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Formulation and Evaluation of an Orodispersible Tablet of Empagliflozin Using a Natural Super-Disintegrating Agent

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Abstract**—***Orodispersible Tablets (ODTs) are pharmacological formulations that are utilised to produce rapid therapeutic effects due to their improved compliance, bioavailability, ease of administration, and superior palatability. ODTs are highly preferable for administration in both paediatric and geriatric patients. The goal of this study was to combine natural disintegrants with the antihyperglycemic drug Empagliflozin to develop ODTs. The purpose of this research project was to use direct compression and a natural super-disintegrating agent to create an orodispersible tablet containing Empagliflozin. Isabgol, Crospovidone, and Sodium Starch Glycolate were the natural disintegrants that were utilised. Using 8 mm flat round punches, the Empagliflozin powder mixture was compacted into 200 mg weight tablets. Evaluation parameters for preformulation and postformulation, including bulk density, tapping density, hardness, weight variation, friability, and disintegration studies, were carried out. The study found that the targeted qualities of the orodispersible Empagliflozin tablets, including their immediate start of action, quick disintegration, enhanced patient compliance, and convenience, had been successfully formulated and tested*.

Keywords**—** *Orodisperible, Empagliflozin, Disintegrants, Preformulation*.

I. INTRODUCTION

ODT was defined by the US FDA as a solid dosage form that contains medication and that, when placed on the tongue, dissolves quickly-typically in a matter of seconds[10].

Because of the super-disintegrant incorporated into the formulation, oral disintegrating tablets quickly dissolve in the mouth in less than a minute without the need for water or chewing, in contrast to typical oral solid instant release dosage forms and other drug delivery systems[6]. Drug delivery systems for the delivery of orodispersible medications are widely used to improve the bioavailability of the medications and boost patient compliance. It is ideal to utilise a super-disintegrant that, even at low concentrations, can efficiently dissolve a tablet. Sodium Starch Glycolate and Crospovidone are the super-disintegrants that are most frequently utilised.

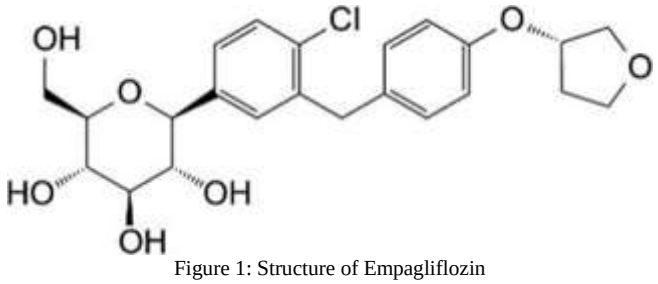

Figure 1: Structure of Empagliflozin

The IUPAC name of Empagliflozin is (2S,3R,4R,5S,6R)-2-[4-chloro-3-[[4-[(3S)-oxolan-3-yl]oxyphenyl]methyl]phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol. The molecular formula is $C_{23}H_{27}ClO_7$, and the molecular weight is 450.91 g/mol. The medication was described as a non-hygroscopic, white to yellowish powder. Empagliflozin was almost insoluble in toluene, soluble in water 1:1 in acetonitrile, sparingly soluble in ethanol and acetonitrile, and soluble in water and methanol.

Empagliflozin, marketed under the trade name Jardiance, is an oral medication that is a strong, highly selective sodium glucose co-transporter 2 (SGLT2) inhibitor. It is an antihyperglycemic that is generally well tolerated and effective for treating individuals with type 2 diabetes. The Food and Drug Administration authorised Empagliflozin in August 2014. When used in conjunction with other anti-diabetic drugs like Metformin and Sulfonylurea, Empagliflozin has few adverse effects. It is not advised to use in patients who are nursing or pregnant. It is not recommended for people with severe kidney disease, even if it might help postpone the progression of mild renal problems[1].

SGLT2, or sodium glucose linked co-transporter 2, is primarily in charge of the proximal tubule's reabsorption of the great majority of glucose filtered by the glomerulus, accounting for 90% of the kidney's glucose reabsorption. In order to create a Na^+ ion inside the tubular cell, Na^+/K^{+-} ATPase on the basolateral membrane of proximal tubular cells actively pumps Na^+ ions into the interstitium surrounding the tubule using ATP. The apical membrane of these cells contains SGLT2, which uses this gradient to promote secondary active co-transport of glucose and Na^+ out of the filtrate. By blocking this co-transport and reabsorbing glucose into the blood, SGLT2 is able to significantly reduce blood glucose levels and increase glucosuria. By increasing glucosuria, Empagliflozin, a strong inhibitor of renal SGLT2 transporters found in the kidney's proximal tubules, lowers blood sugar levels[2].

