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Research Article

**DEVELOPMENT AND CHARACTERIZATION OF
MUCOADHESIVE MICROSPHERES OF ROSIGLITAZONE
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Abstract:

The aim of present study is development and characterization of mucoadhesive microspheres of Rosiglitazone maleate and Empagliflozin by combine the potential advantages of mucoadhesion with controlled drug. Rosiglitazone maleate is an anti diabetic drug precisely controls the blood glucose level in diabetic patient and Empagliflozin works by blocking the sodium-glucose co-transporter-2 (SGLT2) in the kidneys. This reduces the amount of glucose reabsorbed into the blood and increases the amount of glucose excreted in the urine. Mucoadhesive microspheres of Rosiglitazone maleate and Empagliflozin are prepared by using various ratios of carbopol-934, sodium carboxymethyl cellulose and sodium alginate by emulsification solvent evaporation techniques. Various preformulation studies are done to confirm the purity, pharmacopoeial standards and for physicochemical characterisation of the drugs. Six formulations for each drug are prepared using different ratios of carbopol-934, sodium carboxymethyl cellulose and sodium alginate. These formulations are assigned for reproducibility with respect to % yield, particle size, % drug entrapment, % mucoadhesion and % drug release of microspheres. The formulation F1 containing sodium carboxymethyl cellulose showed reproducible results and the best mucoadhesive profile with good surface morphology. Among all the formulations of microspheres, formulation F1 containing sodium carboxymethyl cellulose showed best results, demonstrated the best sustained release efficacy out of all the microsphere formulations

Key Words: mucoadhesive microspheres, Rosiglitazone maleate, Empagliflozin, sodium-glucose co-transporter-2 (SGLT2), carbopol-934.

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1. INTRODUCTION:

Novel drug delivery system delivers a therapeutic substance to the target site in a well-controlled and sustained model.¹ Microspheres or microparticles are defined as a free-flowing spherical particles consisting of polymer matrix and drug. They consist of proteins or synthetic polymers which are biodegradable in nature having a particle size less than 200 μ m.²

Microspheres can be referred as small spherical particles, with diameters in the micrometer range (typically 1 μ m to 1000 μ m). Microspheres can also be called as microparticles. Microspheres had been explored significantly for their use in the subject of drug transport and various polymers had been utilized for the formulation of the microspheres, which in turn have been assessed for distinctive purposes. Eventually the whole dose and few adverse reactions can be decreased due to the fact that a steady plasma concentration is maintained.³

Microspheres are of two types; Microcapsules and Micromatrices. Microcapsules are those in which entrapped substance is surrounded by distinct capsule wall and micromatrices in which entrapped substance is dispersed throughout the microsphere matrix.¹

Advantages of Microspheres^{5,6}

1. Decreased size of microsphere contributes increased surface area thereby increases the potency of the poorly soluble material.
2. Dose frequency and adverse effects can be reduced.
3. Increased patient compliance.
4. Drug packaged with polymer prevent drug from enzymatic cleavage therefore the drug can be protected from various enzymes.
5. Enhances bioavailability.
6. Gastric irritation can be reduced.
7. Biological half-life can be enhanced.
8. First pass metabolism can be reduced.
9. Unpleasant odour and taste of the drug can be masked.

Disadvantages of microspheres⁶

1. Reproducibility is less.
2. The cost of materials and processing is high compared to conventional preparations.
3. Change in process variables such as change in temperature, pH, solvent addition and evaporation/agitation may influence the stability of core particles.
4. The fate of polymer matrix and additives.

Mucoadhesive polymers

The properties of mucoadhesive dosage form such as their surface characteristics, force of adhesion, release pattern of the drug and clearance are influenced by the type of polymer used to prepare dosage forms. Suitable polymers that can be used to prepare mucoadhesive dosage form include soluble and insoluble, non biodegradable and

biodegradable polymers. These can be hydro-gels or thermoplastics, homopolymers, copolymers or blend, natural or synthetic polymers.

Ideal characteristics of mucoadhesive polymers

- The polymer and its degradation product should be non-toxic and should be absorbable from GI tract.
- It should be non-irritant to the mucous membrane.
- It should preferably form a strong non-covalent bond with mucin-epithelial cell surfaces.
- It should adhere quickly to most tissue and should possess some site specificity.
- The polymers must not decompose on storage or during the shelf life of dosage form.
- The cost of polymer should not be high so that prepared dosage form remains competitive.

