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Research Article

FORMULATION AND IN VITRO EVALUATION OF GLICLAZIDE CONTAINING NIOSOMES

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ABSTRACT

In this study niosomal drug delivery system was developed using non-ionic surfactant incorporating Gliclazide by Thin film hydration technique. The prepared niosomal vesicles were quite stable. The formulation was subjected to Entrapment efficiency, Scanning electron microscopy, Invitro release, and Zeta potential analysis. From the results of experimental investigation, we concluded that, formulation F13 containing drug with 300:200 µmol (surfactant:cholesterol) ratio was showing higher percentage entrapment with desired sustained release of Gliclazide. Hence formulation F13 was considered as optimized formulation. Invitro release from optimized Gliclazide niosomal formulation (F13) showed extended release for 24 hours. SEM image revealed the vesicles are exist spherical shape and uniform in size. Scanning electron micrograph shows there is no aggregation between the particles. This confirmed the presence of negative charge inducing agent in formulation. The formulation was checked for sterility as per I.P specification. The optimized formulation passes the sterility test. Stability study was carried out for the period of three months at various storage conditions. The results showed that the formulation remains stable at 4°c. The optimized formulation was found to follow zero order release pattern which was revealed by the linearity shown from the plot of Time Vs cumulative percentage drug release. From the drug release kinetic studies, we concluded that the drug was released from niosome by a zero order diffusion controlled mechanism.

INTRODUCTION

Niosomes or non-ionic surfactant vesicles are minute lamellar structures formed on admixture of non-ionic surfactant of the alkyl or dialkyl polyglycerol ether class and cholesterol with following hydration in watery media. Niosomal vesicle suspension is water-based vehicle. This offers high quiet consistence in correlation with slick dose structures. They have a foundation comprising of hydrophilic, amphiphilic and lipophilic moieties together and subsequently can oblige drug particles.

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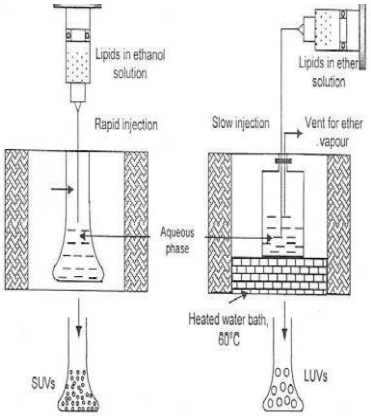


Figure.1 Ether injection Method

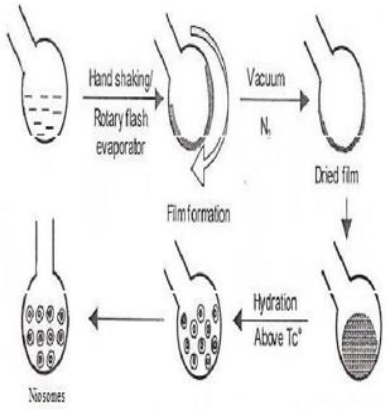


Figure.2 Thin film hydration Method

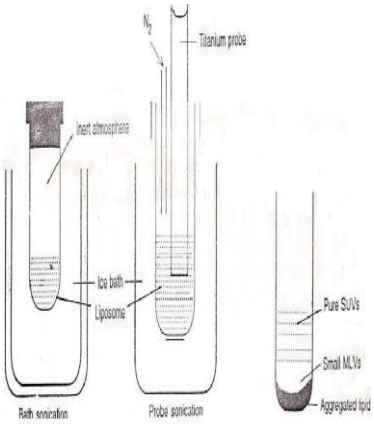


Figure.3 Sonication Method

METHODOLOGY

Preparation of release media

2.38 gm of disodium hydrogen phosphate, 0.19 gm of potassium dihydrogen phosphate and 8gm of sodium chloride were disintegrated in adequate measure of refined water to create 1000ml and pH transformed in accordance with 7.4, if essential.

