Formulation and Evaluation of Ibuprofen Suspension by Using Different Natural Suspending Agent.

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Abstract- **The objective of present investigation was to evaluate *Lepidium sativum, Isapgol* mucilage as a suspending agent, compare this with suspension prepare by using NaCMC as a suspending agent and marketed Ibuprofen suspension(100mg/5ml), and the effect of mucilage concentration on in vitro dissolution rate of Ibuprofen. Suspensions were prepared by using *sodium carboxymethyl cellulose* powder and different mucilage at different concentration (0.1%,0.2%,0.3%,0.4%,0.5%w/v). Suspension were evaluated for pH, sedimentation volume (F), density, drug content, viscosity measurement, In vitro dissolution study, FTIR and stability study. The all formulation showed more than 90% drug release over a period of 60 minutes. The suspensions were found to be stable during the study periods. There was no any change in color, odor and taste was observed. The drug content in all the suspensions was found to be within the limit.**

Keyword: **Lepidium sativum, Isapgol, suspending agent, Ibuprofen, Carboxymethyl cellulose Sodium**

INTRODUCTION:

Mucilage and Natural gums as a important part of formulation with the development of pharmaceutical dosage forms. Ibuprofen Suspension by using different Natural Suspending agent and the suspending agent is Natural, Lepidium Sativum, Isapgoal, Carboxymethylcellulose Sodium. It has use suspending agent in formulation of suspension to increase the viscosity of suspension to make a good formulation. Ibuprofen is the Non-steroidal Anti-inflammatory drug Chemically it is Phenyl Propanoic acid. Ibuprofen has a bitter test. Hence, in the present study as attempt has been made to formulation Ibuprofen suspension by using different Natural Suspending agent by dispersion method using the natural suspending agent is Lepidium Sativum, Isapgoal, Carboxymethyl cellulose Sodium with other excipients like Surfactant and sweetener and flavor to mask the bitter taste and improve odor with a view to develops a convenient means of administration to those patients suffering from difficulties in swallowing, Nausea and Vomiting.

2. MATERIAL AND EQUIPMENTS:

2.1 MATERIAL:

Ibuprofen, Liquid sorbitol, Glycerin Sucrose, Sodium Benzoate, Methyl Paraben, Propyl Paraben, Polysorbate 80

2.2 EQUIPMENTS

Instruments, Hot air oven, Electronic balance, FTIR Spectrophotometer, Brookfield Viscometer, Heating Mental, Magnetic steter, pH meter, UV Spectrophotometer.

Composition of Ibuprofen Suspension:

Table No.1 Ibuprofen suspension batches 1 to 5

Ingredient	IBU 1	IBU 2	IBU3	IBU4	IBU5
Ibuprofen	2gm	2gm	2gm	2gm	2gm
Liquid sorbitol	26gm	26gm	26gm	26gm	26gm
Glycerin	18gm	18gm	18gm	18gm	18gm
Methylparaben	0.106 gm	0.106 gm	0.106 gm	0.106 gm	0.106 gm
Propyl paraben	0.013gm	0.013gm	0.013gm	0.013gm	0.013gm
Sucrose	20 gm	20 gm	20 gm	20 gm	20 gm
Sodium Benzoate	0.53gm	0.53gm	0.53gm	0.53gm	0.53gm
Lepidium Sativum	0.1gm	0.2gm	0.3gm	0.4gm	0.5gm
Isapgoal	0.1gm	0.2gm	0.3gm	0.4gm	0.5gm

Na CMC	0.1gm	0.2gm	0.3gm	0.4gm	0.5gm
Polysorbate 80	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm
Citric acid	0.25gm	0.25gm	0.25gm	0.25gm	0.25gm
Sunset Yellow	0.002gm	0.002gm	0.002gm	0.002gm	0.002gm
Sweet Orange	0.53gm	0.53gm	0.53gm	0.53gm	0.53gm

2.3. Preformulation study:

a) Determination of melting point. The capillary tube was placed in a digital melting point apparatus. The instrument was set to automatically increases the temperature of the heating bath at a rate of 100^0C min rise of temperature per minute. The rise on temperature observed through magnifying lens.

b) Determination of Solubility: The solubility of ibuprofen was performed in solvent water and it is freely soluble in Acetone, soluble in ethanol and practically insoluble in water.

4. Formulation development of the Ibuprofen suspension by using different natural suspending agent : Development of the formulation in the present study was mainly based on the type and concentration of excipients and properties of the drug. various excipients in different concentration were used so as to get suspension with good physical properties.

a. Selection of NSAID as model drug

Ibuprofen selected as model drug Ibuprofen is the drug of choice for treating body pain, Antipyretic.

b. Selection of excipients

The excipient selected should compatible with active drug

c. Surfactant or Wetting agent:

Use of surface active agent for wetting ,leads to formation of excessive foaming. **Example: Polysorbate 80 and Sorbitol ester**. Most surfactant used in concentrations up to 0.1%.

2.4. a) Extraction of mucilage from Lepidium stivum:

Method: In this method the seeds (100 g) were soaked for12 hour in distilled water (1litre). Then mucilage was separated by passing through vacuum pump. After that remaining particulate matter separated by passing through muslin cloth. Then separated clear material was treated with acetone. So as to get precipitated mucilage. Drying was done at 45°C for 6 h. Then powder was passed through 80 # mesh sieve.[48]

b) Extraction of mucilage from Isapgoal

The Plantago ovata seed were soaked in distilled water for 48 hrs and then boiled for 10 minutes. The resulting mass was squeezed through muslin cloth. To the filtrate an equal volume of acetone was added to precipitate the mucilage The isolated mucilage was dried in an oven at 60 degree celcious for 2 hrs ,powder passed through the sieve No.80 and store in a desiccator. .[48]

A) Characterization of mucilage

1) Chemical characterization of Lepidium Sativum Mucilage and Isapgoal

The presence of mucilage in extracted material was confirmed by performing Molisch's test and by treatment with ruthenium red. Both tests were positive for the presence of mucilage.[48]

a) Molisch's test

To the test solution add few drops of alcoholic alpha napthol, then ad few drops of concentrated sulphuric acid through side of test tube, purple to violet color was obtained. .[1]

b) Ruthenium red

Test solution with ruthenium red solution, pink colour is obtained. .[48]

2) Physicochemical characterization of Lepidium sativum mucilage

a) Loss on drying

In this method appropriate quantity of mucilage was weighed and dried at 105 °C for 2 hour. After 2hrs weight was taken and weight loss on drying, percentage loss of moisture on drying was calculated. Weight loss on drying was.[48]determined by

Formula: Initial weight - final weight= Weight loss,

Percentage loss of moisture on drying was calculated using the formula.

$$LOD\ (\%) = (\text{Weight of dry sample}) \times 100$$

b) pH of solution

The pH of the 1% solution was measured with a pH meter. In this 1% solution of mucilage prepare with distilled water. .[48]

c) Swelling ratio

The 1 gm of seed is added in 50 ml measuring cylinder then add 20 ml water shaking for few minuts.exact volume occupied by the seed after a duration of 24 hrs of weeting. .[48]

d) Particle Size

The particle size of the dried powder mucilage was determined by the microscopic method.

e)Viscosity

The viscosity of Ibuprofen Suspension sample was determine on Brookfield rheometer A 600 ml sample of Ibuprofen Suspension was transferred to one liter glass beaker and the viscosity of the sample was determined using spindle number 2.Viscosity is an important physicochemical properties of a liquid .[7]

f) Sedimentation:

The Suspension (100 ml) was stored in a 100 ml measuring cylinder for one days at 30^0 -35^0 C Observation where made at every hr for 1 to 4 hr and then every 24 hrs for one days.

Sedimentation volume (F): F=Vu\Vo

(F = Sedimentation volume, Vu = ultimate volume of the sediment, Vo = original volume of the suspension.)

g) Density:

Density is defined as its mass per unit volume. It is, essentially, a measurement of how tightly matter is crammed together. The principle of density was discovered by the Greek scientist Archimedes .To calculate the density (usually represented by the Greek letter ("*rho*") of an object, take the mass (*m*) and divide by the volume (*v*): *rho* = *m* / *v*The SI unit of density is kilogram per cubic meter (kg/m^3). It is also frequently represented in the cgs unit of grams it per cubic centimeter (g/cm^3).

h) Dissolution study:

Samples were taken at 10, 20, 30, 40, 50, 60 min at 25 rpm, with variations according to the behavior of IBP in every dissolution media. The samples for dissolution procedure were filtered by Whatman's filters paper, assembled into sampling tubes. For analytical determinations, samples were diluted 1:10 in the dissolution medium. The drug absorption intensity was measured in a UV/Vis spectrophotometer at the maximum wavelength of 221 nm. .[86]

i)Mathematical modeling for drug release profile

The cumulative amount of ibuprofen released from the formulated capsules at different time intervals were fitted in to several kinetic models such as Zero order kinetics, first order kinetics, Higuchi model and Korsemayer-peppas model to characterize mechanism of drug release as follows. .[75,76,81]

i)Zero order kinetics : It describes the system in which the drug release rate is independent of its concentration.

$$\mathbf{Q_t = Q_0 + K_0\, t}$$

ii) First order kinetics

It describes the drug release from the systems in which the release rate is concentration dependent.

$$\mathbf{\text{Log } Q_t = \text{Log } Q_0 + K1t/2.303}$$

The data obtained are plotted as *log cumulative percentage of drug remaining vs. time.*

iii) Higuchi model

It describes the fraction of drug release from a matrix is proportional to square root of time.

$$\mathbf{M_t/M_\alpha = KH_t1/2}$$

iv) Korsemayer-Peppas model

The power law describes that the fractional amount of drug release is exponentially related to the release time and adequately describes the release of drug from slabs, cylinders and spheres.

$$\mathbf{\text{Log } [M_t/M_\alpha] = \text{Log } K + n \log_t}$$

Ibuprofen assay:

IBP present in the different dissolution media tested was measured in an UV/Vis spectrophotometer Jasco V650) at 221 nm after appropriate dilution and treatment of samples. A standard curve of IBP was prepared in the range from 5 to 30µg/ml, after making up the volume with the dissolution medium tested. The dissolution media used were: Phosphate buffer, pH 7.2, which were prepared according to USP. [86]

3.RESULTS AND DISCUSSION:

The project was related to Ibuprofen Suspension preparation, evaluation of active drug with excipient and evaluation of natural suspending agent study and the following section shows results of the experimental work done and discussed to specify that it is compiled or not to official compendia.