Molecular characteristics of polymers

Investigations into polymers with various molecular characteristics have to a number of conclusions regarding the molecular characteristics required for mucoadhesion. The properties exhibited by a good mucoadhesive may be summarized as follows:

- Strong hydrogen-bonding groups [-OH, -COOH]
- Strong anionic charges
- Sufficient flexibility to penetrate the mucus network or tissue crevices
- Surface tension characteristics suitable for wetting mucus/mucosal tissue surface
- High molecular weight

2. MATERIALS AND METHODS:

The aim of present study is development and characterization of mucoadhesive microspheres of Rosiglitazone maleate and Empagliflozin by combine the potential advantages of mucoadhesion with controlled drug delivery using various ratios of polymers which provide the drug for a prolonged gastrointestinal absorption in a sustained release manner. Rosiglitazone maleate is an anti diabetic drug belongs to thiazolidinediones class that can precisely control the blood glucose level in diabetic patient. It requires control release owing to its short biological half life of 3-4 hours. It has many side effects like cardiovascular failure, fatigue, weight gain and mild anaemia. Empagliflozin works by blocking the sodium-glucose co-transporter-2 (SGLT2) in the kidneys. This reduces the amount of glucose reabsorbed into the blood and increases the amount of glucose excreted in the urine.

2.1 Method of Preparation of Formulation:

2.1.1 Method of preparation of microspheres

without drug

The 20 ml of aqueous polymer solution will be added drop wise to 200 ml of liquid paraffin containing 0.5% span 20 as an emulsifying agent with constant stirring. The beaker and its content will be heated at 80°C with constant stirring for 4.5 hours until the aqueous phase will be completely removed by evaporation. The liquid paraffin will be decanted and collected microspheres will be 3

times with 100ml of n-hexane, filtered through whattman's filter paper, dried in an oven at 50°C for 2 hours and stored in a desiccator at room temperature. For the purpose of assessing the effect of stirring speed and effect of polymer concentrations on particle size of microspheres, every batches will be prepared at two different stirring speeds (500 and 1000 rpm) and at two different polymer concentrations (2% and 1% conc.).

Table1. Preparation of microspheres without drug

Formulationcode	SodiumCMC	Carbopol-934	Sodiumalginate
MS1	1000mg	--	--
MS2	--	1000mg	--
MS3	--	--	1000mg
MS4	500mg	500mg	--
MS5	500mg	--	500mg
MS6	--	500mg	500mg

2.1.2 Method of preparation of microspheres with drug

Drug loaded microsphere will be prepared by water in oil (w/o) emulsification solvent evaporation method. For this, 100 mg of drug dissolved in 5ml dimethyl sulfoxide, and then it will be dispersed into 45 ml of 2% aqueous polymer solution. A vortex homogenizer will be used for rapid mixing of the drug solution into the aqueous polymer solution for 3 minutes. Then drug and polymer solution will be added drop wise to 400ml of the liquid paraffin containing 0.5% span 20 as an emulsifying agent with constant stirring at 500rpm.

Table2. Preparation of microspheres without drug

Formulationcode	Drug	SodiumCMC	Carbopol-934	Sodiumalginate
F1	100mg	900mg	--	--
F2	100mg	--	900mg	--
F3	100mg	--	--	900mg
F4	100mg	450mg	450mg	--
F5	100mg	450mg	--	450mg
F6	100mg	--	450mg	450mg

All formulations will be prepared at 2% polymer concentration and 500rpm stirringspeed. Span20(0.5%)used as emulsifying agent.

2.1.3Evaluation of microspheres:

- Surface morphology.
- Particle size analysis.
- Drug entrapment efficiency.
- In-vitro mucoadhesivity.
- In-vitro drug release.
- Stability studies.

3.RESULTS AND DISCUSSION:

Physical characterization of microspheres the microspheres were found to be discrete, spherical and free-flowing. The effects of alginate concentrations and polymer ratios on the average particle size of microspheres are shown in Figure 1 & Figure 2.

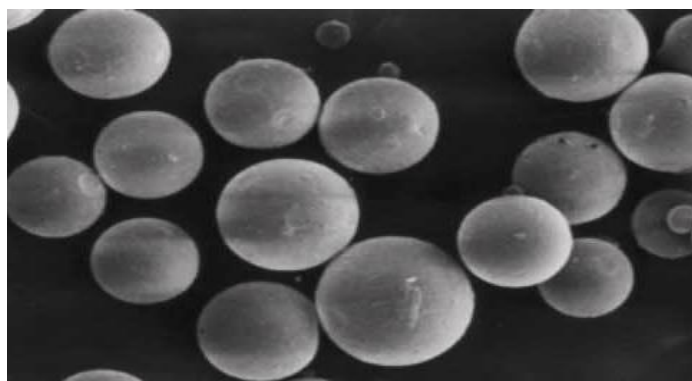


Figure 1: Scanning electron photomicrograph of formulation F1 showing population of microspheres



