Preparation Of Diosgenin-Encapsulated Microspheres By Spray Drying Technique

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Abstract
Diosgenin, a naturally occurring steroid sapogenin possessing diverse therapeutic properties, represents a bioactive compound of interest. However, its complete pharmaceutical utilization has been impeded by inherent challenges, primarily associated with poor aqueous solubility and stability. In the present investigation, we introduce an innovative methodology for fabricating diosgenin-encapsulated microspheres through the utilization of the spray drying technique. The spray drying process involves the transformation of a solution containing diosgenin into finely dispersed microspheres through atomization, followed by rapid drying in a hot air stream. Various formulation parameters, encompassing the selection of encapsulating material, surfactants, and process conditions, were methodically optimized to attain elevated encapsulation efficiency and precise control over release characteristics. The microspheres thus prepared underwent assessment for percentage yield, encapsulation efficiency, particle size, and in vitro drug release. Results indicate the generation of uniform microspheres exhibiting heightened diosgenin encapsulation and enhanced physical stability. Additionally, in vitro release studies demonstrated sustained and controlled diosgenin release from the microspheres, underscoring their potential for protracted therapeutic effects. Encapsulation efficiency, release kinetics, and physicochemical attributes of the microspheres were found to be contingent upon the choice of encapsulating material and process parameters. In conclusion, the fabrication of diosgenin-encapsulated microspheres employing the spray drying technique represents a promising strategy to augment the bioavailability and therapeutic efficacy of diosgenin. These microspheres hold considerable promise for applications within the pharmaceutical and nutraceuticals industries serving as a platform for the advancement of innovative drug delivery systems.

Keywords: Diosgenin, Microspheres, Bioavailability, Spray drying

1. Introduction

Diosgenin, a steroidal sapogenin derived from various plant sources, has emerged as a compelling natural compound with diverse pharmacological properties, including anti-inflammatory, anticancer, and antioxidant effects. [1] Despite its therapeutic potential, the clinical translation of diosgenin faces challenges attributed to its poor aqueous solubility and limited bioavailability. [2] Overcoming these hurdles is imperative for harnessing the full therapeutic benefits of diosgenin.

Microsphere-based drug delivery systems, particularly those formulated through the versatile technique of spray drying, offer a promising solution to enhance diosgenin's solubility, stability, and controlled release. Spray drying facilitates the transformation of a liquid diosgenin-containing formulation into solid microspheres through atomization and drying in a controlled hot air stream.[3] This method enables the encapsulation of hydrophobic drugs, such as diosgenin, within a polymeric matrix, providing a platform to mitigate solubility challenges and tailor drug release profiles.

The current study is dedicated to the development and systematic evaluation of diosgenin-containing microspheres through the utilization of spray drying methodology. The central rationale driving the adoption of microspheres lies in their potential to not only surmount the solubility and bioavailability barriers but also to offer controlled and sustained release, thereby optimizing therapeutic efficacy. This research endeavors to integrate the nuanced pharmacological profile of diosgenin with the engineering intricacies of spray drying, ultimately aiming to formulate a drug delivery system with finely tuned release kinetics and enhanced therapeutic outcomes. The development of diosgenin-containing microspheres using spray drying holds promising prospects for future pharmaceutical applications. Successful formulation could lead to enhanced therapeutic efficacy through controlled and sustained drug release, potentially improving patient compliance. Future research should focus on optimizing formulation parameters, exploring combination therapies, integrating sustainable practices with biodegradable polymers, and advancing drug delivery technologies such as targeted delivery and nanotechnology. Bridging the gap between preclinical findings and clinical applications, conducting pharmacokinetic studies, and adhering to regulatory standards are crucial steps for clinical translation. Patient-centric approaches and alternative administration routes may further enhance the practicality and acceptance of diosgenin-containing microsphere formulations. Overall, this research represents a dynamic intersection of natural product pharmacology and innovative drug delivery, with the potential to reshape therapeutic strategies and contribute to the evolution of pharmaceutical science.

2. Material and methods:

Varieties of materials were employed, including the drug and several excipients and reagents. The chemicals, along with their respective chemical names and sources, are as follows: Diosgenin from Fisher Scientific, Methanol from Fisher Scientific, Ethanol from Fisher Scientific, Sodium chloride from Fisher Scientific, Chloroform from Sigma-Aldrich, Dichloromethane from Sigma-Aldrich, PVA solution from Sigma-Aldrich, and Sodium bicarbonate from Sigma-Aldrich. It is important to note that all chemicals, the drug, and reagents used in this study were of analytical grade.

2.1 Pre formulation study of Diosgenin [5-9]

2.1.1 Physical appearance

Sense organ examined the physical appearance of *Diosgenin*. Organoleptic characteristics including colour, odour, and taste were used to describe it physically.

2.1.2 Melting Point

Grind the Diosgenin sample into a fine powder to ensure uniformity. Fill a small melting point capillary tube with a small amount of the powdered Diosgenin. Tap it gently to pack the powder uniformly. Ensure that the melting point apparatus is clean and calibrated. Insert the filled capillary tube into the melting point apparatus.

2.1.3 Solubility

Accurately weigh a 100gm of Diosgenin. The exact amount will depend on specific experimental needs. Measure a known volume of the solvent you want to use. The volume should be sufficient to dissolve the Diosgenin sample but not so excessive that it dilutes the solution significantly. Add the weighed Diosgenin sample to a clean glass vial or test tube carefully pours the measured solvent over the Diosgenin sample. Depending on the solvent and the solubility of Diosgenin, you may need to gently stir or shake the mixture to facilitate dissolution. Use a stirring rod or a vortex mixer if needed. Monitor the mixture for a specific period, such as 15 minutes, 30 minutes, or an hour.