3.1 PREFORMULATION STUDIES:

1.Determination of melting point

The melting point of Ibuprofen was found to be 74-77.5ºC.

2. **Determination of loss on drying**

Table 3.1: Loss on drying

Sr.No	Name of Mucilage	Loss on drying
1	Lepidium Sativum	5%
2	Isapgoal	4%
3	Carboxymethyl cellulose Sodium	6%

3. **Determination of swelling index**

Table No.3.2 Swelling index

Sr.No	Name of Mucilage	Swelling index
1	Lepidium Sativum	3.9 ± 0.98
2	Isapgoal	10 ± 1.21
3	Carboxymethyl cellulose Sodium	3.6 ± 0.57

4. Determination of pH of all mucilage powder

The pH of all mucilage was found and it is reported in table no 3.3

Table No 3.3 pH of mucilage

Sr.No	pH	Lepidium Sativum	Isapgoal	CMC
1	Acidic	3.98 ± 0.23	3.46 ± 0.52	3.52 ± 0.34
2	Basic	9.11 ± 0.53	8.9 ± 0.73	8.3 ± 0.75
3	Normal	7.8 ± 0.45	6.8 ± 0.84	6.4 ± 0.54

5. Determination of density of all mucilage powder

Table No 3.4 Density of all mucilage

Sr.No	Density	Lepidium Sativum (gm/ml)	Isapgoal (gm/ml)	CMC (gm/ml)
1	δ	1.211 ± 0.01	1.148 ± 0.02	1.165 ± 0.01

6. Melting point of all mucilage

Table No 3.5. Melting point of all mucilage

Sr.No	Melting point	Lepidium Sativum	Isapgoal	CMC
1	Melting point	205^0C	200^0C	274^0C

7.Evaluation parameter of prepared formulation and Marketed formulation:

a) Sedimentation:

Table No 3.6: Sedimentation rate of all formulation

Formulation Code	Time(days)	Sedimentation rate
(Lepidium)		
$IBULF_1$	1	0.2 ± 0.01
$IBULF_2$	2	0.4 ± 0.03
$IBULF_3$	3	0.8 ± 0.05

$IBULF_4$	4	0.94 ± 0.04
$IBULF_5$	5	0.98 ± 0.08
(Isapgoal)		
$IBUIF_1$	1	0.2 ± 0.01
$IBUIF_2$	2	0.5 ± 0.02
$IBUIF_3$	3	0.86 ± 0.06
$IBUIF_4$	4	0.93 ± 0.08
$IBUIF_5$	5	0.96 ± 0.05
(CMC)		
$IBUCF_1$	1	0.2 ± 0.03
$IBUCF_2$	2	0.4 ± 0.01
$IBUCF_3$	3	0.83 ± 0.04
$IBUCF_4$	4	0.89 ± 0.07
$IBUCF_5$	5	0.97 ± 0.05
(Marketed)		
$IBUMF_1$	1	0.6 ± 0.07
$IBUMF_2$	2	0.83 ± 0.04
$IBUMF_3$	3	0.9 ± 0.03
$IBUMF_4$	4	0.95 ± 0.07
$IBUMF_5$	5	0.98 ± 0.08

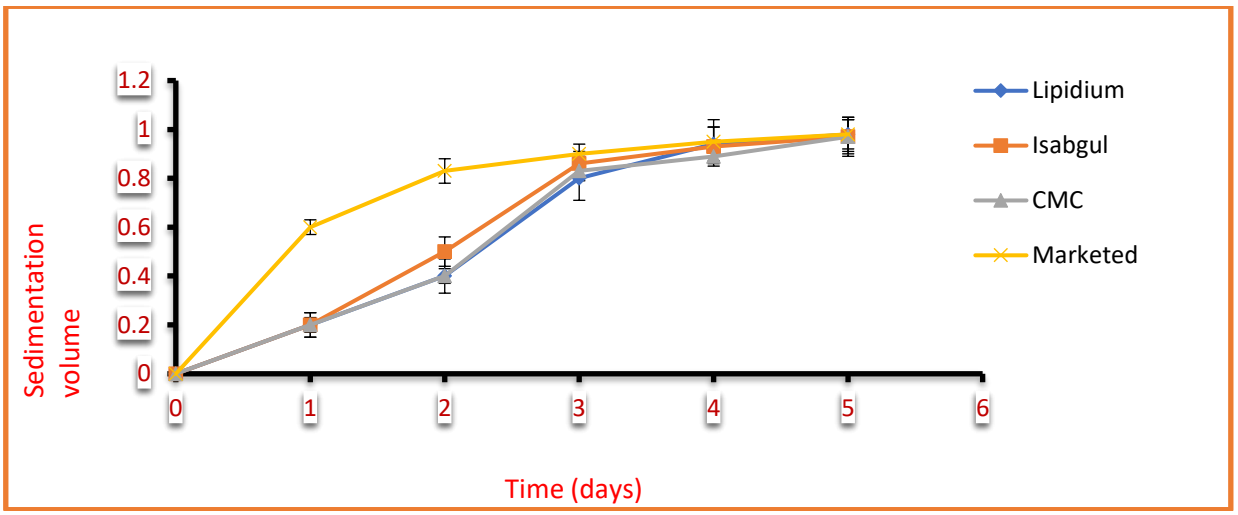


Figure No.3.1: Sedimentation graph of all formulation

8. pH of the prepared and Marketed Formulation:

Suspension prepared from Carboxymethyl Cellulose Sodium and Lepidium Sativum mucilage, Isapgoal mucilage showed a pH in the range of 6.5 to 7.5 and Marketed formulation showed pH 7

Table No.3.7 pH of all formulation

Formulation Code	pH
$IBULF_1$	7.4 ± 0.92
$IBUIF_2$	6.9 ± 0.86
$IBUCF_3$	6.5 ± 0.97
Marketed	7 ± 0.67

9. Density: Density is defined as its mass per unit volume. To calculate the density , take the mass (*m*) and divide by the volume (*v*): ***rho = m / v***

The SI unit of density is kilogram per cubic meter (kg/m^3).

It is also frequently represented in the cgs unit of grams it per cubic centimeter (g/cm^3).

Table No:3.8 Density of prepared and Marketed formulation

Formulation Code	Density (gm/ml)
$IBULF_1$	1.259 ± 0.23
$IBUIF_2$	1.251 ± 0.43
$IBUCF_3$	1.235 ± 0.12
Marketed	1.338 ± 0.43

10. Viscosity:

The viscosity of the Ibuprofen suspension at 0.1 to 0.5 %w/v suspending agent was 49.7 ,46.3 and 41.8 cps respectively for Ibuprofen suspension containing Lepidium sodium and Isapgoal and Na CMC. Suspension with higher concentration of the suspending agent produced suspension with corresponding high sedimentation volume and slow rate of sedimentation. The number of time required for redispersion of the suspension decreased with increase in the concentration of the suspending agent. The redispersion of the suspension was dependent on type and concentration of the suspending agent incorporated as well as the duration of the storage of the Ibuprofen suspension. The viscosity of Lepidium Sativum and Marketed formulation is more than Na CMC and Isapgoal.