The goal of this research project is to create and assess many batches of orodispersible Empagliflozin tablets in varying doses using distinct natural disintegrants.

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II. Materials and Methods

Empagliflozin was procured as a gift sample from Zydus Pharmaceutical Technological Centre, Thane. Microcrystalline Cellulose, Potassium Dihydrogen Orthophosphate, and Methanol from SRL Chemicals; Crospovidone from ACS Chemicals; Sodium Starch Glycolate and Magnesium Stearate from Himedia; Isabgol Husk Powder procured from local market; and Talc from Spectrum Chemicals. Ultra-purified water was obtained from the Milli-Q® system (Millipore, Milford, MA, USA) water purification unit.

A. Preparation of Standard Solution for Calibration Curve

Empagliflozin 50 mg was precisely weighed and then added to a 50 ml volumetric flask. After adding 5 ml methanol and shaking, make up the volume to 50 ml with phosphate buffer pH 6.8. To get a final solution of 100 µg/ml, take 10 ml of the aforementioned solution, transfer it to a 100 ml volumetric flask, and make up the volume with phosphate buffer pH 6.8. From the aforementioned stock solution, pipette out 0.5 ml, 1 ml, 1.5 ml, 2 ml, 2.5 ml, and 3 ml. Then use phosphate buffer pH 6.8 to bring the volume to 10 mL to obtain a medicinal solution containing 5, 10, 15, 20, 25 and 30 µg/mL empagliflozin.

B. Precompression Parameters

Angle of Repose (θ)

The angle of repose is used to assess interparticle forces, or forces between particles, as well as the powder properties. The maximum angle that can occur between a pile of grains or powder's surface and the horizontal plane is called the angle of repose.

$\tan \theta$ = height/radius

θ = the angle of repose

TABLE 1: Angle of Repose I.P. Limits

Sr. No.	Angle of Repose	Flow of Powder
1.	< 25	Excellent
2.	25-30	Good
3.	30-40	Passable
4.	> 40	Very Poor

Bulk Density

Bulk density is the mass-to-bulk volume ratio of a powder. The key elements affecting powder's bulk density are its particle shape, particle size distribution, and adhesion tendency. The consistency of bulk powdered components is checked using bulk density, which is then used to determine the size of the empty gelatin capsules, production equipment, packing materials, and containers.

$$\text{LBD (Loose Bulk Density)} = \frac{\text{Weight of the Powder (g)}}{\text{Volume of Packing}}$$

Tapped Density

It is calculated by dividing the mass of the powder (including pores and smaller intra-particle pores) by its volume. A helium densitometer is used to measure this. The measuring cylinder containing a known amount of mix was tapped for a preset period of time. Both the blend's weight and the cylinder's minimum volume were measured.

$$\text{TBD (Tapped Bulk Density)} = \frac{\text{Weight of the Powder (g)}}{\text{Tapped Volume of Packing}}$$

Hausner's Ratio

Hausner's ratio is a measure of powder flow easiness that is not direct. Better flow characteristics are indicated by a lower Hausner's ratio.

Hausner's ratio = Tapped Density/Bulk Density

TABLE 2: Hausner's Ratio I.P. Limits

Sr. No.	Hausner's Ratio	I.P. Limit
1.	Excellent	1.00-1.11
2.	Good	1.1-1.18
3.	Fair	1.19-1.25
4.	Passable	1.26-1.34
5.	Very Poor	1.35-1.45
6.	Very, Very Poor	> 1.60

Carr's Index

It is critical to keep tablet weight constant. A graduated cylinder that has been tared is gently filled with the roughly weighed powder. The powder's initial weight and volume were noted. After 25 taps, the final volume is noted of the graduated cylinder that is set on a tap density tester.

$$\text{Carr's Index \%} = \frac{\text{Tapped Density - Bulk Density x 100}}{\text{Tapped Density}}$$

TABLE 3: Carr's Index I.P. Limits

Sr. No.	Carr's Index	I.P. Limits
1.	Excellent	> 10
2.	Good	11-15
3.	Fair	16-20
4.	Passable	21-25
5.	Poor	26-31
6.	Very Poor	32-37
7.	Very, Very Poor	> 38

C. Formulation Development

Empagliflozin orodispersible tablets were manufactured by a direct compression method. Several natural disintegrating agents are used in the preparation of these orodispersible tablets containing Empagliflozin. The following table's formula was used to determine the addition of these naturally occurring super-disintegrants. The bulk components, excipients, and APIs were precisely weighed in accordance with the formulation formula. Gradually, all the components were combined, triturated using a mortar and pestle, and then run through a #60 sieve mesh. The powder was compressed using a direct compression process in 200 mg tablets using a rotary tablet punching machine equipped with B tooling, matching die, and 8 mm flat round punches.