Determination of Absorbance most extreme (λmax)

Gliclazide was dissoled in phosphate cushion saline pH 7.4. Arrangement with 20 µg/ml focus was ready by appropriate weakening.The Gliclazide drug in arrangement was checked in UV spectrophotometer from 200 to 400 nm utilizing phosphate cushion saline pH 7.4 as clear. Absorbance most still up in the air as 267 nm. The medication was subsequently evaluated by guesstimating the absorbance at 267 nm in phosphate cushion saline pH7.4.

Standard bend for Gliclazide (by UV metohod)

Preparation of Primary stock solution

Gliclazide 100 mg was gauged and disintegrated in phosphate cushion saline pH7.4 in a 100 ml volumetric flagon. The flagon was shaken and volume was left up to the imprint with phosphate cushion brackish pH 7.4 to give an answer containing 1000 µg/ml.

Preparation of secondary stock solution

From the Primary stock solution, pipette out 2 ml and set into 100 ml volumetric flagon. The volume was left up to imprint with phosphate support saline pH 7.4 to give a stock arrangement containing 20 µg/ml.Fitting volumes of aliquots (1 to 10 ml) from standard Gliclazide auxiliary stock arrangement were moved to various volumetric cups of 10 ml limit. The volume was acclimated to the imprint with phosphate cushion saline pH 7.4 to get groupings of 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 µg/ml. Absorbance of every arrangement against phosphate cradle saline pH 7.4 as clear were estimated at 267 nm and the chart of absorbance against focus were plotted and displayed in Figure.

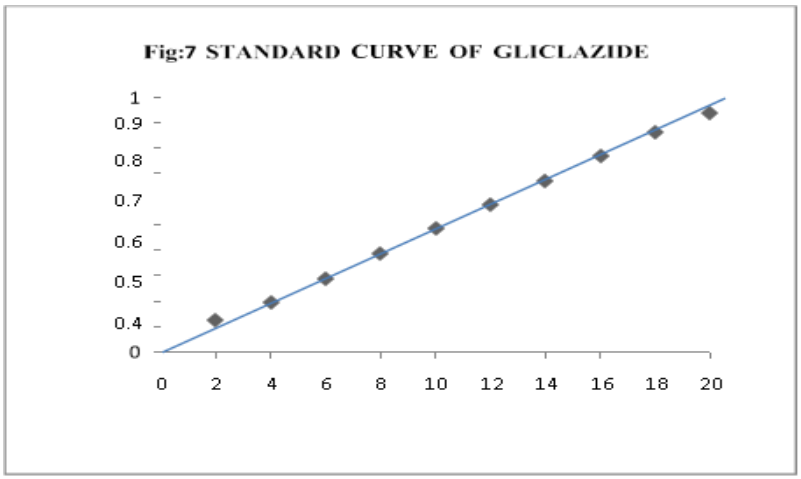


Figure.4 Standard curve

Table.1 Calibration curve table

Concentration in µg/ml	Absorbance at 267 nm
2	0.124
4	0.195
6	0.290
8	0.385
10	0.483
12	0.576
14	0.671
16	0.769
18	0.864
20	0.939

RESULTS AND DISCUSSION

INFRARED SPECTROSCOPIC STUDIES

IR study remained done for distinguishing proof of unadulterated medication. IR spectroscopy (utilizing Perkin Elmer) by KBr pellet technique was done on medicate. They are compacted under 15 tones tension in a water driven press to frame a straightforward pellet.

OPTIMIZATION PROCESS FOR NIOSOME PREPARATION

By using a dainty film hydration method, empty vesicles were prepared. Cholesterol was broken down in a chloroform-methanol mix proportion (2:1v/v), and a fluid stage was prepared by dissolving precisely measured amounts of surfactant in a 100 ml round base carafe. In order to obtain a thin coating on the mass of the flagon, the dissolvable mixture was removed from the fluid stage using a rotating evaporator at 45–60 °C and varying rotation speeds of 75–150 rpm.