Calculate the solubility of Diosgenin in the solvent by dividing the mass of Diosgenin that was added (in grams) by the volume of solvent used (in milliliters). The result will give you the solubility in grams per milliliter (g/mL) or another appropriate unit.

2.1.4 Partition coefficient

A drug's capacity to penetrate a cell membrane and its lipophilicity are both determined by the partition coefficient. The ratio of unionised medicine that is evenly distributed across the organic and aqueous layers at equilibrium is what is meant by this term. You may find out a drug's partition coefficient by shaking it until equilibrium is reached with equal quantities of two immiscible solvents (the organic layer, which is saturated with water and the aqueous drug solution). The value is computed when the drug content in one of the layers has been established. A ratio unionised (Diosgenin) diffuse between an equilibrium organic and aqueous water system may be used to define the partition coefficient. The material will still be spread along (two) layers in a ratio of varied concentration if it is added to the immiscible (not miscible) solvents in an amount insufficient to submerge the solution. If C1 and C2 are in equilibrium, then C1/C2=K. Here, K is referred to as the partition coefficient or distribution ratio.

2.1.5 Loss on Drying

Loss on Drying is the weight loss, given as a percentage of weight, caused by the evaporation of water and other volatile substances under certain circumstances. A carefully prepared, well-mixed sample of the substance is used for these tests. Initial dose of the medication, Diosgenin, was put on a Petri disc and heated to 105°C in a hot air oven. After a while, the medication was removed from the hot air oven, and weight was collected. Formula was used to determine weight loss: -

Loss on Drying = [(Initial weight of material –final weight of material)/Initial weight of material] X 100

2.1.6 Determination of flow properties of pure drug [10-11]

Bulk density

The ratio between the mass of an untouched powder sample and its volume, including the contribution of the interparticulate void volume, is the bulk density of a powder. As a result, both the density of the powder particles and their spatial arrangement in the powder bed affect the bulk density. In gram per millilitre (g/mL), the bulk density is specified.

Bulk density= Mass of powder/volume of powder

2.1.7 Tapped density

The ratio between these two measured densities is used to determine a powder's "flowability. Following the determination of the bulk density, measuring cylinders were mechanically tapped on a holder in the tapped density tester, which produces a fixed drop at a nominal rate of 300 drops per minute (rate).
The volume (tapped) Vt was determined to the closest graded unit after tapping the measuring cylinder about 500 times at first.

Tapped volumes were computed after 100 additional taps were made. The following formula was used to determine the final tapped (volume) and measure the tapped densities: -
Tapped density = Mass of powder/Tapped volume

2.1.8 Compressibility index and Hausner ratio

The compressibility of a powder is usually determined using the Carr index in pharmaceutics. The bulk density and tapped density in a free-flowing powder would be near in value, resulting in a low Carr index.
The Hausner ratio, or simply p,/pb, or the tapped density divided by bulk density, is a more often used expression. Hausner first used this ratio in 1967 to describe metal particles, but medicinal powders now frequently utilize it as well. The flow is poorer the larger the Hausner ratio. For a free-flowing powder, the Hausner ratio is around 1.2; for a cohesive powder, it is 1.6. Many different sectors utilize the Hausner ratio as a measure of a powder's flowability. A Hausner ratio above 1.25 to 1.4 is seen as a sign of poor flowability. The Carr index (C), another sign of flowability, and the Hausner ratio (H) are connected.
The Carr's compressibility index (CI) and Hausner ratio (HR), which were computed using a formula, demonstrated the differentiation.
Carr's index = TD-BD/TD×100
Where,
TD=Tapped density
BD=Bulk density
Hausner ratio= TD/BD
Hausner ratio, <=1.25(good flow)

Table 1: Carr's index standard value

S. No.	Carr's index	Flow character
1.	5-15	Excellent
2.	12-16	Good
3.	18-21	Fair to passable
4.	23-35	Poor
5.	33-38	Very poor
6.	>40	Very very poor

2.1.9 Angle of repose

The angle of repose or repose angle of the material in question is described as being the base angle of the cone created. In the absence of any forces that might cause adhesion, the mutual friction between the particles in the conical pile determines the repose angle of a particular material. The flow attribute of a product may be found by using fairly straightforward procedures. Glass funnels were secured in place by a clamp on a ring that supported over a plate (Glass). The funnel's aperture was sealed with a thumb after adding around 50g of powder to it. The granules were released from the funnel when the thumb was pulled out. With the scale, the pile height (h) and base radius (r) were computed. The following formula was used to compute the angles of repose: -
Tan θ =h/r
θ = tan-1h/r
Where,
h= height of pile (cm)
r= radius of pile (cm)

Table 2: Standard value of angle of repose

Angle of repose(θ)	Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

3. Method of preparation of Microspheres

3.1 Preparation of Diosgenin microspheres by spray drying technique. [12-13]

The preparation of Diosgenin microspheres by spray drying involves the conversion of a Diosgenin-containing solution or suspension into solid microspheres through the process of atomization and drying. This method is used for various applications, such as controlled drug release and encapsulation. Dissolve Diosgenin and the polymer material in the chosen solvent. Stir the solution or suspension until all components are well-dispersed. Set up the spray drying equipment according to the manufacturer's instructions. This includes ensuring proper air inlet and outlet, nozzle or atomization device, and temperature control. Set the parameters on the spray dryer, including inlet and outlet air temperatures, feed rate, and atomization pressure. These parameters will depend on the specific system and equipment being used. The selection of these parameters is critical for the formation of microspheres. Start the spray drying process by activating the pump, which will deliver the Diosgenin-polymer solution to the atomization device.