Table No.3.9 Viscosity of prepared and Marketed formulation

RPM	IBUL	IBUI	IBUC	Marketed
20	36.4	28.8	29.7	36.2
30	42.8	31.2	40.4	41.9
50	46.7	35.6	43.7	46.4
60	48.2	37.7	47.3	48.8
100	49.7	41.8	48.4	50.3

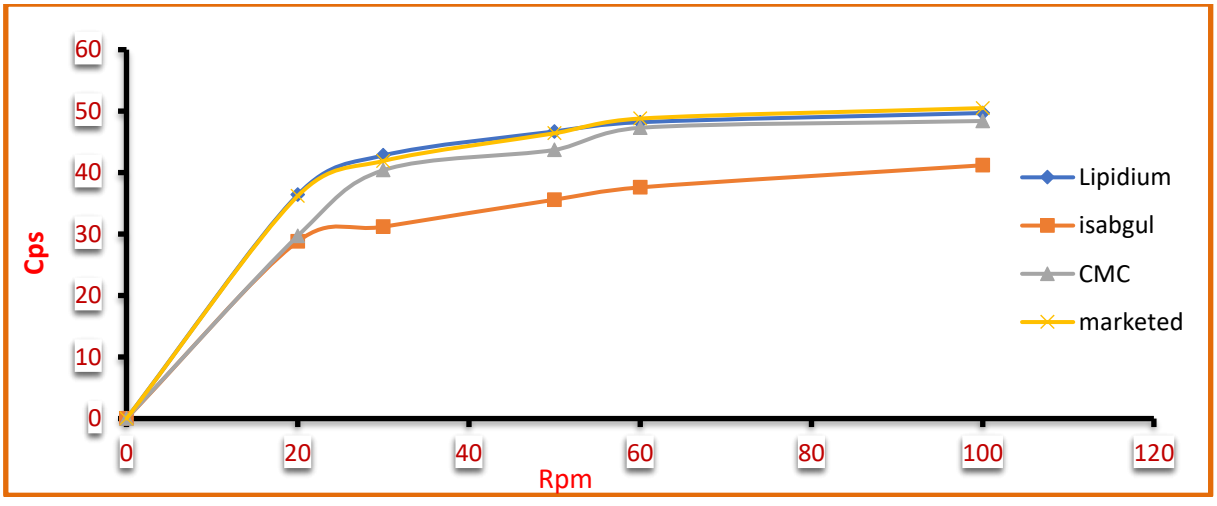


Figure No 3.2 Comparison of viscosity of all prepared formulation and Marketed formulation

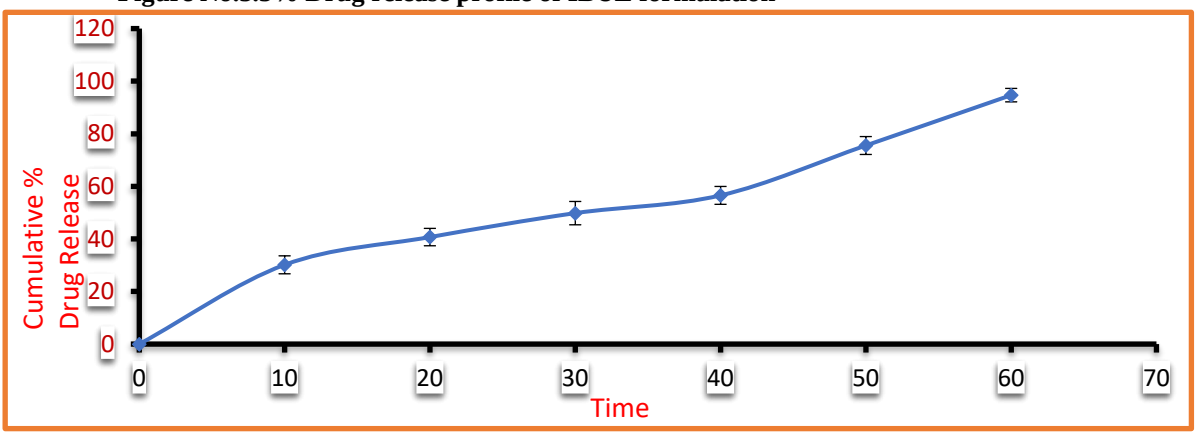
11. Dissolution study: A. In vitro release of formulation of IBUL was studied using USP II apparatus in phosphate buffer pH 7.2 and the release were show in the table.. the cumulative percent drug release was 94.68 % for 60 min. The graph was depicted in figure.3.3

Table No.3.10 Drug release profile of IBUL formulation

Time	%DR±SD
10	30.14 ± 3.41
20	40.70 ± 3.31
30	49.81 ± 4.43
40	56.56 ± 3.39

50	75.53 ± 3.40
60	94.68 ± 2.56

Figure No.3.3% Drug release profile of IBUL formulation



B. In vitro release of formulation of IBUI was studied using USP II apparatus in phosphate buffer ph 7.2 and the release were show in the table.. the cumulative percent drug release was 91.75 % for 60 min. The graph was depicted in figure.3.4

Table No.3.11 Drug release profile of IBUI formulation

Time	%DR±SD
10	39.29 ± 4.69
20	46.99 ± 2.85
30	56.26 ± 2.99
40	68.37 ± 2.80
50	84.53 ± 3.08
60	91.75 ± 4.50

All values are expressed as mean ±SD, n=3

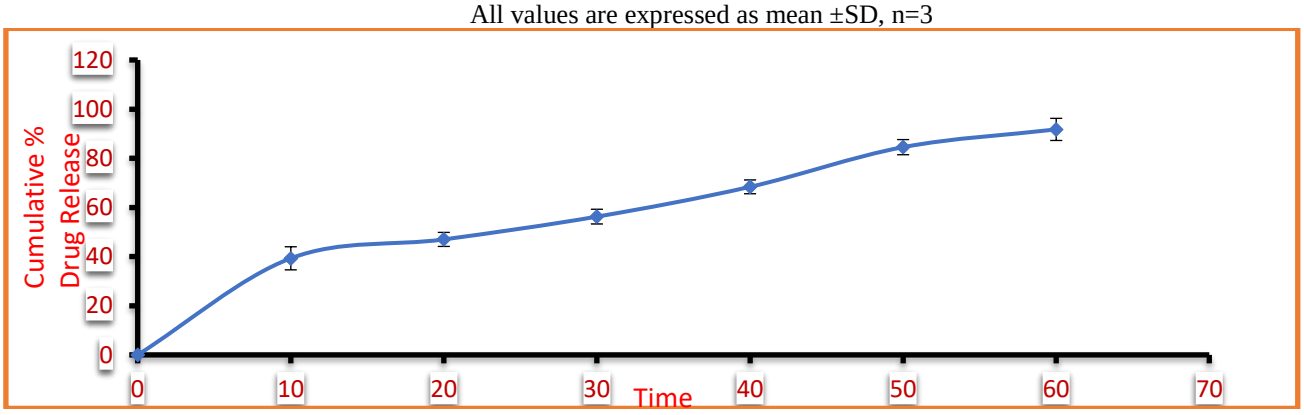


Figure No.3.4.% Drug release profile of IBUI formulation

C. In vitro release of formulation of IBUC was studied using USP II apparatus in phosphate buffer ph 7.2 and the release were show in the table.. the cumulative percent drug release was 94.77 % for 60 min. The graph was depicted in figure 6.5

Table No.3.12 Drug release profile of IBUC formulation

Time	%DR±SD
10	40.22 ± 2.89
20	49.99 ± 3.59
30	68.85 ± 2.69
40	73.09 ± 0.57
50	91.17 ± 2.86
60	94.77 ± 1.72

All values are expressed as mean ±SD, n=3

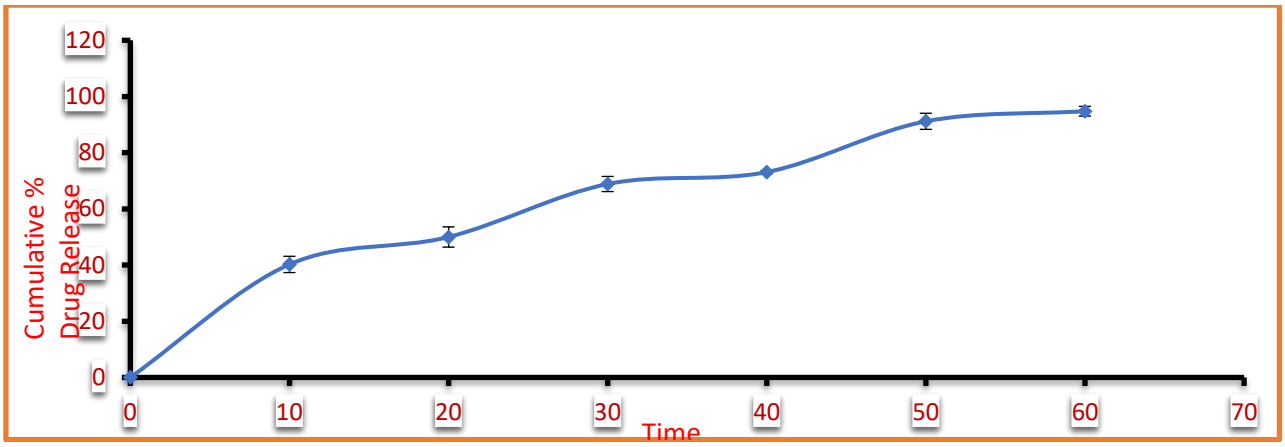


Figure No.3.5% Drug release profile of CMC formulation

D. In vitro release of formulation of IBUM was studied using USP II apparatus in phosphate buffer pH 7.2 and the release were show in the table.. the cumulative percent drug release was 95.92 % for 60 min. The graph was depicted in figure 3.6

Table No.3.13 Drug release profile of IBUM formulation

Time	% DR ± SD
10	41.76 ± 2.58
20	47.26 ±3.51
30	61.53 ± 2.07
40	78.05 ± 4.98
50	92.08 ± 3.87
60	95.92 ± 4.84

expressed as mean All values are ±SD, n=3

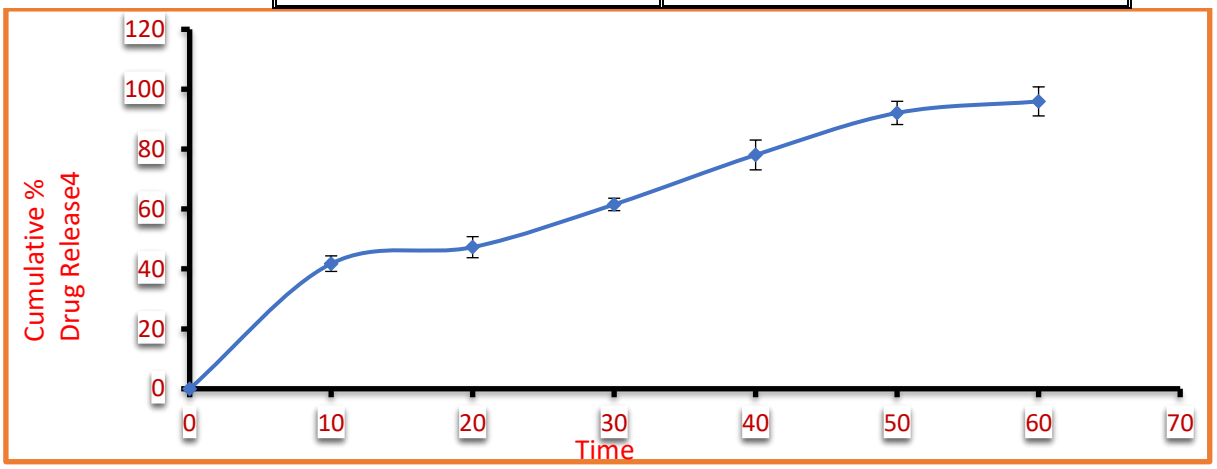


Figure No.3.6 % Drug release profile of Marketed formulation

Comparison release data for Ibuprofen suspension by using different suspending agent.