Figure 2: Scanning electron photomicrograph of formulation F2 showing population of microspheres

Table 3: Effect of stirring speed on particle size of Rosiglitazone maleate microspheres of batches of MS1, MS2, MS3, MS4, MS5 and MS6

Formulation code	Particle size (μm) At 500rpm	Particle size (μm) at1000rpm
MS1	31.54±2.43	26.87±1.43
MS2	29.20±1.88	25.36±1.79
MS3	37.54±3.24	29.22±2.45
MS4	32.62±2.78	26.85±1.95
MS5	35.12±2.84	28.33±2.32
MS6	33.85±3.15	27.85±1.85

Values are represented as mean ± standard deviation (n=3).

All batches will be prepared at 2% polymer concentration and every batch will be prepared at two different stirring speeds (500rpm and 1000rpm).

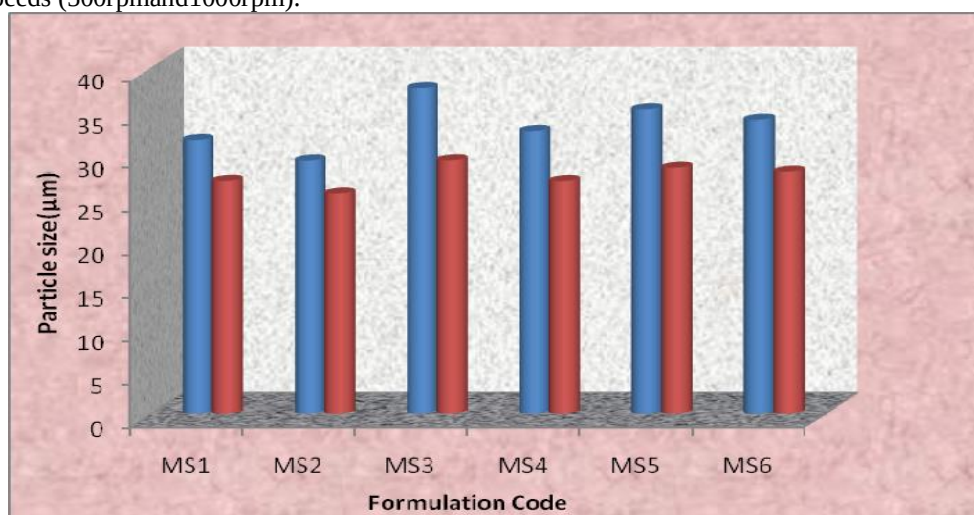


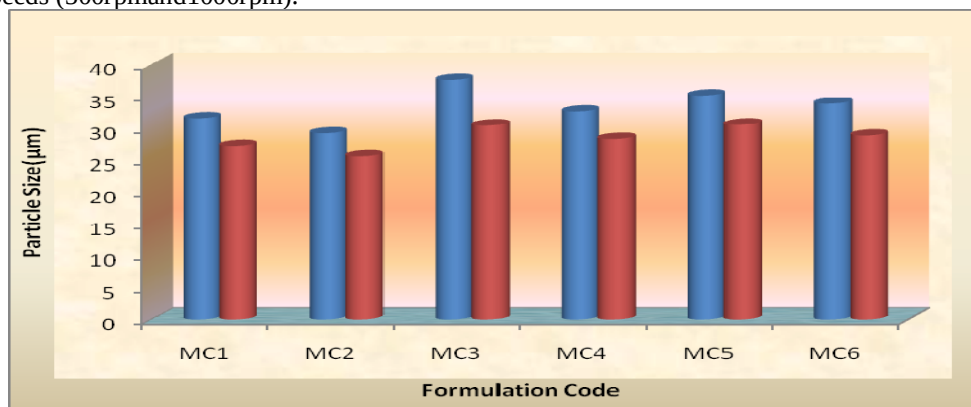
Figure 3: Effect of stirring speed on particle size of Rosiglitazone maleate microspheres of batches of MS1, MS2, MS3, MS4, MS5 and MS6

Table: 4. Effect of stirring speed on particle size of Empagliflozin microspheres of batches of MS1, MS2, MS3, MS4, MS5 and MS6