Table 3: Optimization of Components of Loaded Microspheres Formulation

S.NO	Batch Code (MS)	Drug: Polymer	Pump Speed	Nozzle Size
1.	MS-1	1: 0.25	2	1.5 mm
2.	MS-2	1:0.5	2	1.5 mm
3.	MS-3	1:0.75	2	1.5 mm
4.	MS-4	1:1	2	1.5 mm
5.	MS-5	1: 0.25	4	1.5 mm
6.	MS-6	1:0.5	4	1.5 mm
7.	MS-7	1:0.75	4	1.5 mm
8.	MS-8	1:1	4	1.5 mm
9.	MS-9	2:0.25	2	1.5mm
10.	MS-10	2:0.5	2	1.5mm
11.	MS-11	2:0.75	2	1.5mm
12.	MS-12	2:1	2	1.5mm
13.	MS-13	1:1.25	4	1.5mm
14.	MS-14	1:1.5	4	1.5mm
15.	MS-15	1:1.75	4	1.5mm

4. Evaluation of microspheres

The prepared microspheres were evaluated for percentage yield, encapsulation efficiency, particle size, In vitro drug release & other parameters. [14-17]

4.1 Yield Percentage

Regarding the total amount of raw materials utilized for the formulation, the quantity of microspheres produced was calculated. The microspheres were weighed, and the formulations' % yield was determined using the formula below:

$$\text{Percentage of loading} = \frac{Amount\ of\ practical\ yield}{Theoratical\ yield} \times 100$$

4.2 Particle size, size distribution and zeta potential

The stability of therapeutic goods made possible by microspheres in complicated biological settings and the particle size distribution are crucial factors in determining the efficacy, safety, and quality of those products. Dynamic light scattering (DLS), while having a poor resolution, has been a staple of pharmaceutical technology with the advent of NEP.

Understanding the size range of the microspheres requires knowledge about their particle size distribution. The stability of colloidal dispersion is implied by the zeta potential, which is a measurement of the surface charges of microspheres. By using a dynamic light scattering approach, the average particle size, size distribution, and zeta potential of loaded microspheres were investigated. At a temperature of 25°C, a scattering angle of 90° was used for the analysis. Before observation, samples were diluted with Milli-Q water.

4.3 Encapsulation Efficiency

20 mg of microspheres were accurately weighed and crushed by using mortar and pestle. Crushed microspheres were suspended in 10 ml methanol and stirred for half an hour. Then the suspension was filtered through Whatman filter paper No. 44. Then 1 ml of this solution was diluted to 100 ml with distilled water and absorbance was measured against solvent as a blank. The drug content was determined from the standard curve. Encapsulation efficiency was calculated from following relationship.

$$\textbf{Encapsulation efficiency} = \frac{Estimated\ drug\ content}{Thoratical\ drug\ content} \times 100$$

4.4 Swelling index of microspheres

For estimating the swelling index, the microspheres were suspended in simulated gastric fluid (pH 1.2) Particle size was monitored by the microscopy technique using an optical microscope. The increase in particle size of microspheres was noted for every time interval and the swelling index was calculated using the following formula: **% Swelling = $W_T - W_0 / W_0$ X 100**

Where, W_T= weight of microspheres after swelling, W_0 = Initial weight of microspheres

4.5 In Vitro drug Release

Cumulative release of microspheres is evaluated in phosphate buffer pH 7.4 and the results are displayed in Table 14.

5. Results and discussion

5.1 Pre formulation studies:

Diosgenin was received for the preformulation studies.

5.1.1 Organoleptic properties

The organoleptic properties include drug substance appearance, colour and odour. They are sensory experiences of the distinctive attributes or qualities of a thing. It is a qualitative evaluation type in which the morphological and sensory characters of drugs are studied. Study of a drug's macroscopy involves its visual appearance to the naked eye. The properties are shown in table 4.

Table 4: The organoleptic properties of Diosgenin

S.No	Properties	Outcome
1.	Colour	White to off white
2.	Shape	Crystalline
3.	Odour	Not known for its odor.
4.	Texture	Powder
5.	Taste	Not known for its taste.

Figure 1: Diosgenin powder

5.1.2 Melting point

The melting point (or, rarely, liquefaction point) of a substance is the temperature at which it changes state from solid to liquid. At the melting point the solid and liquid phase exists in equilibrium. The melting point of the medicine (Diosgenin) was measured using Melting-Temp apparatus equipped with a digital thermometer and was found 205-207°C (401-405°F) as shown in table 5.

Table 5: Melting point of Diosgenin

Crude drug	Melting point
Diosgenin	205-207°C (401-405°F)

5.1.3 Solubility of Diosgenin

Diosgenin, a naturally occurring compound found in certain plant species, exhibits diverse solubility characteristics when introduced to various solvents. In pharmaceutical and chemical applications, understanding these solubility properties is crucial for formulating and processing diosgenin-containing substances. Diosgenin demonstrates limited solubility in water, being practically insoluble in aqueous

solutions. However, it shows moderate solubility in polar organic solvents such as ethanol, methanol, acetone, and chloroform, dissolving at approximately 20-25% w/w.

Table 6: Solubility of Diosgenin in different solvents

S.No	Parameters % w/w	Solubility
1.	Water	Practically insoluble in water
2.	Methanol	Solubility in methanol, at around 20-25% w/w
3.	Ethanol	Solubility in ethanol, at around 20-25% w/w
4.	Acetone	Moderately soluble in acetone and can dissolve at around 20-25% w/w
5.	Chloroform	Moderately soluble in chloroform and can dissolve at around 20-25% w/w
6.	Pet. Ether	Insoluble in petroleum ether

5.1.4 Loss on drying of Diosgenin

The loss of drying test is a technique for calculating the sample's weight loss during drying under the circumstances listed in each monograph. The value was found to be 12.23 and shown in table 7.