COMPOSITION OF GLICLAZIDE NIOSOMES VARIABLES

Table.2 Formulation table

Formulation code	Gliclazide (mg)	Surfactant	Surfactant:Cholesterol (µM)
F1	10	Span 20	100:100
F2	10	Span 20	200:100
F3	10	Span 20	300:100
F4	10	Span 20	100:200
F5	10	Span 20	200:200
F6	10	Span 20	300:200
F7	10	Span 20	400:200
F8	10	Tween 20	100:100
F9	10	Tween 20	200:100
F10	10	Tween 20	300:100
F11	10	Tween 20	100:200
F12	10	Tween 20	200:200
F13	10	Tween 20	300:200
F14	10	Tween 20	400:200

OPTIMIZATION OF PROCESS RELATED

Table.3 Optimization

Surfactant: Cholesterol	Speed of Rotation (rpm)	Hydration Time (min)	Chloroform: methanol	Hydration volume	Vesicle Size (µM)
100:100	75	30	2:1	5 ml	10.29±1.48
	100	60			9.41±1.09
	125	120			9.11±1.88
	150	120			8.69±1.88

Percentage drug entrapment efficiency

Table.4 evaluation tests

Volume of hydration medium (ml)	Hydration time (min)	Percentage entrapment (%)
3	60	60.74 ± 0.98
4	60	68.84 ± 0.76
4	60	73.38 ± 0.58
5	120	89.45 ± 0.88
5	180	81.45 ± 0.93

Table.5 Evaluation tests

Formulation code	Surfactant: Cholesterol (µM)	Surfactant used	Percentage of free Drug (%)	Percentage entrapment Efficiency
F1	100:100	Span 20	37	63
F2	200:100	Span 20	26	74
F3	300:100	Span 20	32	68
F4	100:200	Span 20	38	62
F5	200:200	Span 20	28	72
F6	300:200	Span 20	16	84
F7	400:200	Span 20	29	71
F8	100:100	Tween 20	32	68
F9	200:100	Tween 20	19	81
F10	300:100	Tween 20	27	73
F11	100:200	Tween 20	29	71
F12	200:200	Tween 20	15	85
F13	300:200	Tween 20	8	92
F14	400:200	Tween 20	24	76

OPTIMISED FORMULATION

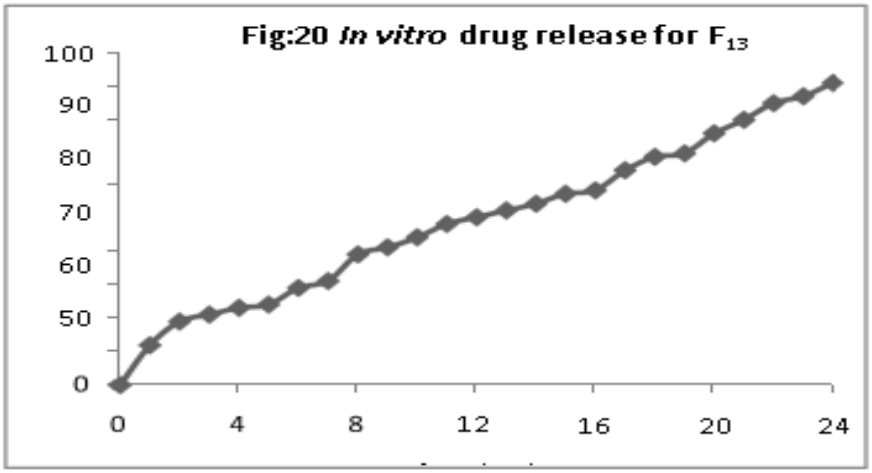


Figure.5 in vitro release of F13

In vitro release study of Gliclazide niosomes

Table.6 In vitro release

Formulation code	Surfactant Cholesterol (µM)	Surfactant used	Total release period (Hrs)	Cumulative percentage drug release
F1	100:100	Span 20	16	61.58
F2	200:100	Span 20	17	72.69
F3	300:100	Span 20	16	67.64
F4	100:200	Span 20	24	59.57
F5	200:200	Span 20	24	71.65
F6	300:200	Span 20	24	81.97
F7	400:200	Span 20	14	70.63
F8	100:100	Tween 20	16	65.61
F9	200:100	Tween 20	18	79.74
F10	300:100	Tween 20	18	71.68
F11	100:200	Tween 20	24	69.61
F12	200:200	Tween 20	24	83.78
F13	300:200	Tween 20	24	90.86
F14	400:200	Tween 20	20	73.69