D. Evaluation of Tablets

Thickness

All formulations of instant release tablets had mean thicknesses that were nearly identical, falling between 2.85 mm and 3.40 mm. Using a Vernier calliper, the thickness of the Empagliflozin tablets was determined.

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TABLE 4: Composition of Empagliflozin Orodispersible Tablets with Different Super Disintegrants

Sr. No.	Excipients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
1.	Empagliflozin	10	10	10	10	10	10	10	10	10
2.	Sodium Starch Glycolate	8	10	12	-	-	-	-	-	-
3.	Isabgol	-	-	-	8	10	12	-	-	-
4.	Crospovidone	-	-	-	-	-	-	8	10	12
5.	Microcrystalline Cellulose	178	176	174	178	176	174	178	176	174
6.	Magnesium Stearate	2	2	2	2	2	2	2	2	2
7.	Talc	2	2	2	2	2	2	2	2	2

Hardness

The degree of hardness of a tablet indicates how effectively it can withstand associated mechanical stresses. Tablet hardness was determined using a Monsanto hardness tester. The unit of measurement is kg.

Friability

The Roche friabilator was used to assess the friability of tablets. Percentages are used to express it. Ten tablets were weighed and put in a friabilator at first. For four minutes, the friabilator was operated at 25 rpm, or up to 100 revolutions. The tablets were weighed again. The friability percentage was then calculated using the following formula.

$$F = \frac{(W_{initial} - W_{final}) \times 100}{W_{initial}}$$

Friability of tablets less than 1% is considered acceptable.

Weight Variation

As per the USP weight variation test, ten tablets are needed for weight variation. Calculate the average weight and compare the weight of each tablet with the average weight. It was also determined what the standard deviation was from the mean weight.

TABLE 5: Maximum percent weight deviations I.P. Limit

Sr. No.	Average Weight of Tablets (mg)	Maximum% Difference Allowed
1.	130 or less	±10
2.	130-324	±7.5
3.	More than 324	±5

In vitro Disintegration Test

Demolition is the process of breaking a tablet into smaller pieces. Using the Disintegration Test Apparatus, the in vitro disintegration time of a tablet was measured in accordance with I.P. requirements. Fill each of the six tubes in the basket with one tablet. Put a disc in each tube and operate the device with an immersion liquid of pH 6.8 phosphate buffer kept at 37 ± 2°C. The assembly has to be raised and lowered in the pH 6.8 phosphate buffer at 37 ± 2°C for 30 cycles per minute. The amount of time, measured in seconds, needed for the tablet to entirely disintegrate and disappear from the instrument was calculated and noted.

III. Result and Discussion

Melting Point Determination

To find out how pure a drug is, its melting point is measured. The capillary method was used to find the drug Empagliflozin's melting point. Using this procedure, a capillary that was closed on one side and filled with the powdered drug was put inside the melting point device. The drug's melting point was observed, and it was determined to be between 151-153°C, which is comparable to the typical melting point of Empagliflozin.

UV Spectrophotometer

Phosphate buffer pH 6.8 was used to create solutions of Empagliflozin (5, 10, 15, 20, 25, 30 µg/ml), and a UV-visible spectrophotometer was used to measure absorbance at 223 nm. Plotting absorbance against concentration (µg/ml) yielded the calibration graph. The absorbance measured at various concentrations was recorded and graphed on an Empagliflozin calibration curve in phosphate buffer with a pH of 6.8. It was found that the drug responded linearly throughout the examined concentration range. The linear regression equation was $y = 0.041x + 0.0025$ with a correlation coefficient (R^2) of 0.9999, and the determined range was 5-30 µg/ml.