Table 7: Loss on drying

Crude drug	Loss on drying (% w/w)*
Diosgenin	12.23

5.1.5 Preparation of Phosphates buffer pH 7.4 Diosgenin

The UV absorbance of standard solutions in the range of 0-25 µg/ml of drug in phosphate buffer pH 7.4 showed linearity at λmax. Concentration (measured in µg/ml) and Absorbance at a specific wavelength (λ nm). As the concentration of the substance increases, the absorbance also increases. This suggests a positive correlation between concentration and absorbance. The absorbance values are linearly spaced. In other words, the change in absorbance with each unit increase in concentration is constant. This is common in spectrophotometric data, as absorbance often follows Beer's law.

Table 8: Absorbance of working standard solution

S. No	Concentration (µg/ml)	Absorbance at λ nm
1.	0	0.0834
2.	2	0.1156
3.	5	0.1478
4.	10	0.1800
5.	12	0.2122
6.	15	0.2444
7.	25	0.2766

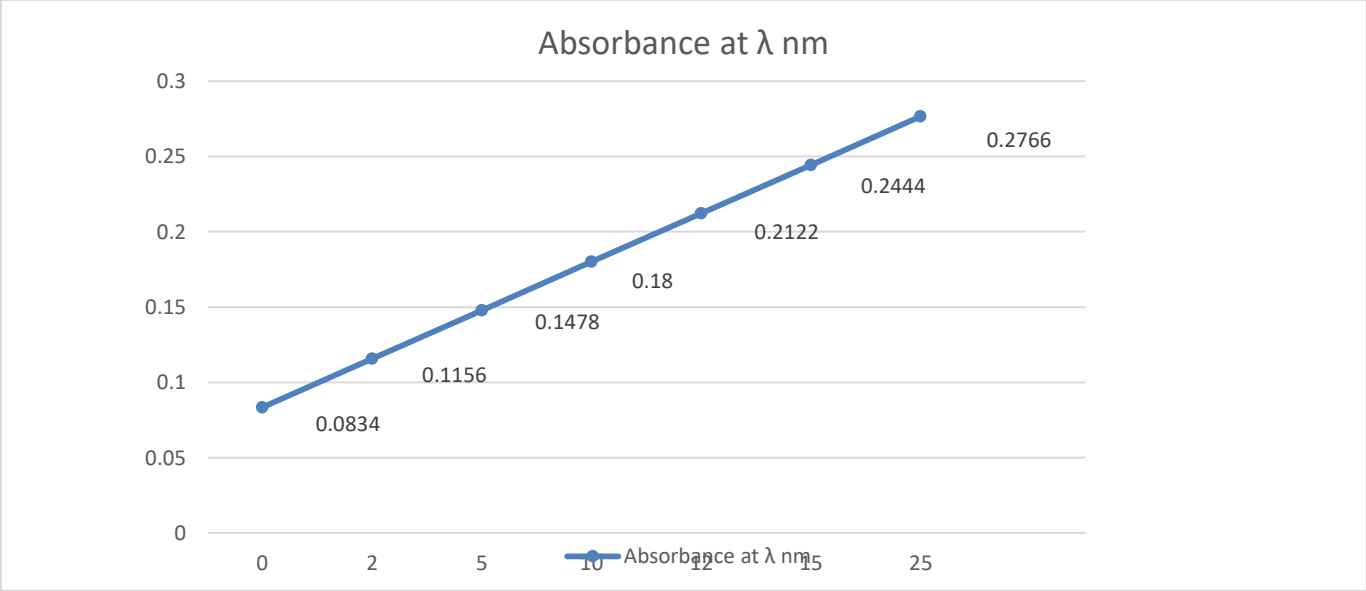

Figure 2: Graph of Phosphates buffer pH 7.4 Diosgenin

5.1.6 Preparation of standard curve of Diosgenin in Methanol

The UV absorbance of standard solutions in the range of 0-25 µg/ml of drug in Methanol showed linearity at λmax. Concentration (measured in µg/ml) and Absorbance at a specific wavelength (λmax).As the concentration of the substance increases, the absorbance (at λmax) also increases. This indicates a positive linear relationship between concentration and absorbance, which is commonly observed in spectrophotometric analysis when Beer's Law applies. The data spans a range of concentrations from 0 µg/ml to 25 µg/ml, which is important for establishing the dynamic range of the analytical method. Understanding the upper and lower limits of the method's linear response is crucial for accurate quantification. This dataset can be used to create a calibration curve, which is a graphical representation of the relationship between concentration and absorbance. A linear regression analysis can be performed on this curve to determine the equation that relates concentration to absorbance. Beer's Law states that absorbance is directly proportional to concentration in a linear fashion, assuming other conditions are met.

Table 9: Absorbance of working standard solution (Diosgenin in Methanol)