Formulation code	Particle size(μm) at 500rpm	Particle size(μm) at 1000rpm
MS1	30.41 $\pm$ 2.66	25.31 $\pm$ 1.22
MS2	28.13 $\pm$ 1.41	24.14 $\pm$ 1.33
MS3	36.22 $\pm$ 1.91	28.15 $\pm$ 1.26
MS4	31.44 $\pm$ 2.16	25.33 $\pm$ 1.28
MS5	34.05 $\pm$ 2.16	27.26 $\pm$ 2.21
MS6	32.17 $\pm$ 3.24	26.35 $\pm$ 1.33

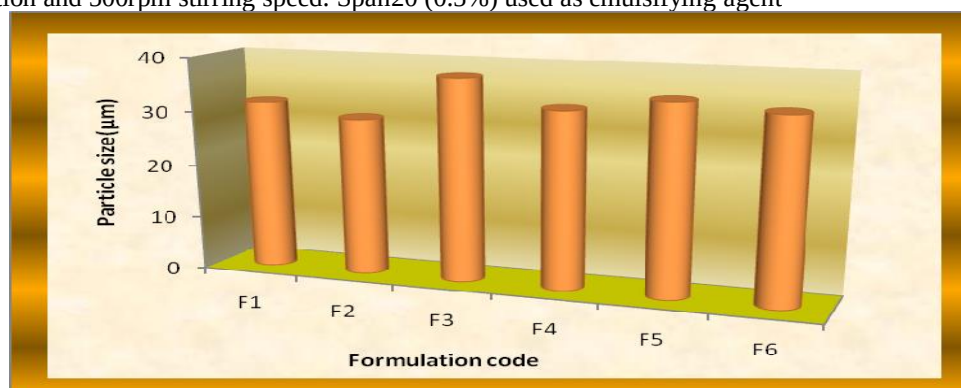
Values are represented as mean $\pm$ standard deviation (n=3).

All batches will be prepared at 2% polymer concentration and every batch will be prepared at two different stirring speeds (500rpm and 1000rpm).

**Figure 4: Effect of polymer concentration (2%,1%) on particle size of Rosiglitazone maleate microspheres batches of MC1, MC2, MC3, MC4, MC5 and MC6****Table 5: Particle size of Rosiglitazone maleate microsphere of formulations F1, F2, F3, F4, F5 and F6.**

Formulation code	Particle size(μm)
F1	31.54 $\pm$ 2.43
F2	29.20 $\pm$ 1.88
F3	37.54 $\pm$ 3.24
F4	32.62 $\pm$ 2.78
F5	35.12 $\pm$ 2.84
F6	33.85 $\pm$ 3.15

Values are represented as mean $\pm$ standard deviation (n=3). All formulation will be prepared at 2% polymer concentration and 500rpm stirring speed. Span20 (0.5%) used as emulsifying agent

**Figure 5: Particle size of Rosiglitazone maleate microsphere of formulations F1, F2, F3, F4, F5 and F6.****Table 6: Particle size of Empagliflozin microsphere of formulations F1, F2, F3, F4, F5 and F6.**

Formulation code	Particle size(μm)
F1	30.01 $\pm$ 2.19
F2	28.14 $\pm$ 1.45
F3	36.19 $\pm$ 3.15
F4	30.55 $\pm$ 2.41
F5	33.18 $\pm$ 2.51
F6	32.16 $\pm$ 3.04

Values are represented as mean $\pm$ standard deviation (n=3). All formulation will be prepared at 2% polymer concentration and 500rpm stirring speed. Span20 (0.5%) used as emulsifying agent

Table 7: Comparative cumulative % drug release from microsphere of Rosiglitazone maleate formulation F1,F2,F3,F4,F5andF6