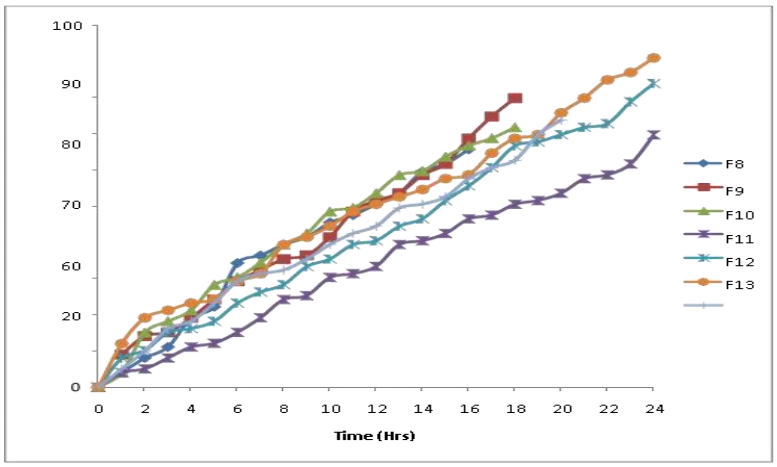


Figure.6 %Drug release

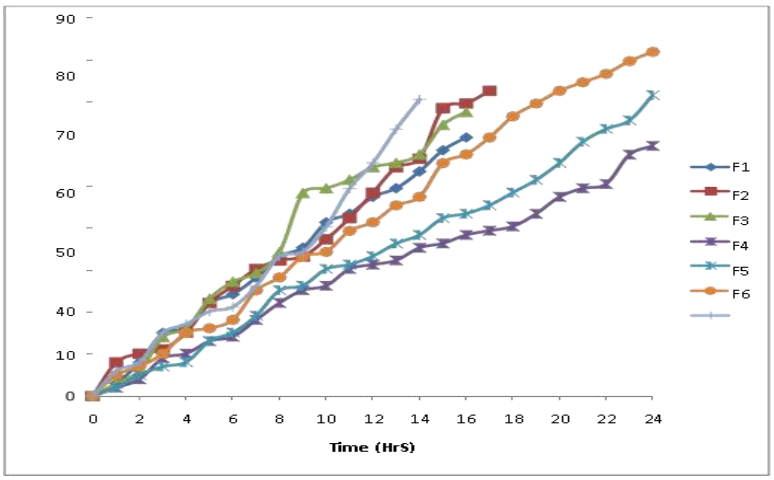


Figure.7 %Drug release

In vitro data for optimized formulation F13 stability study at 4ºC

Table.7 optimized formulation F13 stability study

Time(Hrs)	Cumulative % drug release		
	1st month (%)	2nd month (%)	3rd month (%)
1	7.0	4.0	8.0
2	9.07	8.04	10.08
3	13.09	13.08	11.10
4	19.13	15.13	17.11
5	24.19	16.15	19.17
6	25.24	22.16	23.19
7	32.24	25.22	24.23
8	39.32	29.25	28.24
9	48.39	35.29	31.28
10	50.48	42.35	32.31
11	54.50	44.42	35.32
12	56.54	49.44	39.35
13	60.56	50.49	44.39
14	63.60	53.50	45.44
15	65.63	59.53	52.44
16	69.65	61.59	59.52
17	72.69	63.61	63.59
18	75.72	70.63	64.63
19	77.75	72.70	68.64
20	81.77	74.72	74.68
21	82.81	78.74	75.74
22	83.82	80.78	79.75
23	87.83	84.80	83.79
24	89.87	88.84	87.83