S. No.	Concentration (µg/ml)	Absorbance
1.	0	0
2.	2	0.1
3.	5	0.170
4.	10	0.289
5.	15	0.40
6.	20	0.511
7.	25	0.622

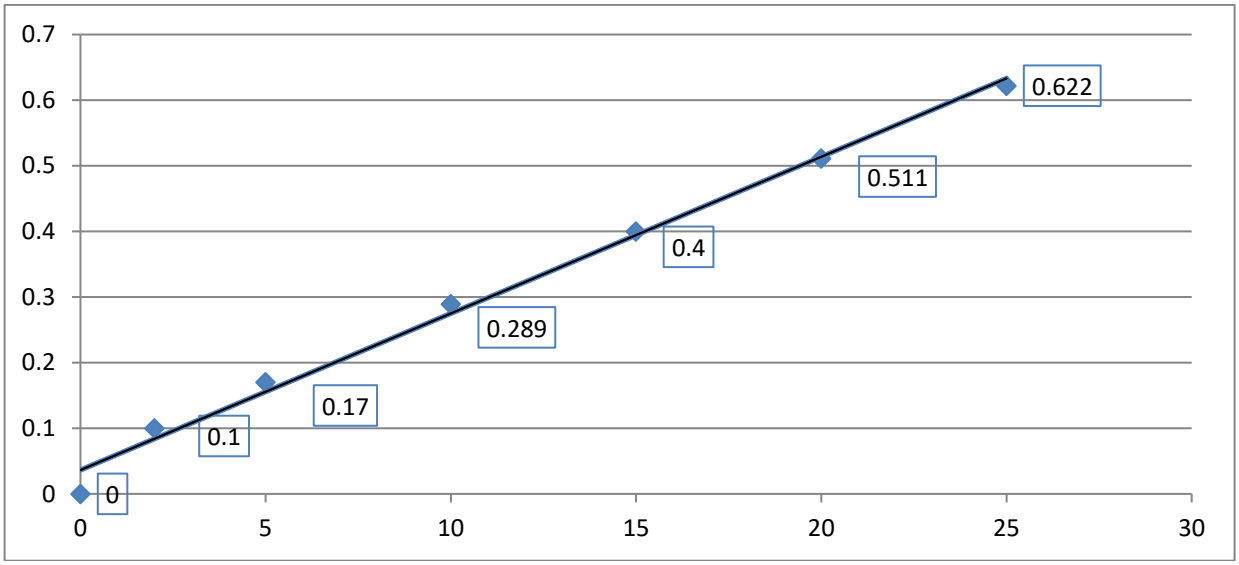

Figure 3: Graph of standard curve of Diosgenin in Methanol

5.1.7 FTIR of Diosgenin

The Fourier-transform infrared spectroscopy (FTIR) spectrum of diosgenin, a naturally occurring steroidal saponin found in various plants, exhibits characteristic peaks associated with its molecular structure. Here are some common characteristic peaks and their corresponding functional groups for diosgenin in an FTIR spectrum:

O-H Stretching Vibration: A broad and strong peak in the region of 3200-3600 cm^{-1} is typically associated with the O-H stretching vibration of hydroxyl (-OH) groups. Diosgenin contains hydroxyl groups, and this peak is a strong indicator of their presence.

C-H Stretching Vibration: Peaks in the region of 2800-3000 cm^{-1} are associated with C-H stretching vibrations of aliphatic hydrocarbon groups. These vibrations can be found in the hydrocarbon portion of the diosgenin molecule.

C=O Stretching Vibration: A peak in the region of 1700-1750 cm^{-1} is indicative of the C=O stretching vibration, which is typically associated with carbonyl groups. Diosgenin contains a ketone functional group (C=O), which contributes to this peak.

C-C and C-O-C Stretching: Peaks in the region of 1000-1300 cm^{-1} are associated with various stretching vibrations, including C-C and C-O-C stretching. These vibrations are related to the structure of diosgenin, which contains multiple carbon-carbon (C-C) and ether (C-O-C) linkages.

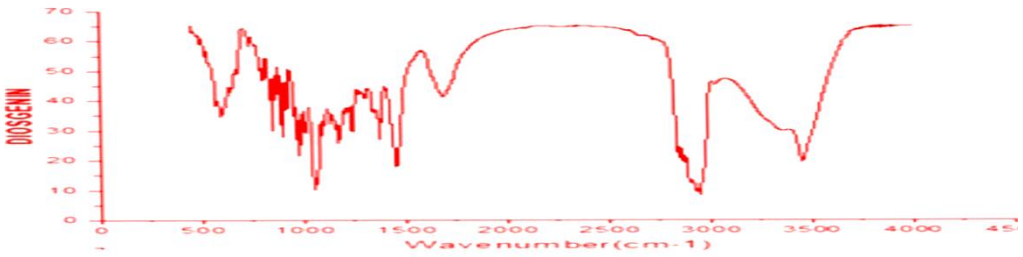

Figure 4: FTIR of Diosgenin

5.1.8 Bulk density and tapped density

Bulk density is determined by measuring the volume of a known mass of powder sample that has been passed through a screen into a graduated cylinder. After observing the initial volume, the cylinder is mechanically tapped, and volume readings are taken until little further volume change is observed. The bulk density of the pure drug is 0.43 g/ml. The tapped density of the pure drug is 0.596 g/ml. The values are shown in table 10.

Table 10: Determination of flow properties of pure drug

Parameters	Values
Bulk density	0.43
Tapped density	0.596

5.1.9 Compressibility index, hausner ration and angle of repose

The compressibility index, hausner ratio and angle of repose were found to be 26.67, 1.36 and 28.36^0 and are shown in table 11. The compressibility index is 26.67%. A higher compressibility index indicates that the material is more compressible or less free-flowing. Hausner ratio is 1.36. A higher Hausner ratio typically suggests poorer flow-ability, and a value greater than 1.25 is often considered indicative of poor flow. The angle of repose is 28.36 degrees. The angle of repose is a critical parameter for assessing the flow properties of powders and granules. A higher angle of repose typically indicates poorer flowability.