TABLE 6: Absorbance of Empagliflozin Solutions

Concentration (µg/ml)	Absorbance
5	**0.205**
10	**0.413**
15	**0.617**
20	**0.828**
25	**1.025**
30	**1.23**

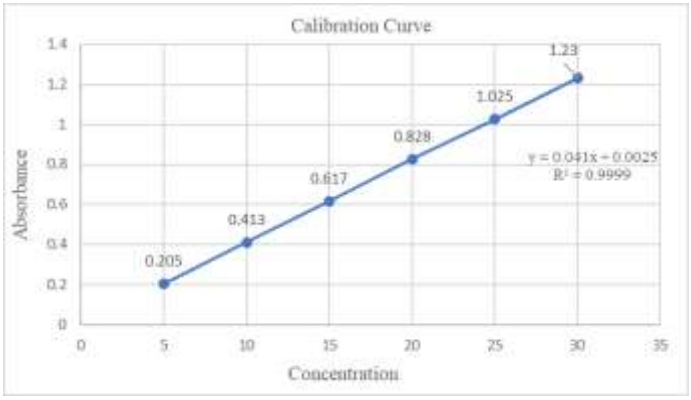

Figure 2: Calibration Curve of Empagliflozin

Angle of Repose

TABLE 7: Result of Angle of Repose

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Angle of Repose	35.62	39.25	37.80	29.56	28.86	27.00	32.40	34.21	30.58

Nine formulations were created during the early stages of research utilising various super-disintegrant concentrations (such as Crospovidone, Isabgol, and Sodium Starch

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Glycolate). The angle of repose demonstrated the powder's flowability. The powder's good to exceptional flow characteristics are indicated by an angle of repose less than 30°. The values discovered for the angle of repose of each formulation are tabulated in the above table. The formulation including Sodium Starch Glycolate (i.e., F1, F2, and F3 with concentrations of 8%, 10%, and 12%, respectively) exhibits acceptable flow characteristics, as indicated by the above result, since the angle of repose values range from 30° to 40°. The angle of repose values of Isabgol formulations F4, F5, and F6, which are 8%, 10%, and 12%, respectively, range from 25° to 30°, which are regarded as having good flow qualities by I.P. limits. According to I.P. limitations, the formulations F7, F8, and F9 that contain Crospovidone as a super-disintegrant exhibit acceptable flow qualities with angle of repose values between 30° and 40°, respectively.

Bulk Density and Tapped Density

TABLE 8: Results of Bulk Density and Tapped Density

Sr. No.		F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Bulk Density (gm/cm^3)	0.38	0.37	0.38	0.42	0.4	0.4	0.38	0.38	0.39
2.	Tapped Density (gm/cm^3)	0.5	0.47	0.49	0.47	0.46	0.47	0.47	0.47	0.47

The bulk density of tablets that were created with different super-disintegrating agents ranged from 0.37 to 0.42 g/cm^3. The USP standard limit is between 0.1 and 0.7 g/cm^3, and these values are within that range. The values of the tapped density vary from 0.46 to 0.5 g/cm^3. Sodium Starch Glycolate is a super-disintegrant found in F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. The bulk density and tapped density values, which range from 0.37 to 0.42 g/cm^3 and tap density from 0.46 to 0.5 g/cm^3, respectively, are within the specified limit as per USP, meaning that the powder blends possess the necessary flow properties for direct compression.

Hausner's Ratio

TABLE 9: Result of Hausner's Ratio

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Hausner's Ratio	1.32	1.27	1.29	1.12	1.15	1.18	1.24	1.24	1.21

Carr's compressibility index and Hausner's ratio were calculated using these density data. Sodium Starch Glycolate is a super-disintegrant found in formulations F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. As per the I.P. limitations, the powder flows well in formulations F4, F5, and F6 (1.12, 1.15, and 1.18), fairly in formulations F7, F8, and F9 (1.24, 1.24, and 1.21), and passably in formulations F1, F2, and F3 (1.32, 1.27, and 1.29), respectively.

Carr's Index

TABLE 10: Results of Carr's Index

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Carr's Index	24%	21%	22%	11%	13%	15%	19%	19%	17%

Sodium Starch Glycolate is a super-disintegrant found in formulations F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. As per the I.P. limitations, formulations F4, F5, and F6 exhibit good flow qualities with 11%, 13%, and 15%, fair flow of powder in formulations F7, F8, and F9 with 19%, 19%, and 17%, and acceptable flow with (24%, 21%, and 22%), respectively, for formulations F1, F2, and F3.