Time(hrs)	F1	F2	F3	F4	F5	F6
1	10.22 $\pm$ 0.95	07.11 $\pm$ 1.23	05.22 $\pm$ 1.90	08.44 $\pm$ 1.23	06.22 $\pm$ 0.90	07.22 $\pm$ 0.94
2	24.33 $\pm$ 1.40	22.33 $\pm$ 2.32	10.33 $\pm$ 2.44	16.10 $\pm$ 1.35	12.21 $\pm$ 1.10	14.55 $\pm$ 1.42
3	36.43 $\pm$ 1.50	31.22 $\pm$ 1.95	17.43 $\pm$ 1.22	27.22 $\pm$ 1.56	20.33 $\pm$ 1.22	24.42 $\pm$ 1.56
4	48.45 $\pm$ 1.45	38.22 $\pm$ 2.21	22.11 $\pm$ 2.10	33.22 $\pm$ 2.11	30.44 $\pm$ 1.3	32.22 $\pm$ 1.65
5	58.22 $\pm$ 1.90	49.00 $\pm$ 2.45	2.00 $\pm$ 2.34	42.22 $\pm$ 2.94	38.44 $\pm$ 1.33	40.11 $\pm$ 1.39
6	67.55 $\pm$ 1.98	56.21 $\pm$ 2.34	36.12 $\pm$ 3.45	51.44 $\pm$ 2.55	44.55 $\pm$ 1.87	48.43 $\pm$ 2.26
7	72.12 $\pm$ 2.43	64.22 $\pm$ 2.45	40.11 $\pm$ 2.67	66.00 $\pm$ 3.94	52.22 $\pm$ 1.94	58.08 $\pm$ 2.89
8	80.32 $\pm$ 3.20	70.22 $\pm$ 3.18	46.75 $\pm$ 2.95	73.22 $\pm$ 2.45	58.56 $\pm$ 2.22	65.78 $\pm$ 3.24
9	86.32 $\pm$ 2.80	76.05 $\pm$ 2.38	50.24 $\pm$ 2.33	79.90 $\pm$ 3.19	62.09 $\pm$ 2.34	72.45 $\pm$ 3.33
10	91.45 $\pm$ 2.55	83.43 $\pm$ 2.55	56.23 $\pm$ 2.10	84.22 $\pm$ 3.33	67.54 $\pm$ 3.44	78.76 $\pm$ 2.33
11	95.10 $\pm$ 2.10	90.32 $\pm$ 1.85	61.44 $\pm$ 2.80	90.22 $\pm$ 3.65	72.45 $\pm$ 3.21	84.55 $\pm$ 2.12
12	98.55 $\pm$ 1.15	95.65 $\pm$ 1.70	64.32 $\pm$ 2.35	93.43 $\pm$ 2.10	76.33 $\pm$ 3.90	92.33 $\pm$ 1.95

Values are represented as mean $\pm$ standard deviation (n=3). .

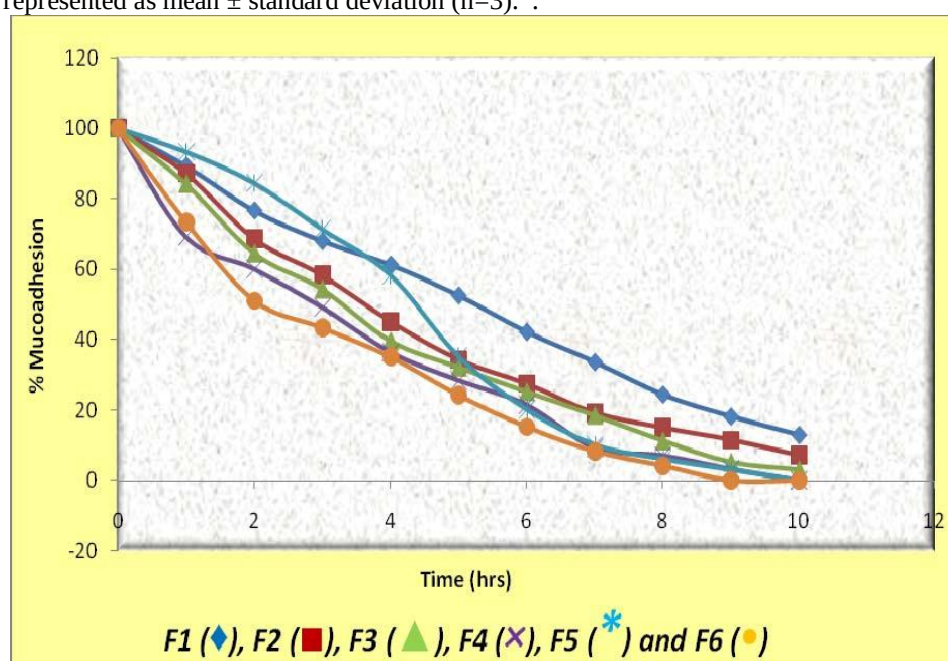


Figure 6 : Comparative % mucoadhesion of microspheres of rosiglitazone maleate formulations F1,F2,F3,F4,F5andF6

Table 8: Comparative % mucoadhesion of microspheres of Empagliflozin formulations F1, F2, F3, F4,F5 and F6