Table 11: Determination of flow properties of pure drug

Parameters	Values
Compressibility index (%)	26.67
Hausner ratio	1.36
Angle of repose	28.36^0

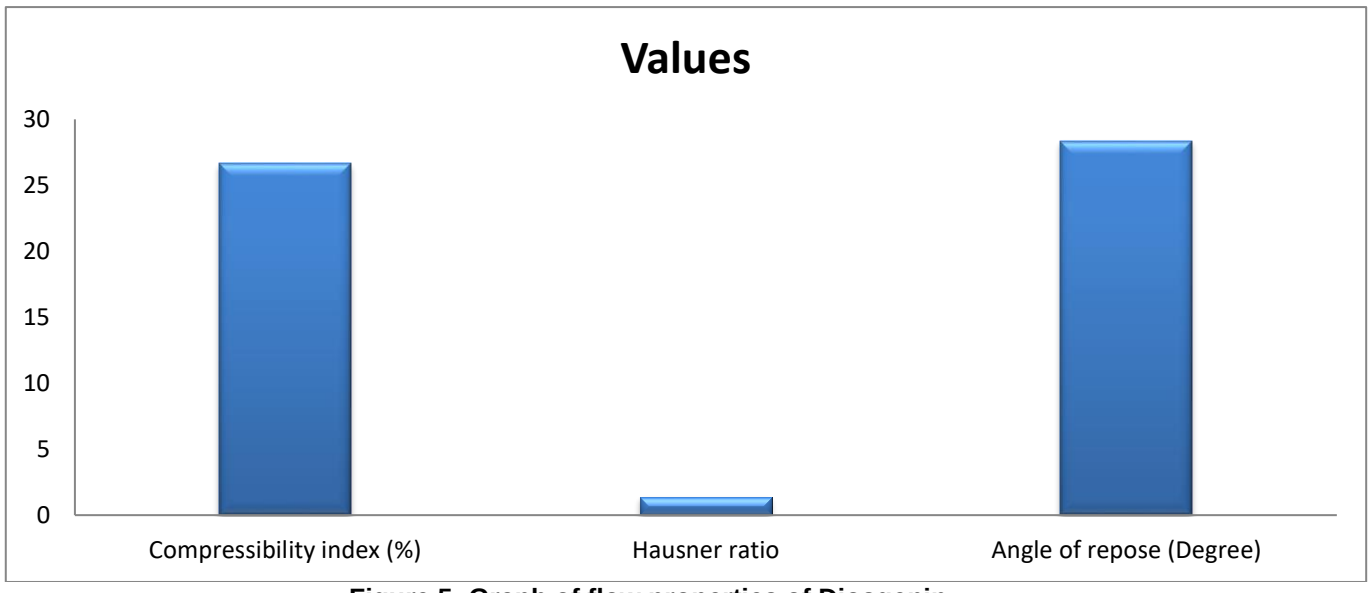

Figure 5: Graph of flow properties of Diosgenin

5.1.10 Characterization of Diosgenin microspheres

Zeta potential is an important parameter that describes the surface charge of the microspheres. It is measured in millivolts (mV). The values range from approximately 21.23 mV to 26.12 mV, indicating variations in the

surface charge of the microspheres. Particle size represents the size of the microspheres and is measured in micrometers (µm). Particle sizes range from approximately 92.18 µm to 180.24 µm, indicating differences in the size distribution among the microspheres. Yield percentage is a measure of the efficiency of the microsphere preparation process. It represents the percentage of the intended product that was successfully obtained. Yield percentages range from approximately 63.11% to 92.10%, suggesting variations in the success of the production process. Depending on the specific goals of the formulation, additional analysis and characterization may be required to assess factors such as drug loading, release kinetics, and stability.

Table 12: Evaluation of different formulations of microspheres

Formulation (MICROSPHERES -MS)	Zeta potential(mv)	Particle size (µm)	Yield Percentage (%)
MS-1	21.23	160	91.16
MS-2	23.56	95.65	73.23
MS-3	24.11	110.21	84.21
MS-4	25.63	116.54	63.11
MS-5	24.56	95.01	78.47
MS-6	25.93	92.18	89.33
MS-7	26.12	105.20	90.45
MS-8	25.62	180.24	74.43
MS-9	23.12	113.02	71.12
MS-10	22.36	140.05	90.56
MS-11	24.11	125.76	77.65
MS-12	25.63	120.33	77.89
MS-13	24.56	130.15	92.10
MS-14	25.93	110.83	87.51
MS-15	26.12	102.11	79.02

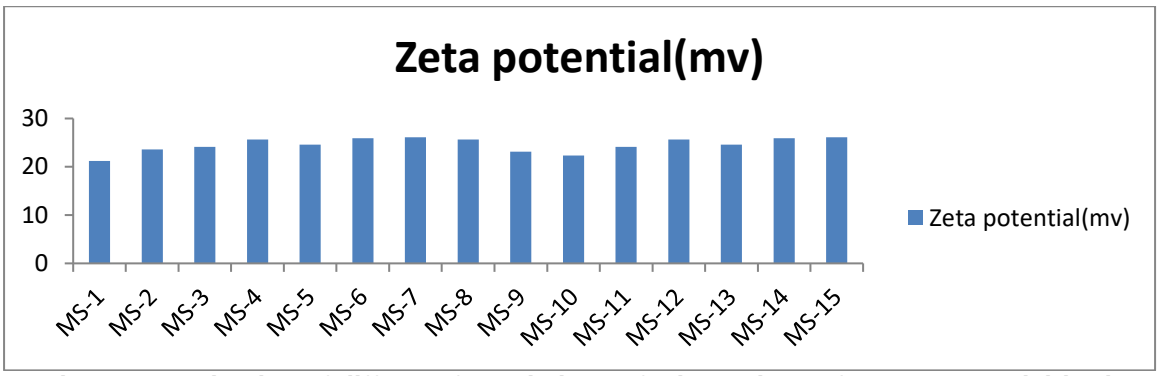

Figure 6: Evaluation of different formulations of microspheres for Zeta potential (mv)