Thickness

TABLE 11: Result of Thickness

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Thickness (mm)	3.24	3.22	3.31	3.25	3.26	3.24	3.12	3.20	3.18

The mean thickness of the tablet was determined to be within the range of 3.12-3.31 mm and was nearly consistent across all formulations. An orally dispersible tablet should have a thickness between 2.85-3.40 mm. Sodium Starch Glycolate is a super-disintegrant found in F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. Out of the other two types of disintegrants, F4, F5, and F6 contain the most precise thickness (i.e., 3.25, 3.26, and 3.24). Based on the above result, we conclude that all of the other two types of disintegrants are within the range. Because all formulations are within the optimal range, all formulations made using Sodium Starch Glycolate, Isabgol, and Crospovidone can be used as orally dispersible tablets. We deduced that every tablet formed had the same diameter based on the preceding finding.

Hardness

TABLE 12: Result of Hardness

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Hardness (kg)	4	4	4	4	4	4	4	4	4

Sodium Starch Glycolate is a super-disintegrant found in F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. Tablet hardness was determined using a Monsanto hardness tester. The range of 4-6 kg is the recommended limit for tablet

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hardness. The foregoing result leads us to the conclusion that all of the tablet's hardness was within the 4 kg range, indicating that the instant release tablets have good strength.

Weight Variation

TABLE 13: Result of Weight Variation

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Weight variation (g)	0.173 ± 7.5%	0.175 ± 7.5%	0.186 ± 7.5%	0.174 ± 7.5%	0.176 ± 7.5%	0.178 ± 7.5%	0.185 ± 7.5%	0.185 ± 7.5%	0.186 ± 7.5%

Weight variation (% weight within the Pharmacopoeia limits of ± 7.5% of the average weight) was assessed for each formulation. Sodium Starch Glycolate is a super-disintegrant found in F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. Based on the I.P. limitations, we deduced that every formulation shows extremely little weight variation, falling between the Pharmacopoeia limits of ± 7.5%.

Friability

TABLE 14: Result of Friability

	F1	F2	F3	F4	F5	F6	F7	F8	F9
% Friability	0.57	0.57	0.26	0.96	0.32	0.64	0.90	0.75	0.80

Sodium Starch Glycolate is a super disintegrant found in F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. Based on the aforementioned findings, we may infer that all formulations had a percentage friability of less than 1%, which guaranteed the formed tablets mechanical stability.

In vitro Disintegration Time

TABLE 15: Result of In vitro Disintegration Time

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Disintegration Time (sec)	20	25	22	15	10	18	20	25	28

Sodium Starch Glycolate is a super-disintegrant found in F1, F2, and F3 at concentrations of 8%, 10%, and 12%, respectively. Isabgol is present in F4, F5, and F6 at quantities of 8%, 10%, and 12%, respectively, as a super-disintegrant. Crospovidone is a super-disintegrant found in F7, F8, and F9 at quantities of 8%, 10%, and 12%, respectively. In comparison to a formulation comprising Crospovidone and Sodium Starch Glycolate, one containing Isabgol dissolves faster. Isabgol tablets have a disintegration time of 15 seconds, 10 seconds and 18 seconds in that order. Fast dissolving tablets employ Isabgol, a natural super-disintegrant, to improve dissolution. It is less expensive than other chemical disintegrants and is readily available. The Isabgol containing formulation yielded satisfactory results.

IV. CONCLUSION

All precompression and postcompression parameters were assessed in the paper that was presented, Formulation and Evaluation of an Orodispersible Tablet of Empagliflozin Using a Natural Super-Disintegrating Agent, and the findings fell within the I.P. limits. Out of the three disintegrating agents, Isabgol, a natural super-disintegrant formulation, F4, F5, and F6 demonstrated superior outcomes in comparison to Sodium Starch Glycolate and Crospovidone, based on the author's observation and analysis. Every formulation of Empagliflozin disintegrated in less than 30 seconds. Throughout the research project, no interactions between drugs and excipients were noted. We can draw the following conclusions from the data, Isabgol has demonstrated good results in formulations F4, F5, and F6, and direct compression of Isabgol can improve bioavailability, patient compliance, rapid disintegration, and quick onset of action in Empagliflozin tablets. Isabgol is a cost-effective natural superdisintegrant that is readily available in local markets. Therefore, Isabgol can be directly compressed and utilised as a natural super-disintegrant during the routine development and assessment of Empagliflozin tablets.

Authors Contributions

Every author made an equal contribution to the planning, execution, analysis, and preparation of the research work manuscript.

Conflict of interests

There were no conflicts of interest related to this study.

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