Table No.3.14 Drug release profile of all formulation

Time	LS	IS	CMC	Marketed
0	0	0	0	0
10	30.14 ± 3.41	39.29 ± 4.69	40.22 ± 2,89	41.76 ± 2.58
20	40.7 ± 3.31	46.99 ± 2.85	49.99 ± 3.59	47.26 ± 3.51
30	49.81 ± 4.43	56.29 ± 2.99	68.85 ± 2.69	61.53 ± 2.07
40	56.56 ± 3.39	68.37 ± 2.80	73.09 ± 0.57	78.03 ± 4.98
50	75.53 ± 3.40	84.53 ± 3.08	91.17 ± 2.86	92.08 ± 3.87
60	94.68 ± 2.56	91.75 ± 4.50	94.77 ± 1.72	95.92 ± 4.84

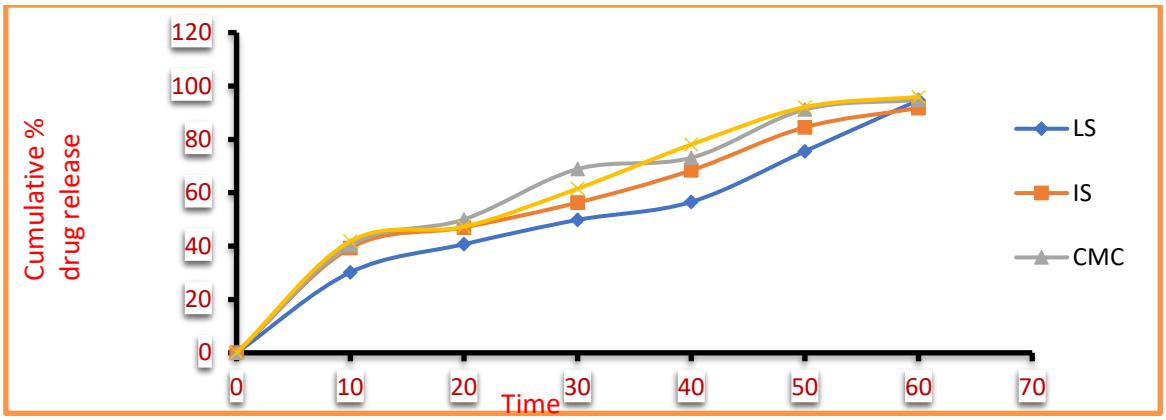


Figure No .3.7 % Drug release profile for different suspending agent.

Mathematical modeling for drug release

The dissolution data were examined for models of first order, zero order, Higuchi, Korsemeyer- peppas model shown in table no.

Table No.3.15 In -vitro drug release kinetic data for IBUL formulation

Zero order		First order		Higuchi's data		Korsemayer-peppas data	
Time (min)	Cumulative %drug release	Time (min)	Log Cumulative %ofdrug release remaining	SQRT of time	Cumulative %drug release	Log time	Log Cumulative %ofdrug release
10	30.14	10	1.8442	3.1622	30.14	1	1.4791
20	40.7	20	1.7730	4.4721	40.7	1.3010	1.6095
30	49.81	30	1.7006	5.4772	49.81	1.4771	1.6973
40	56.56	40	1.6378	6.3245	56.56	1.6020	1.7525
50	75.53	50	1.3886	7.0710	75.53	1.6989	1.8781
60	94.68	60	0.7259	7.7459	94.68	1.7781	1.9762

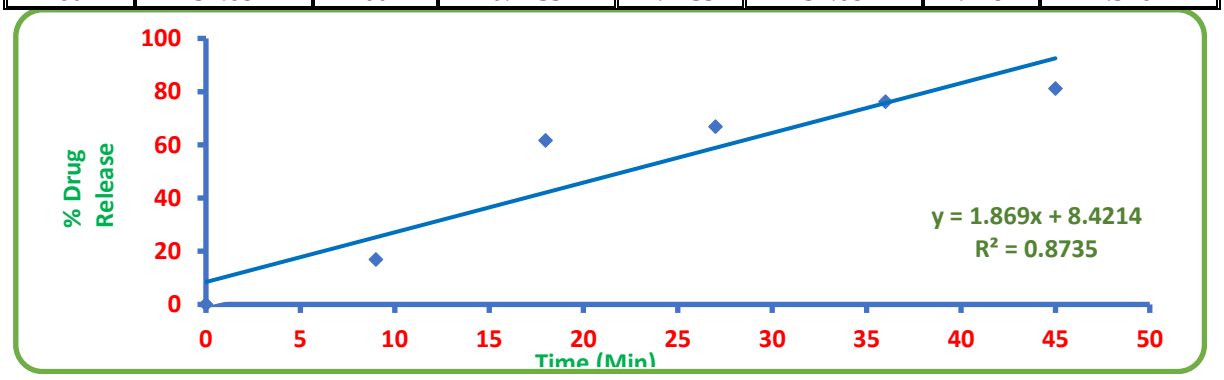


Figure No 3.8 In vitro drug release kinetics data(Zero order plots) for formulation IBUL

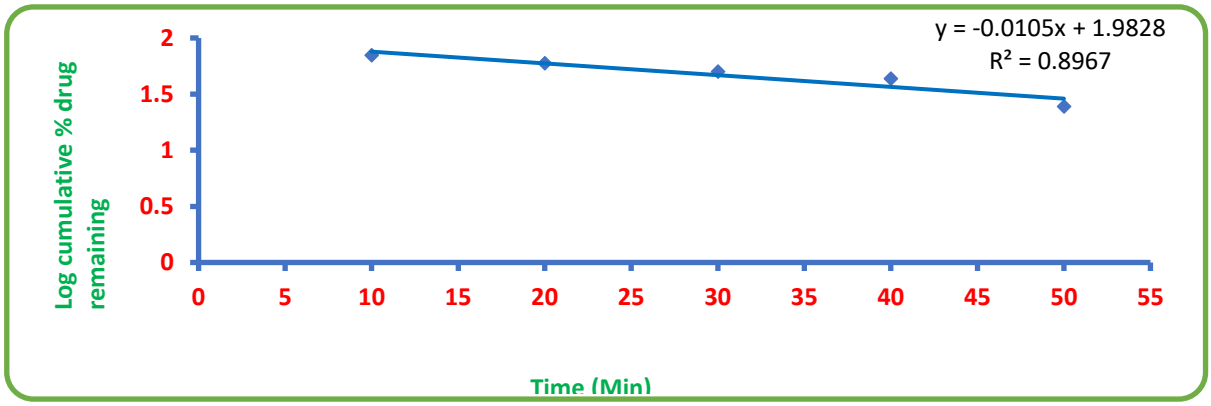


Figure No 3.9 In vitro drug release kinetics data(frist order plots) for formulation IBUL

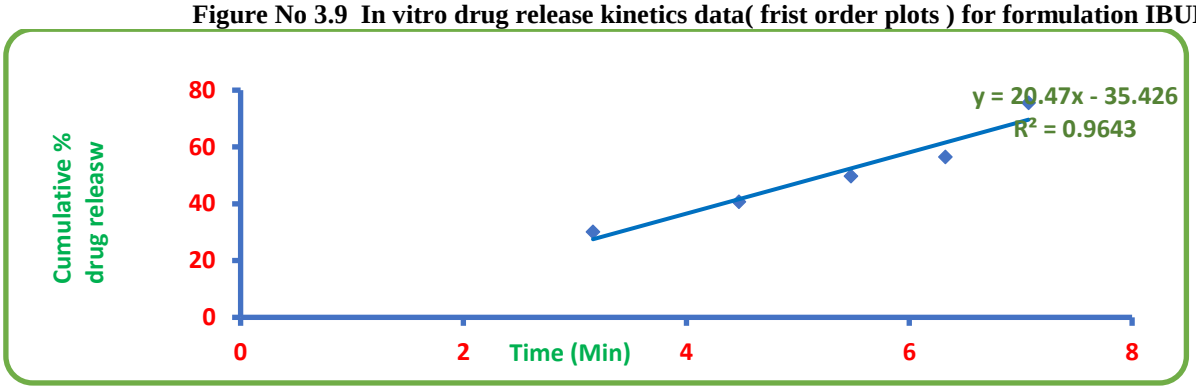


Figure No 3.10 In vitro drug release kinetics data(Higuchi data plots for formulation IBUL