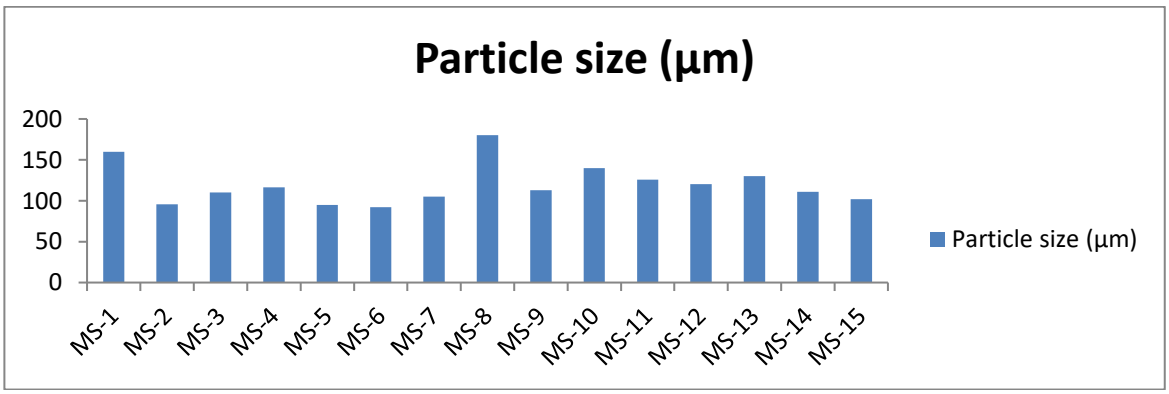

Figure 7: Evaluation of different formulations of microspheres for Particle size (µm)

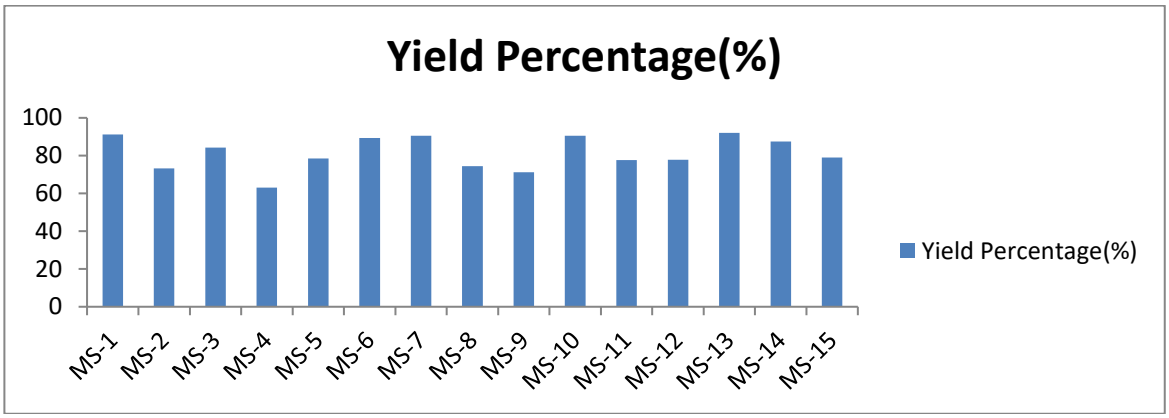

Figure 8: Evaluation of different formulations of microspheres for Yield Percentage (%)

5.1.10 Evaluation of different formulations of microspheres

Swelling index measures the extent to which the microspheres swell when exposed to a liquid medium. It is a dimensionless value, and the values range from approximately 0.955 to 1.736 among the different formulations. Higher values indicate greater swelling behavior. Encapsulation efficiency represents the percentage of the intended substance (e.g., a drug) that is successfully encapsulated within the microspheres during their formation. The % encapsulation efficiency values range from approximately 80.24% to 93.27%, indicating variations in the success of the encapsulation process. In vitro drug release profile of microspheres is shown in Table 14.

Table 13: Evaluation of different formulations of microspheres

Formulation (MICROSPHERES -MS)	Swelling Index	% Encapsulation Efficiency
MS-1	0.955	80.24
MS-2	1.025	82.16
MS-3	1.087	83.64
MS-4	1.655	85.61
MS-5	1.150	86.27
MS-6	1.504	88.11
MS-7	1.034	89.57
MS-8	1.082	88.49
MS-9	1.736	90.99
MS-10	1.107	90.71
MS-11	1.190	91.04
MS-12	1.103	91.42
MS-13	1.024	92.26
MS-14	1.064	93.17
MS-15	1.087	93.27

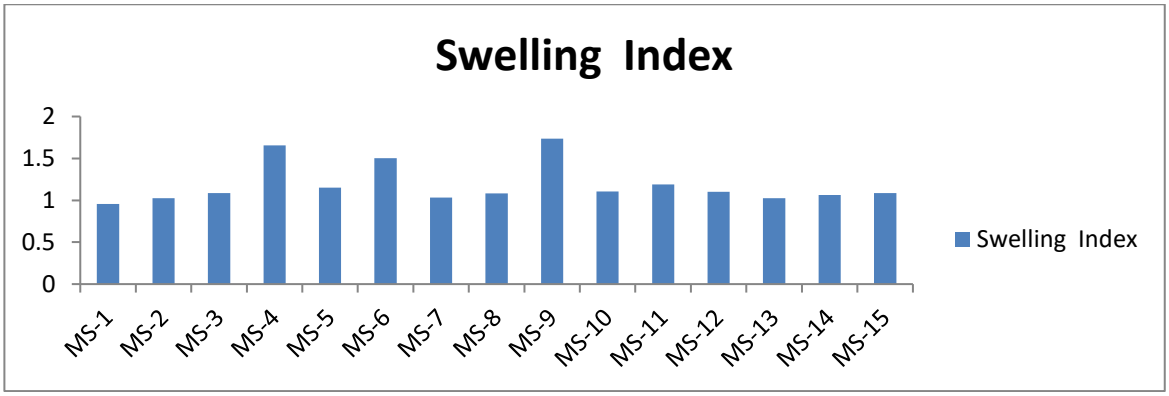

Figure 9: Evaluation of different formulations of microspheres (Swelling Index)