STABILITY STUDY RELEASE DATA FOR FORMULATION F13 AFTER THREE MONTHS AT 4°C

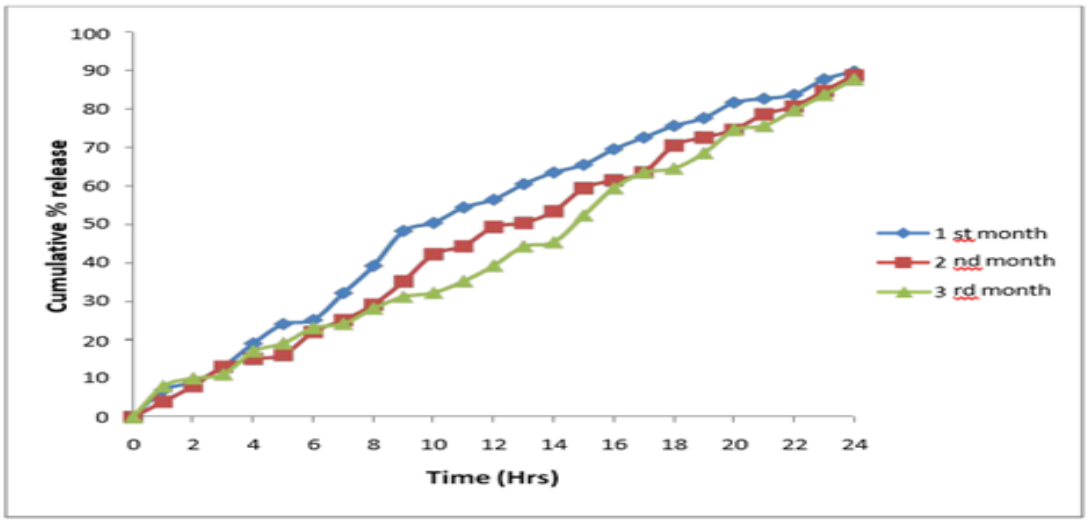


Figure.8 Stability studies for drug release

In vitro data for optimized formulation F13 stability study

Table.8 optimized formulation F13 stability study

Time (Hrs)	Cumulative % drug release		
	1st month (%)	2nd month (%)	3rd month (%)
1	7.0	5.0	5.0
2	9.07	7.05	7.05
3	12.09	13.07	14.07
4	16.12	17.13	20.14
5	19.08	24.17	22.20
6	23.19	29.24	26.22
7	24.23	31.29	27.26
8	29.24	34.31	32.27
9	33.29	39.34	34.32
10	34.33	45.39	37.34
11	39.34	47.45	39.37
12	41.39	49.47	42.38
13	45.41	51.49	44.42
14	47.45	53.51	48.42
15	49.47	56.53	50.48
16	50.49	61.56	51.50
17	62.50	63.61	58.51
18	63.62	68.63	60.58
19	69.63	69.68	66.60
20	70.69	71.69	67.66
21	76.70	72.71	69.67
22	79.76	77.72	74.69
23	83.79	80.77	77.74
24	85.83	82.80	78.77

In vitro data for optimized formulation F13 stability study at 45°c/75%RH

Table.9 optimized formulation F13 stability study at 45°c/75%RH

Time (Hrs)	Cumulative % drug release		
	1st month (%)	2nd month (%)	3rd month (%)
1	5.0	6.0	4.0
2	9.05	11.06	8.04
3	16.09	13.11	10.08
4	18.16	17.13	13.10
5	22.18	21.17	14.13
6	24.22	22.21	19.14
7	27.24	26.22	25.19
8	29.27	28.26	28.25
9	33.29	30.28	30.28
10	37.33	31.30	32.30
11	38.37	34.31	35.32
12	44.38	40.34	36.35
13	45.44	42.40	40.36
14	49.45	48.42	41.40
15	55.49	51.48	43.41
16	57.55	53.51	46.43
17	62.57	57.53	48.45
18	69.62	59.57	49.48
19	70.69	61.59	54.49
20	74.70	63.61	55.54
21	76.74	67.63	61.55
22	77.76	68.67	64.61
23	79.77	73.68	66.64
24	81.79	75.73	70.66