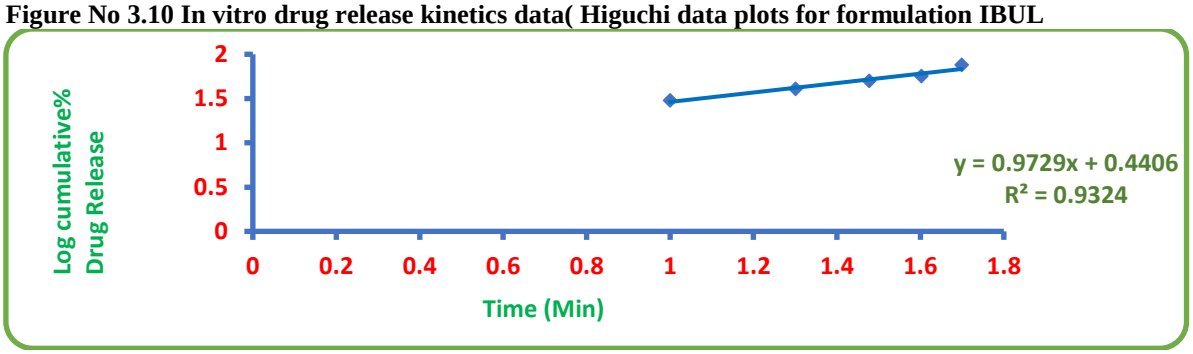


Figure No 3.11 In vitro drug release kinetics data(korsemayer-pepps plots for formulation IBU

Compatibility between Drug and Excipients:

12. Fourier Transform Infra-Red (FTIR) Spectrum

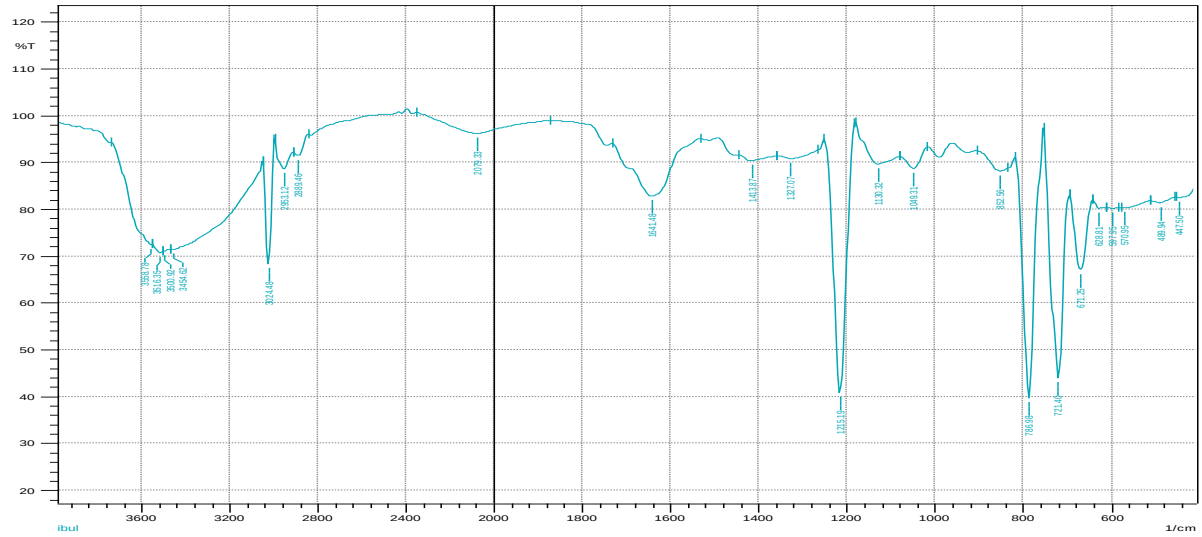


Figure No.3.12 IR Spectrum of Lepidium Sativum formulation

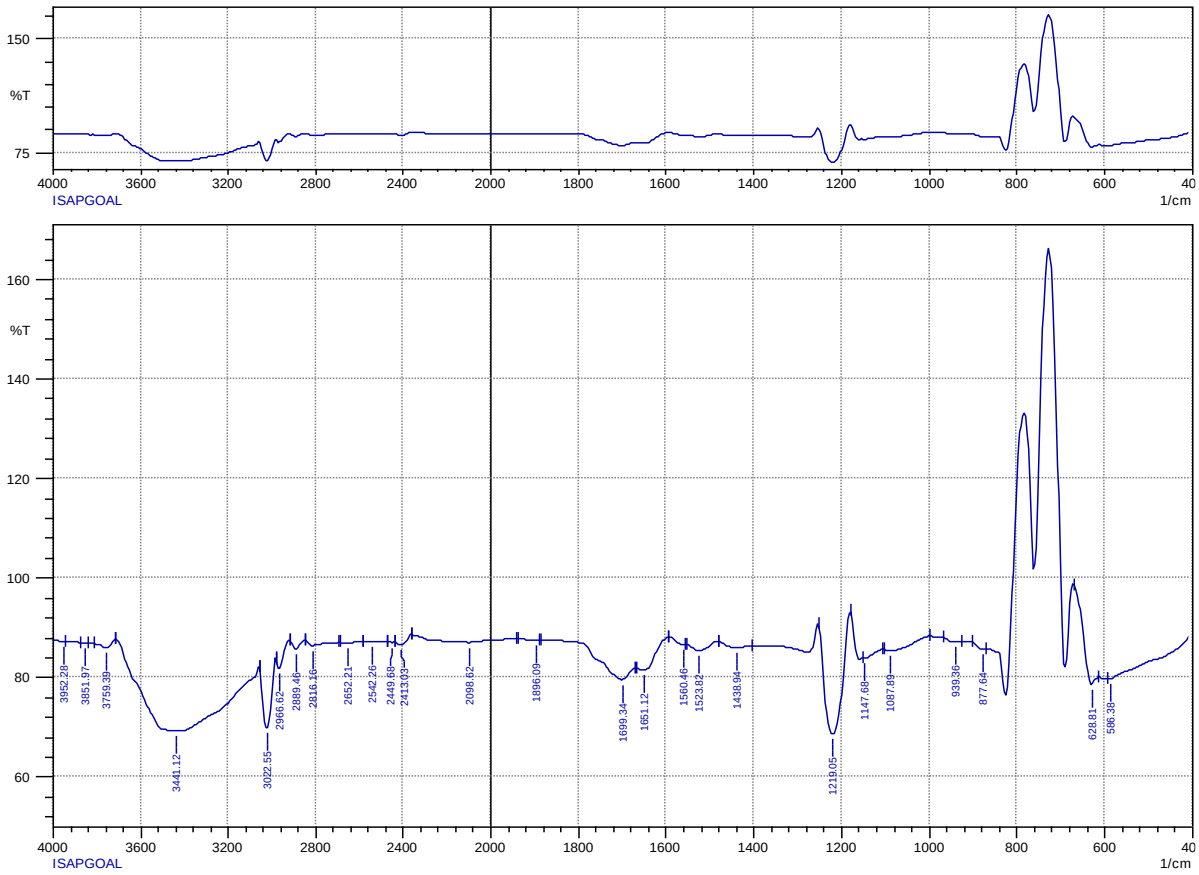


Figure No.3.13 IR Spectrum of Isapgoal formulation

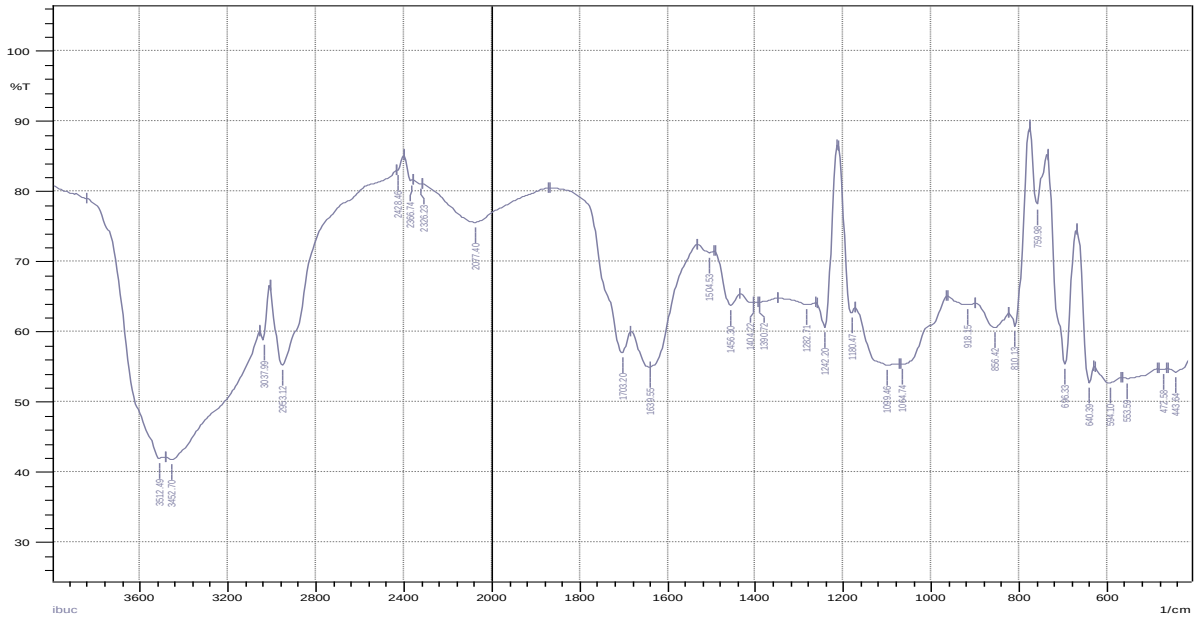


Figure No.3.14 IR Spectrum of NaCMC formulation

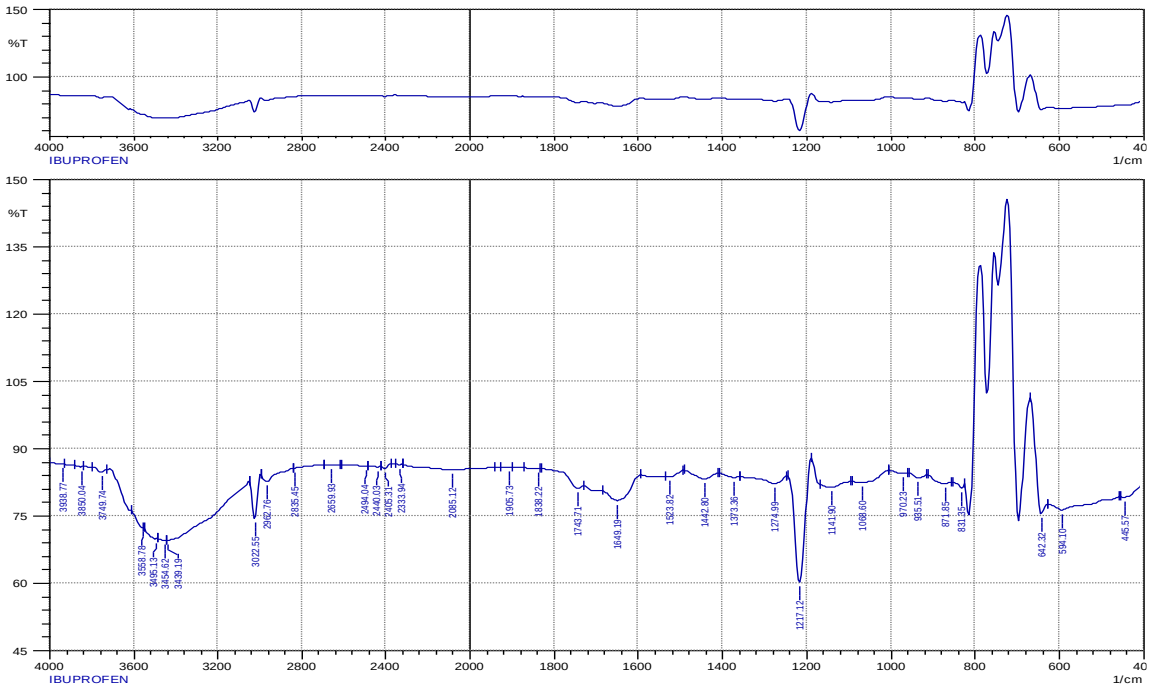


Figure No.3.15 IR Spectrum of marketed Ibuprofen formulation

Table No 3.16 Peaks observed in spectrum

Peaks (cm^{-1})				Characteristics Functional Groups
IBUL	**IBUI**	**IBUC**	**IBUM**	
1641.48	1699.34	1703.20	1743.17	Carbonyl stretching of isopropionic acid group(-OH)stretching linked to (-C=O)
2953.12	2966.62	2953.12	2662.76	Carbonyl stretching of isopropionic acid group(-OH)stretching linked to (-C-H)

The blend or prepared formulation showed almost the same characteristics peaks of pure formulation indicating no interaction.In The spectra almost of the formulation.C=O stretching of isopropionic acid group of the Ibuprofen was shifted towards the lower frequencies and other peaks are almost the same.This indicated that overall symmetry of the molecule is not significantly affected.

13.Accelerated Stability Studies:

.The sample was exposed to 25^0C,40^0C and at room temperature and analysed 0 to1 month intervals.The various parameter analysed were reported on stability data and from this the shelf life of the preparation was predicted.The various parameter such as pH ,viscosity measurement ,sedimentation rate, density,drug content,and both the sample stored at room temperature 25^0C,40^0C.

Table No 3.17 Evaluation parameter for stability study at 25^0C 40%

Parameter	Viscosity (cps)	Density(gm/ml)	Drug Content%	Sedimentation
Initial batch	49.7	1.25	95.85	0.98
1st month	49.2	1.26	94.82	0.99

Ibuprofen suspension content characterization

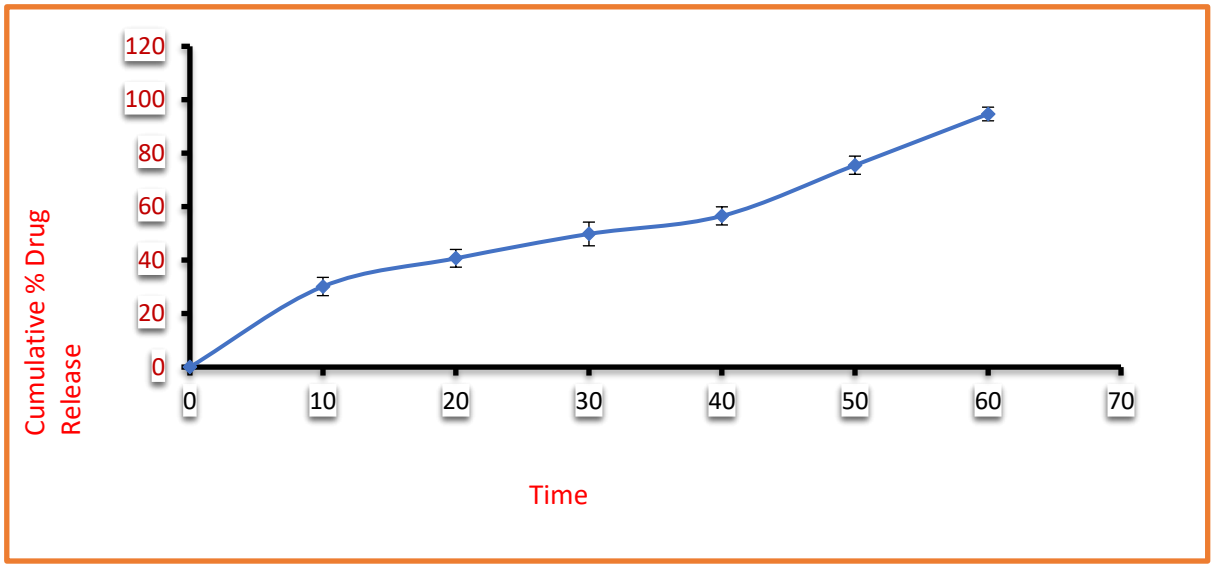
Table No.3.18 Ibuprofen suspension content characterization

Drug Content %	Viscosity (cps)	Density(gm/ml)
IBUL=95.85	49.7	1.259
IBUI=94.28	41.8	1.251
IBUC=95.64	48.4	1.235
IBUM=97.21	50.3	1.338

Table No 3.19 Dissolution data for stability study at 25^{0}C at 40% RH (IBUL)

	Cumulative % drug release	
Time(min)	**Initial batch**	**1st month**
10	30.14 ±3.41	29.37±3.41
20	40.70 ±3.31	38.33±3.31
30	49.81 ±4.43	48.80.79±4.43
40	56.56 ±3.39	55.54±3.39
50	75.53 ±3.40	74.53±3.40
60	94.68 ±2.56	93.59±2.56

Figure No 3.16 Dissolution data for stability study at 25^{0}Cat 40% RH(IBUL)



Dissolution data for stability study at 25^{0}C at 40% RH (IBUI)

Table No 3.20 Dissolution data for stability study at 25^{0}C at 40% RH (IBUI)

	Cumulative % drug release	
Time(min)	**Initial batch**	**1st month**
10	39.29 ±4.69	38.24 ±4.69
20	46.99 ±2.85	45.99±2.85
30	56.26 ±2.99	54.25 ±2.99
40	68.37±2.80	66.28 ±2.80
50	84.53 ±3.08	83.53 ±3.08
60	91.75 ±4.50	90.72 ±4.50