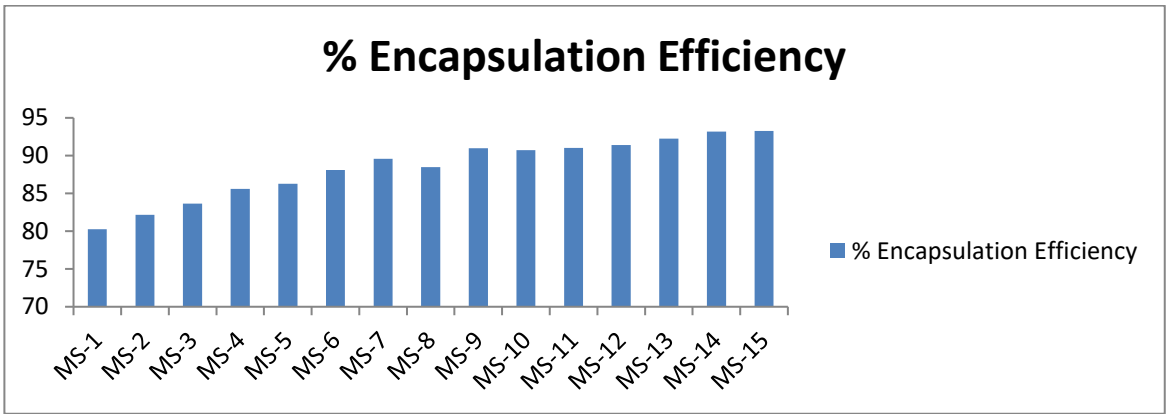

Figure 10: Evaluation of different formulations of microspheres (% Encapsulation Efficiency)

Table 14 (a): Cumulative Drug Release (In Vitro)

Time (h)	Cumulative % drug released							
	MS-1	**MS-2**	**MS-3**	**MS-4**	**MS-5**	**MS-6**	**MS-7**	**MS-8**
0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
1	14.28±1.02	12.03±1.16	28.11±1.83	29.09±1.22	22.19±1.33	21.19±1.02	24.06±1.22	31.40±1.00
2	32.50±1.21	32.30±1.22	38.00±1.56	32.23±1.52	31.40±1.52	31.47±1.11	30.13±1.04	36.30±1.05
4	45.36±1.01	40.02±1.11	49.50±1.02	51.09±2.04	52.11±1.11	41.08±1.07	44.30±1.71	52.02±1.03
6	82.70±1.11	70.13±1.31	84.27±1.64	84.41±1.02	85.02±2.90	76.08±1.07	79.94±1.08	84.96±1.30
8	85.07±1.09	84.96±1.07	94.25±1.74	95.29±2.99	95.02±1.80	85.06±1.01	87.09±1.06	83.07±1.02

Table 14 (b): Cumulative Drug Release (In Vitro)

Time (h)	Cumulative % drug released						
	MS-9	MS-10	MS-11	MS-12	MS-13	MS-14	MS-15
0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
1	20.09±1.08	13.99±1.90	18.361±1.01	28.11±1.02	21.09±1.03	22.10±1.22	23.16±1.02
2	30.22±1.71	33.10±1.62	34.10±1.04	38.03±1.52	36.55±1.50	33.48±1.09	35.13±1.84
4	54.36±1.54	53.02±1.26	47.94±1.13	53.09±1.64	55.72±1.05	49.08±1.27	47.08±1.01
6	85.71±1.07	75.67±1.99	85.26±1.04	81.68±1.22	84.02±2.02	77.43±1.07	77.94±1.88
8	85.07±1.89	88.96±1.97	93.05±1.14	91.23±2.09	95.05±1.00	88.06±1.19	87.63±1.11

6. Conclusion

The organoleptic properties include drug substance appearance, colour and odour. They are sensory experiences of the distinctive attributes or qualities of a thing. The melting point of the medicine (Diosgenin) was measured using Melting-Temp apparatus equipped with a digital thermometer and was found 205-207°C (401-405°F). Diosgenin demonstrates limited solubility in water, being practically insoluble in aqueous solutions. However, it shows moderate solubility in polar organic solvents such as ethanol, methanol, acetone, and chloroform, dissolving at approximately 20-25% w/w. On the other hand, diosgenin is entirely insoluble in nonpolar solvents like petroleum ether. The loss of drying test is a technique for calculating the sample's weight loss during drying under the circumstances listed in each monograph. The value was found to be 12.23 % w/w. Tapped density is achieved by mechanically tapping a measuring cylinder containing a powder sample. After observing the initial volume, the cylinder is mechanically tapped, and volume readings are taken until little further volume change is observed. The bulk density of the pure drug is 0.43 g/ml. the tapped density of the pure drug is 0.596 g/ml. The compressibility index, hausner ratio and angle of repose were found to be 26.67, 1.36 and 28.36. Particle sizes range from approximately 92.18 µm to 180.24 µm, indicating differences in the size distribution among the microspheres. Yield percentage is a measure of the efficiency of the microsphere preparation process. It represents the percentage of the intended product that was successfully obtained. Yield percentages range from approximately 63.11% to 92.10%, the % encapsulation efficiency values range from approximately 80.24% to 93.27%, indicating variations in the success of the encapsulation process. Cumulative % Drug release ranges from 83.07 % to 95.29 %.

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Conflict of Interest

Authors declare no conflict of interest.

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