs. Journal of Drug Delivery Science and Technology 2024; 99: 105915.
19. Bhaghyasree S: Design and Evaluation of Colon Specific Drug Delivery System Containing Indomethcin Microsponge Oral Tablet (Master's thesis, Rajiv Gandhi University of Health Sciences (India).
20. Chauhan S: [Other authors if any]. Formulation and evaluation of nicotinamide microsponges: optimization by factorial design. Int J Pharm Sci Drug Res 2024; 16(4): 546–556.
21. Formulation and evaluation of micro sponges loaded with anti-inflammatory drug sulfasalazine doi:10.5281/ZENODO.6908424
22. Yadav N and Deshmukh R: *In-silico* modeling, formulation, optimization, and in vitro evaluation of candidonemicrosponges for the management of colorectal cancer. J Appl Pharm Sci 2024; 14(10): 219–228. doi:10.7324/JAPS.2024.1706009587
23. Jadiya S, Upmanyu N, Sathiyanarayanan A, Jain V, Dubey R and Buwade P: Formulation and development of novel sulfasalazine bilayer tablets for the treatment of arthritis associated with IBD: *in-vitro* and *in-vivo* investigations. J Pharm Sci 2024; 113(7): 1919–1926. doi: 10.1016/j.xphs.2024.02.019. Epub 2024 Feb 23. PMID: 38401631.
24. Sivakumar R and Shafin P: Design of colon specific delivery of sulfasalazine loaded nanoparticles for inflammatory bowel syndrome: application of experimental design. RJPT 2024; 17(3): 1272–1276.
25. Indian Pharmacopoeia. 1st ed. New Delhi: Controller of Publications, Ministry of Health and Family Welfare, Government of India; 1996.

How to cite this article:
Kamble S, Girme S, Kulkarni A, Shelar A, Mendake S and Rathod P: Formulation and evaluation of colon specific drug delivery system of sulfasalazine. Int J Pharm Sci & Res 2026; 17(2): 703-20. doi: 10.13040/IJPSR.0975-8232.17(2).703-20.