All values are expressed as mean ±SD, n=3

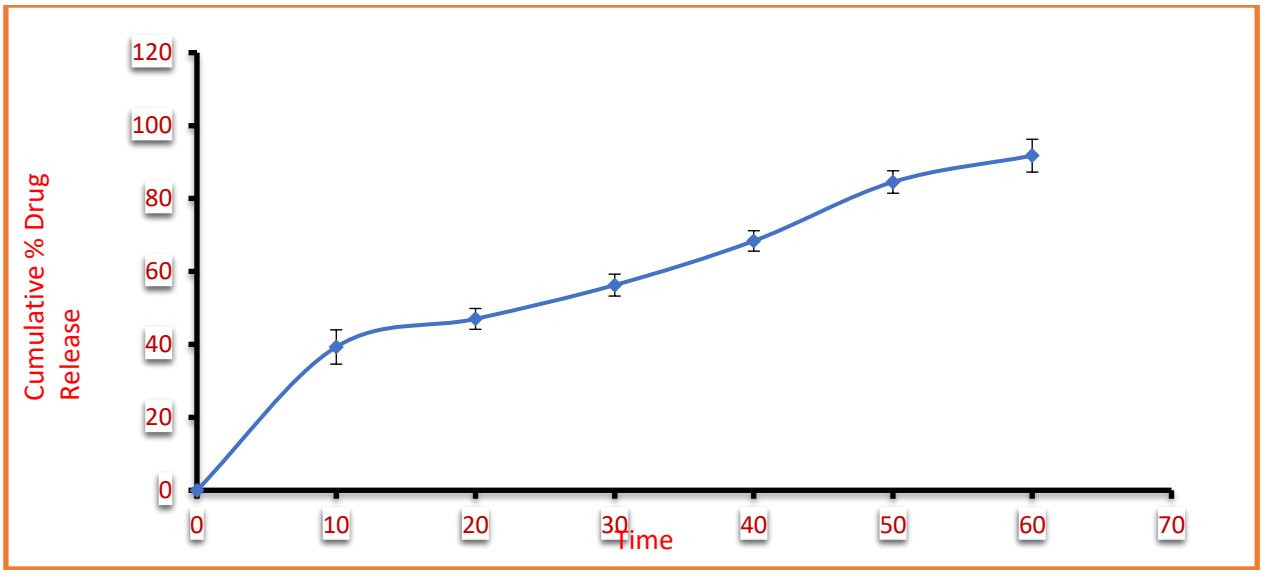


Figure No 3.17 Dissolution data for stability study at 25^{0}Cat 40% RH(IBUI)

Dissolution data for stability study at 25^{0}C at 40% RH (IBUC)

Table No 3.21 Dissolution data for stability study at 25^{0}C at 40% RH (IBUC)

	Cumulative % drug release	
Time	**Initial batch**	**1st month**
10	40.22±2.89	38.22 ±2.89
20	49.99±3.59	45.89±3.59
30	68.85±2.69	64.2 ±2.69
40	.73.09±0.57	70.28±0.57
50	91.17±2.86	89.53±2.86
60	94.77±1.72	93.72±1.73

All values are expressed as mean ±SD, n=3

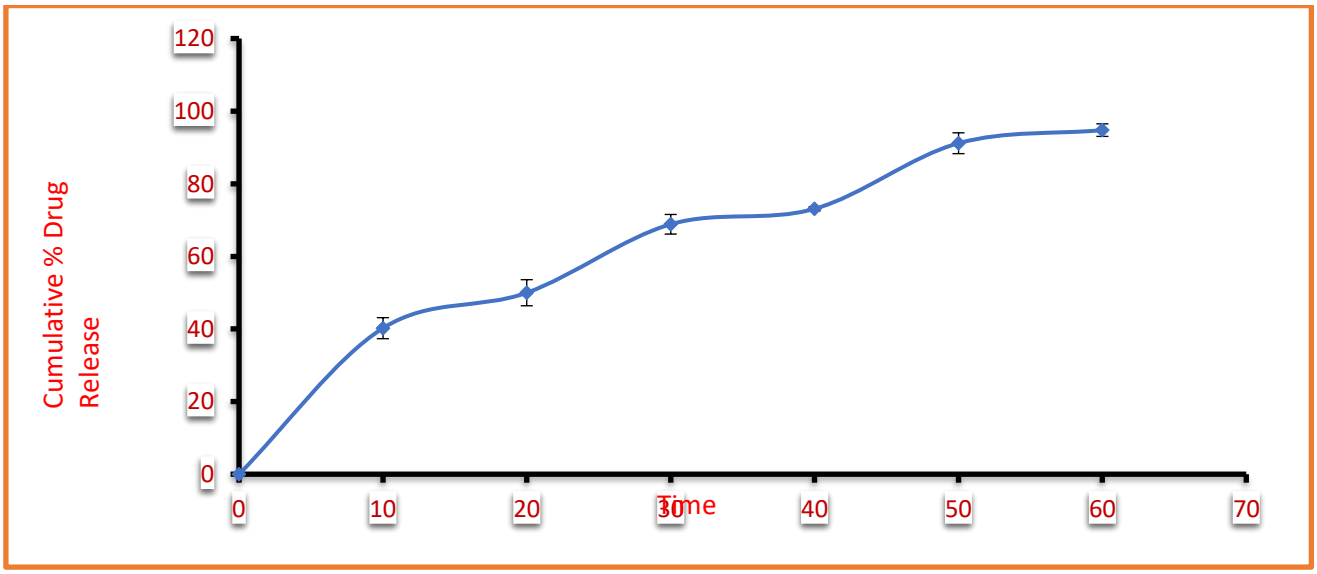


Figure No 6.18 Dissolution data for stability study at 25^{0}Cat 40% RH (IBUC

Dissolution data for stability study at 25^{0}C at 40% RH (IBUM)

Table No 3.22 Dissolution data for stability study at 25^{0}C at 40% RH (IBUM)

	Cumulative % drug release	
Time	**Initial batch**	**1st month**
10	41.76 ± 2.58	40.68±2.58
20	47.26 ±3.51	45.20±3.51
30	61.53 ± 2.07	61.49±2.07
40	78.05 ± 4.98	77.03±4.98
50	92.08 ± 3.87	90.06±3.87
60	95.92 ± 4.84	94.88±4.84

All values are expressed as mean ±SD, n=3

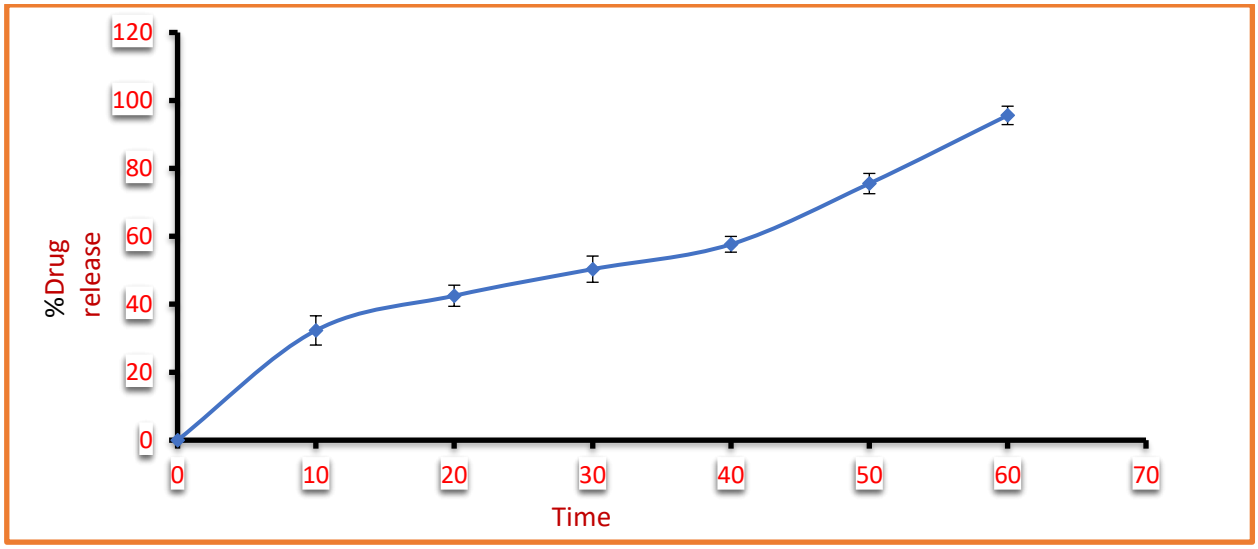


Figure No 3.19 Dissolution data for stability study at 25^{0}Cat 40% RH (IBUM)

Table No 3.23 Evaluation parameter for stability study at 40^{0}Cat 60%RH

Parameter	Viscosity (cps)	Density(gm/ml)	Drug Content%	Sedimentation
Initial batch	49.7	1.25	95.85	0.98
1st month	49.2	1.26	94.82	0.99

Table No 3.24Dissolution data for stability study at 40^{0}C at 60% RH (IBUL)

	Cumulative % drug release	
Time(min)	**Initial batch**	**1st month**
10	30.14 ±3.41	30.37±3.41
20	40.70 ±3.31	39.33±3.31
30	49.81 ±4.43	48.80.79±4.43
40	56.56 ±3.39	56.54±3.39
50	75.53 ±3.40	74.58 ±3.40
60	94.68 ±2.56	94.59±2.56

All values are expressed as mean ±SD, n=3

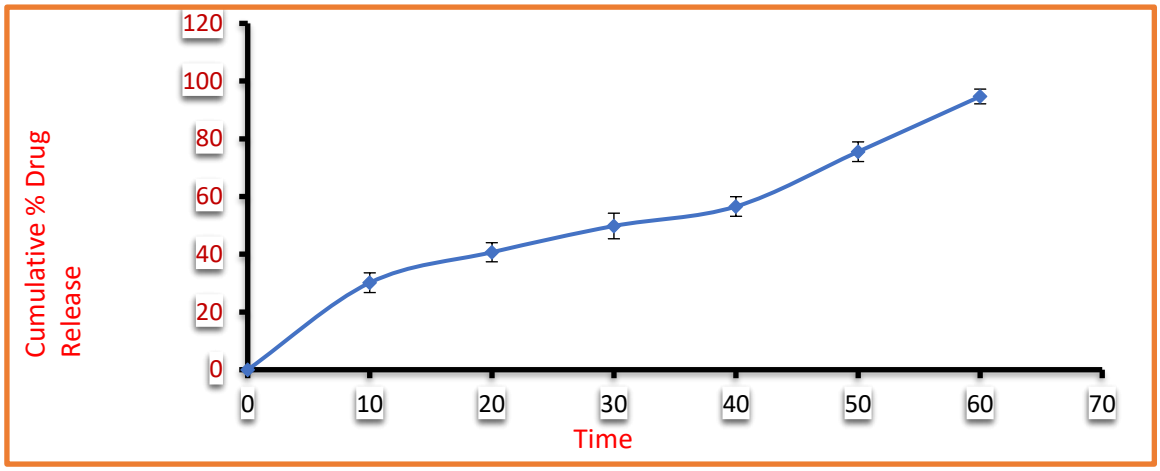


Figure No 3.20 Dissolution data for stability study at 40^{0}Cat 60% RH (IBUL)