Time(hrs)	F1	F2	F3	F4	F5	F6
1	88.21 $\pm$ 2.18	86.21 $\pm$ 2.22	83.18 $\pm$ 2.63	68.21 $\pm$ 1.94	92.33 $\pm$ 2.15	72.44 $\pm$ 2.02
2	75.66 $\pm$ 2.14	67.66 $\pm$ 2.93	63.54 $\pm$ 3.82	62.08 $\pm$ 1.23	83.44 $\pm$ 3.34	50.09 $\pm$ 3.13
3	69.00 $\pm$ 1.18	57.33 $\pm$ 1.73	52.34 $\pm$ 1.09	48.18 $\pm$ 1.60	70.33 $\pm$ 2.51	42.33 $\pm$ 2.60
4	60.33 $\pm$ 1.68	44.22 $\pm$ 3.12	38.65 $\pm$ 1.69	34.43 $\pm$ 1.58	56.37 $\pm$ 2.53	34.08 $\pm$ 2.28
5	51.64 $\pm$ 1.70	33.43 $\pm$ 1.58	32.35 $\pm$ 2.12	27.43 $\pm$ 1.75	33.24 $\pm$ 2.16	23.20 $\pm$ 2.73
6	41.31 $\pm$ 1.75	25.54 $\pm$ 1.89	24.17 $\pm$ 1.68	23.52 $\pm$ 1.37	21.22 $\pm$ 1.85	13.22 $\pm$ 2.42
7	32.76 $\pm$ 1.50	17.32 $\pm$ 1.47	17.50 $\pm$ 1.25	08.26 $\pm$ 1.26	10.15 $\pm$ 1.31	08.31 $\pm$ 1.63
8	23.52 $\pm$ 1.53	15.14 $\pm$ 1.41	10.32 $\pm$ 1.51	05.08 $\pm$ 1.35	06.08 $\pm$ 0.15	04.11 $\pm$ 1.10
9	17.34 $\pm$ 1.15	10.65 $\pm$ 1.08	05.24 $\pm$ 1.10	03.01 $\pm$ 0.80	03.43 $\pm$ 0.90	00.00 $\pm$ 0.00
10	12.12 $\pm$ 1.15	07.29 $\pm$ 1.25	03.05 $\pm$ 0.74	00.00 $\pm$ 0.00	00.00 $\pm$ 0.00	00.00 $\pm$ 0.00

Values are represented as mean $\pm$ standard deviation (n=3).

Table 9: Comparative % mucoadhesion, drug entrapment, particle size and % yield of microspheres of Rosiglitazone maleate formulations F1, F2, F3, F4, F5 and F6.

Formulation code	%Mucoadhesion after 1hrs	%Drug entrapment	Particle size (μm)	%yield
F1	89.33 $\pm$ 2.33	68 $\pm$ 2.45	31.54 $\pm$ 2.43	78.45 $\pm$ 3.20
F2	87.22 $\pm$ 2.43	80 $\pm$ 3.23	29.20 $\pm$ 1.88	74.56 $\pm$ 2.80
F3	84.23 $\pm$ 2.83	56 $\pm$ 2.86	37.54 $\pm$ 3.24	81.10 $\pm$ 2.95
F4	69.20 $\pm$ 1.90	78 $\pm$ 2.75	32.62 $\pm$ 2.78	79.52 $\pm$ 2.84
F5	93.33 $\pm$ 2.95	62 $\pm$ 2.84	35.12 $\pm$ 2.84	76.12 $\pm$ 3.10
F6	73.44 $\pm$ 2.32	53 $\pm$ 3.68	33.85 $\pm$ 3.15	77.44 $\pm$ 2.60

Values are represented as mean $\pm$ standard deviation (n=3).

**Figure 7 : Comparative % mucoadhesion, drug entrapment and % yield of microspheres of Rosiglitazone maleate formulations F1, F2, F3, F4, F5 and F6 (■ % mucoadhesion, ■ % drug entrapment, ■ % yield)****Table 10: Comparative % mucoadhesion, drug entrapment, particle size and % yield of microspheres of formulations F1, F2, F3, F4, F5 and F6.**

Formulation code	%Mucoadhesion after 1hrs	% Drug entrapment	Particle size (μm)	%yield
F1	86.23 $\pm$ 1.33	68 $\pm$ 2.45	29.54 $\pm$ 2.41	75.45 $\pm$ 3.21
F2	86.22 $\pm$ 1.41	82.1 $\pm$ 3.23	28.21 $\pm$ 1.84	72.56 $\pm$ 2.73
F3	81.21 $\pm$ 3.13	53 $\pm$ 2.26	34.54 $\pm$ 1.14	78.10 $\pm$ 1.85
F4	67.20 $\pm$ 1.70	76 $\pm$ 2.25	32.63 $\pm$ 1.38	75.51 $\pm$ 1.14
F5	90.31 $\pm$ 2.45	62 $\pm$ 2.15	31.12 $\pm$ 1.54	73.12 $\pm$ 2.14
F6	70.42 $\pm$ 1.12	50 $\pm$ 3.61	31.85 $\pm$ 2.19	71.44 $\pm$ 1.40