KINETICS OF DRUG RELEASE

Zero order plot for formulation F13

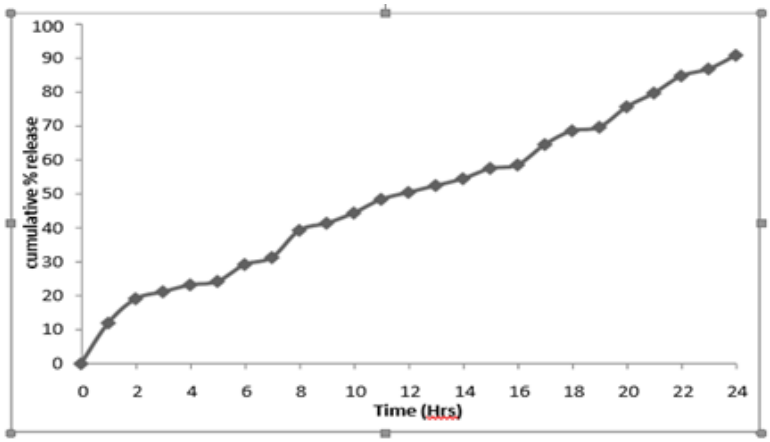


Figure.9 Zero order

First order plot

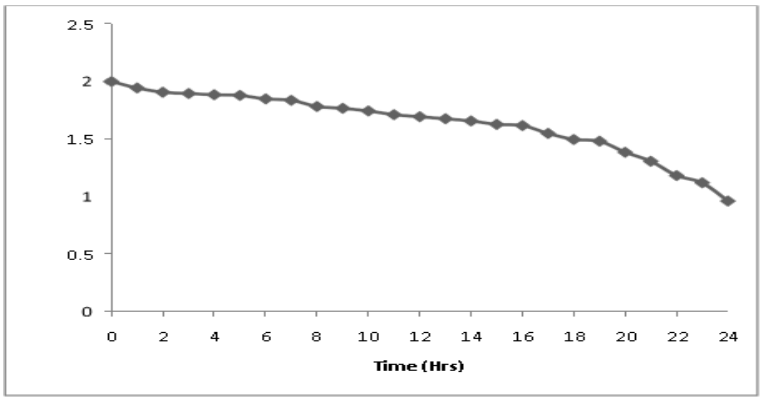
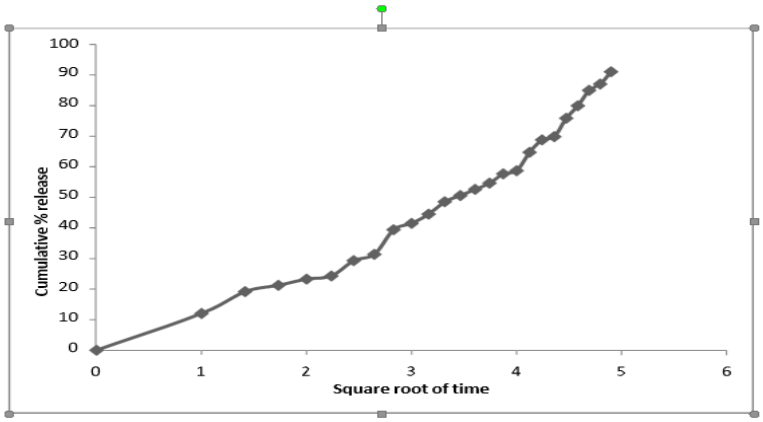