Dissolution data for stability study at 40^{0}C at 60% RH (IBUI)

Table No 3.25 Dissolution data for stability study at 40^{0}C at 60% RH (IBUI)

	Cumulative % drug release	
Time(min)	**Initial batch**	**1st month**
10	39.29 ±4.69	39.24 ±4.69
20	46.99 ±2.85	48.99±2.85
30	56.26 ±2.99	54.25 ±2.99
40	68.37±2.80	67.28 ±2.80
50	84.53 ±3.08	83.58 ±3.08
60	91.75 ±4.50	91.79 ±4.50

All values are expressed as mean ±SD, n=3

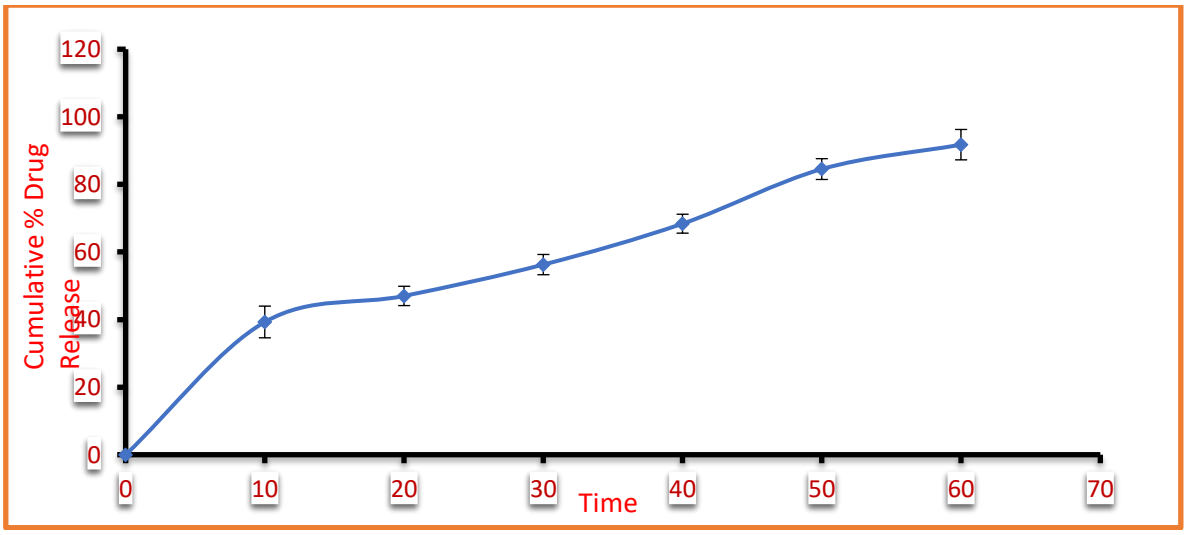


Figure No 3.21 Dissolution data for stability study at 40^{0}Cat 60% RH (IBUI)

Dissolution data for stability study at 40^{0}C at 60% RH (IBUC)

Table No 3.26 Dissolution data for stability study at 40^{0}C at 60% RH (IBUC)

	Cumulative % drug release	
Time	**Initial batch**	**1st month**
10	40.22±2.89	39.25 ±2.89
20	49.99±3.59	49.89±3.59
30	68.85±2.69	67.89 ±2.69
40	.73.09±0.57	74.28±0.57

50	91.17±2.86	91.53±2.86
60	94.77±1.72	94.79±1.73

All values are expressed as mean ±SD, n=3

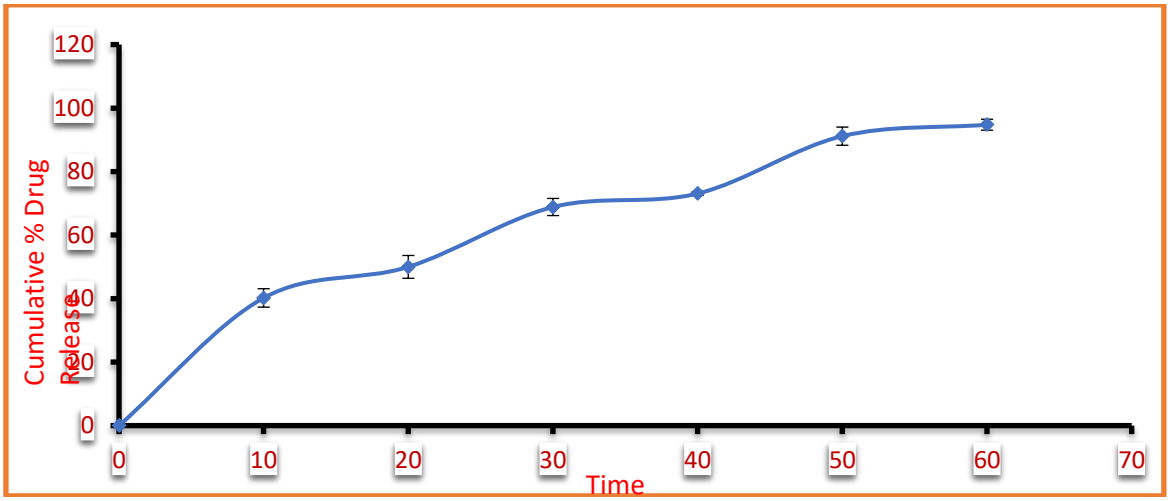


Figure No 3.22 Dissolution data for stability study at 40^{0}Cat 60% RH (IBUC)

Dissolution data for stability study at 40^{0}C at 60% RH (IBUM)

Table No 3.27 Dissolution data for stability study at 40^{0}C at 60% RH (IBUM)

	Cumulative % drug release	
Time	**Initial batch**	**1st month**
10	41.76 ± 2.58	41.88±2.58
20	47.26 ±3.51	46.28±3.51
30	61.53 ± 2.07	61.49±2.07
40	78.05 ± 4.98	78.43±4.98
50	92.08 ± 3.87	92.06±3.87
60	95.92 ± 4.84	95.88±4.84

All values are expressed as mean ±SD, n=3

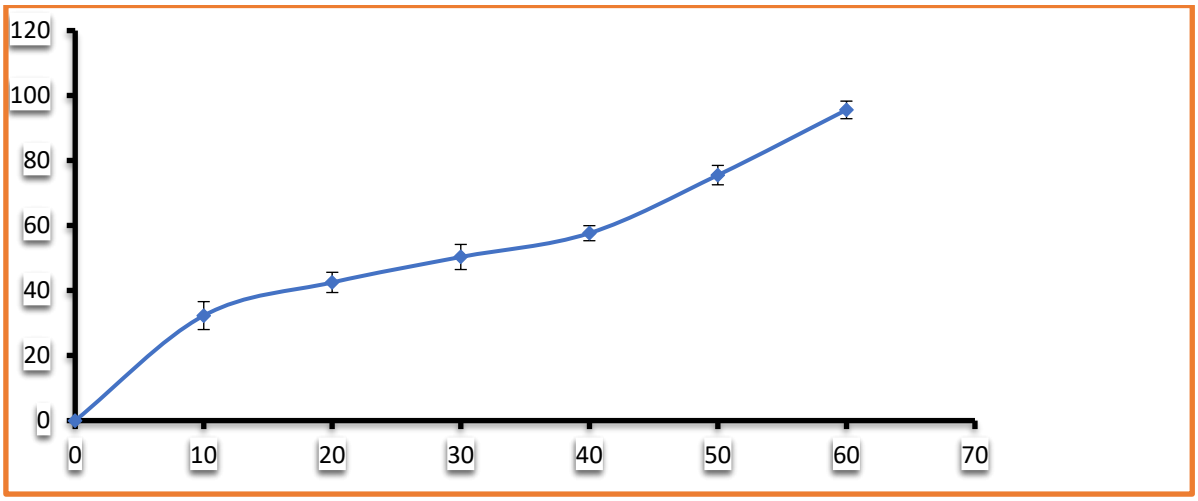


Figure No 3.23 Dissolution data for stability study

CONCLUSION

The extracted mucilage of Lepidium sativum, Isapgol has the potential as a suspending agent even at lower concentrations and can be used as a pharmaceutical adjuvant. In view of these properties, mucilage of *Lepidium sativum, Isapgol* can be employed as stabilizer and thickener of choice when high viscosity is desired especially in cosmetics, pharmaceutical and food industries. Quick

onset of action is desired in case of immediate release suspension. The FTIR a study was indicates group present ,type of compound and bonds present in mucilage from *Lepidium sativum, isapgol, NaCMC*. Based on results obtained, it can be concluded that the Ibuprofen suspension was prepared successfully using natural suspending agents Lepidium sativum and Isapgul. The extracted powder of Lepidium sativum, Isapgul may be used as a suspending agent in pharmaceutical preparations.

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