Values are represented as mean $\pm$ standard deviation (n=3). All formulation will be prepared at 2% polymer concentration and 500 rpm stirring speed

Table 11: Comparative cumulative % drug release from microspheres of Rosiglitazone maleate formulations F1, F2, F3, F4, F5 and F6

Time (hrs)	F1	F2	F3	F4	F5	F6
1	10.22 $\pm$ 0.95	07.11 $\pm$ 1.23	05.22 $\pm$ 1.90	08.44 $\pm$ 1.23	06.22 $\pm$ 0.90	07.22 $\pm$ 0.94
2	24.33 $\pm$ 1.40	22.33 $\pm$ 2.32	10.33 $\pm$ 2.44	16.10 $\pm$ 1.35	12.21 $\pm$ 1.10	14.55 $\pm$ 1.42
3	36.43 $\pm$ 1.50	31.22 $\pm$ 1.95	17.43 $\pm$ 1.22	27.22 $\pm$ 1.56	20.33 $\pm$ 1.22	24.42 $\pm$ 1.56
4	48.45 $\pm$ 1.45	38.22 $\pm$ 2.21	22.11 $\pm$ 2.10	33.22 $\pm$ 2.11	30.44 $\pm$ 1.3	32.22 $\pm$ 1.65
5	58.22 $\pm$ 1.90	49.00 $\pm$ 2.45	2.00 $\pm$ 2.34	42.22 $\pm$ 2.94	38.44 $\pm$ 1.33	40.11 $\pm$ 1.39
6	67.55 $\pm$ 1.98	56.21 $\pm$ 2.34	36.12 $\pm$ 3.45	51.44 $\pm$ 2.55	44.55 $\pm$ 1.87	48.43 $\pm$ 2.26
7	72.12 $\pm$ 2.43	64.22 $\pm$ 2.45	40.11 $\pm$ 2.67	66.00 $\pm$ 3.94	52.22 $\pm$ 1.94	58.08 $\pm$ 2.89
8	80.32 $\pm$ 3.20	70.22 $\pm$ 3.18	46.75 $\pm$ 2.95	73.22 $\pm$ 2.45	58.56 $\pm$ 2.22	65.78 $\pm$ 3.24
9	86.32 $\pm$ 2.80	76.05 $\pm$ 2.38	50.24 $\pm$ 2.33	79.90 $\pm$ 3.19	62.09 $\pm$ 2.34	72.45 $\pm$ 3.33
10	91.45 $\pm$ 2.55	83.43 $\pm$ 2.55	56.23 $\pm$ 2.10	84.22 $\pm$ 3.33	67.54 $\pm$ 3.44	78.76 $\pm$ 2.33
11	95.10 $\pm$ 2.10	90.32 $\pm$ 1.85	61.44 $\pm$ 2.80	90.22 $\pm$ 3.65	72.45 $\pm$ 3.21	84.55 $\pm$ 2.12
12	98.55 $\pm$ 1.15	95.65 $\pm$ 1.70	64.32 $\pm$ 2.35	93.43 $\pm$ 2.10	76.33 $\pm$ 3.90	92.33 $\pm$ 1.95

Values are represented as mean $\pm$ standard deviation (n=3).