Figure.10 First Order

Higuchi plot for formulation F13



Slope = 1.8921

Regression = 0.9539

Figure.11 Higuchi Plot

Korseyemer plot for formulation F13

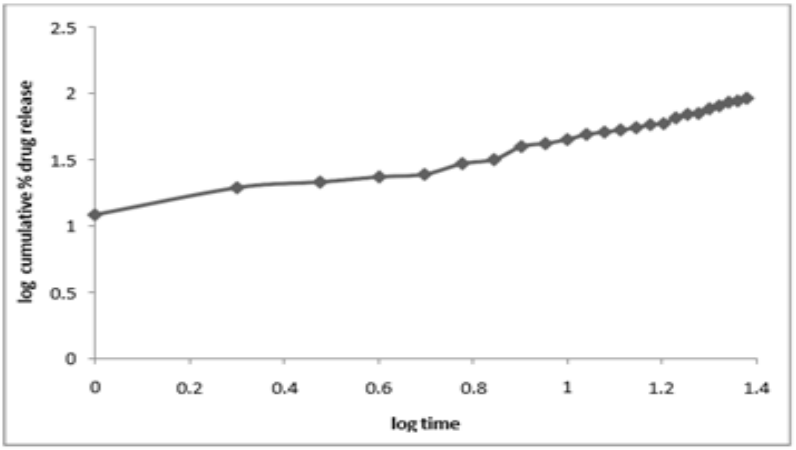


Figure.12 Peppas Plot

Observation of the sterility test done in soyabean casein digest medium

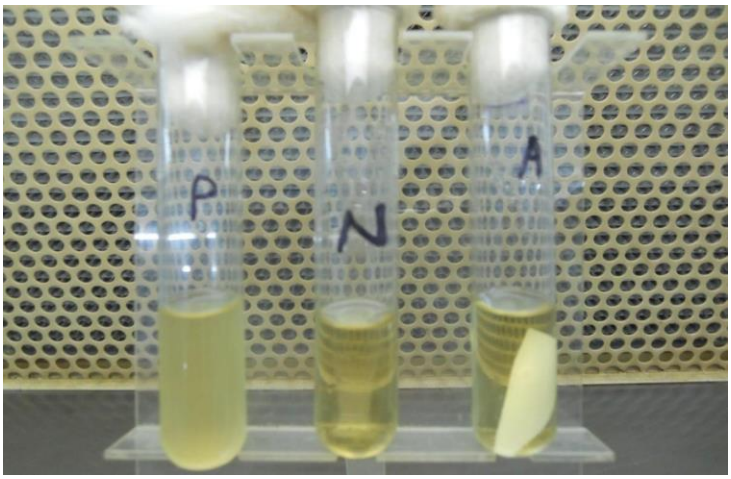


Figure.13 Sterility test

Observation of the sterility test done in soyabean casein digest medium (SCDM).

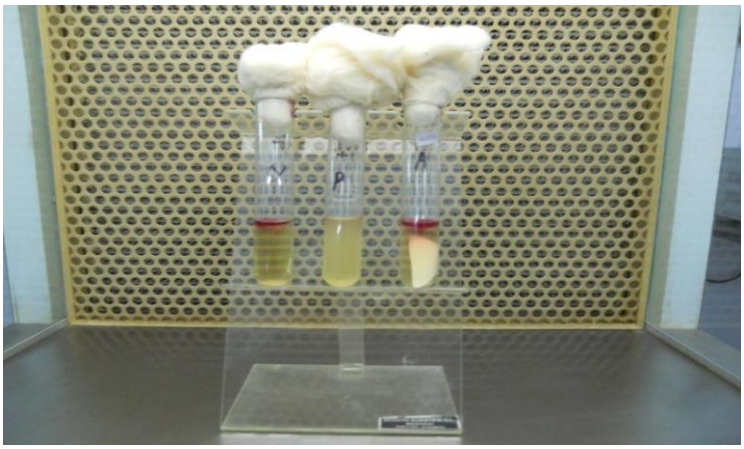


Figure.14 Sterility test

SUMMARY AND CONCLUSION

In this study niosomal drug conveyance framework was created utilizing non-ionic surfactant consolidating Gliclazide by Flimsy film hydration procedure. The arranged niosomal vesicles were very steady.The detailing was exposed to Entanglement productivity, Checking electron microscopy, Invitro delivery, and Zeta likely investigation. From the consequences of trial examination, that's what we presumed, detailing F13 containing drug with 300:200 µmol (surfactant:cholesterol) proportion was showing higher rate capture with wanted supported arrival of Gliclazide. Thus detailing F13 was considered as upgraded definition.Invitro discharge from streamlined Gliclazide niosomal detailing (F13) showed expanded discharge for 24 hours.Steadiness study was done for the time of 90 days at different capacity conditions. The outcomes showed that the definition stays stable at 4°c.

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