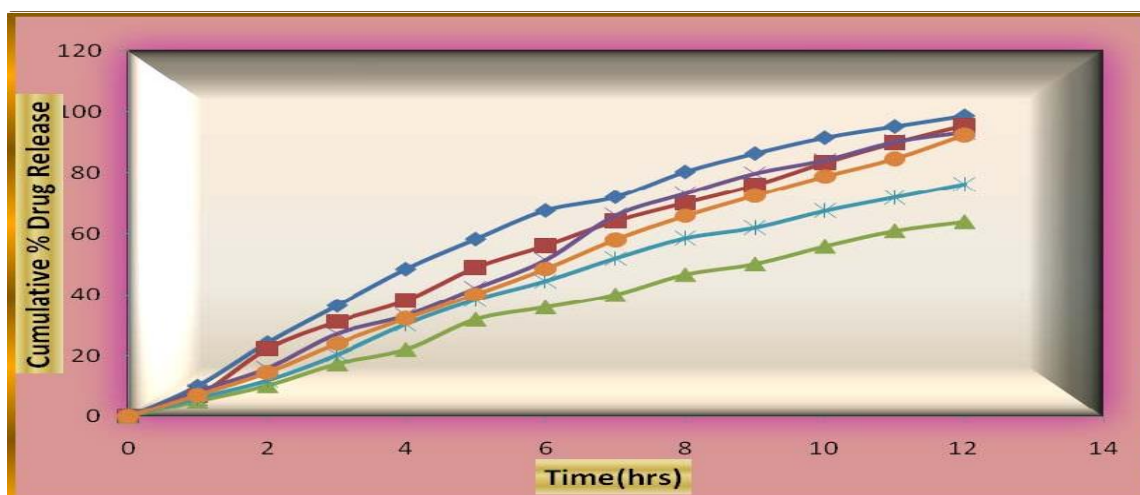


Figure 8: Comparative cumulative % drug releases from microspheres of Rosiglitazone maleate formulations F1(♦), F2(■), F3(▲), F4(×), F5 (*) and F6(●)

Table 12: Comparative cumulative % drug release from microsphere of Empagliflozin formulations F1, F2, F3, F4, F5 and F6

Time(hrs)	F1	F2	F3	F4	F5	F6
1	10.21±0.91	07.13±1.23	05.24±1.90	08.41±1.23	06.32±0.91	07.21±0.91
2	22.33±1.41	21.33±1.31	11.31±1.42	15.10±1.15	11.22±1.13	12.51±1.41
3	32.41±1.51	30.22±1.65	17.13±1.12	25.22±1.36	21.33±1.32	23.42±1.26
4	47.45±1.35	35.22±1.21	20.11±1.10	32.22±1.11	31.44±1.3	31.22±1.35
5	56.22±1.40	48.00±2.45	31.00±2.34	41.22±2.94	38.43±1.33	41.11±1.39
6	66.55±1.98	56.21±2.14	36.12±3.45	51.45±2.55	43.55±1.87	49.43±2.26
7	73.12±2.43	65.22±2.45	41.11±2.67	68.00±3.94	53.22±1.91	58.09±2.89
8	81.32±3.20	72.22±3.13	44.75±2.15	71.22±2.43	58.53±2.12	65.79±3.24
9	84.32±2.81	74.05±2.68	50.21±2.33	79.90±3.18	62.09±2.35	72.45±3.33
10	92.45±2.55	83.45±2.55	56.26±2.10	84.22±3.53	67.56±3.44	78.79±2.33
11	95.14±2.10	90.32±1.65	61.44±2.80	90.25±3.65	72.46±3.21	84.55±2.32
12	98.56±1.15	95.65±1.80	64.32±2.35	93.41±2.10	76.34±3.90	92.35±1.95

Values are represented as mean ± standard deviation (n=3).

4. CONCLUSION:

Rosiglitazone maleate and Empagliflozin are oral antidiabetic drugs that are been widely used in management of diabetes type-2. Being an antidiabetic drugs, they are safe and efficacious candidate for treating diabetes type-2. To achieve optimum therapeutic drug level over extended period of time, a controlled release system in the form of mucoadhesive microspheres are developed using widely accepted and physiologically safe excipient and using simple techniques and reproducible methodologies.

Mucoadhesive microspheres of Rosiglitazone maleate and Empagliflozin are designed to increase its residence time in stomach by interacting with mucus membrane. Mucoadhesive microspheres of Rosiglitazone maleate and Empagliflozin are prepared by using various ratios of carbopol-934, sodium carboxymethyl cellulose and sodium alginate by emulsification solvent evaporation techniques. Various preformulation studies are done to confirm the purity, pharmacopoeial standards and for physicochemical characterisation of the drugs. Six formulations for each drug are prepared using different ratios of carbopol-934, sodium

carboxymethyl cellulose and sodium alginate. These formulations are assigned for reproducibility with respect to % yield, particle size, % drug entrapment, % mucoadhesion and % drug release of microspheres.

The mean particle size of microspheres are influenced by stirring speed and concentration of polymeric solution. The % mucoadhesion, % drug entrapment and percent drug release of microspheres are influenced by type of polymer used for the preparation of microspheres.

Among the mucoadhesive microspheres of Rosiglitazone maleate and empagliflozin prepared using sodium carboxy methyl cellulose, carbopol-934 and sodium alginate polymers, the formulation F1 containing sodium carboxymethyl cellulose showed reproducible results and the best mucoadhesive profile with good surface morphology. Among all the formulations of microspheres, formulation F1 containing sodium carboxymethyl cellulose showed best results, demonstrated the best sustained release efficacy out of all the microsphere formulations. The polymer Sodium carboxymethyl cellulose proved to be the most promising carrier for the controlled delivery of these antidiabetic agents.

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