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THE EFFECT OF SPHERONIZATION SPEED, DRYING TIME AND BINDER CONCENTRATION ON THE CHARACTERISTICS OF HERBAL PELLETS MADE BY EXTRUSION SPHERONIZATION METHOD

SWAMI D* AND MORE S

Progressive Education Society Modern college of Pharmacy (For Ladies) Moshi, Pune-412105, Savitribai Phule Pune University, Pune

***Corresponding Author: Ms. Dakshayani Swami: E Mail: swamidakshayani19@gmail.com**

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ABSTRACT

The aim of this present work is that the Influence of Spheronization Speed, drying time and binder concentration on The Properties of Herbal Pellets Produced by Extrusion Spheronization Technique. Pellets are aggregates of small, freely flowing, round or semi-spherical solid units made up of fine powders or granules of excipient and bulk pharmaceuticals. The different types of method are used in the formulation along with the technique, several techniques are available there out of which extrusion spheronization is one of them which form the small, free flowing pellets, The speed of the extrusion machine leads to formation of different types of pellets as the speed is less it will lead to formation of small pellets and as the speed increased the size of the pellets also get increased so, depending upon the size the availability of the pellets is depend. Drying time also affect the formation of the pellets depending upon the concentration of the solvent used in the formulation. So, the concentration of the binder also plays the major role in the physiological properties of the pellets. So, extrusion spheronization leads to formation of the proper pellets which passes through all the evaluation parameters.

Keywords: Aggregates, Drying time, Extrusion, Granules, Herbal, Spheronization etc.

INTRODUCTION: [1, 2]

Pellets are aggregates of small, freely flowing, round or semi-spherical solid units made up of fine powders or granules of excipient and bulk pharmaceuticals. This solid dosage form consists of typically size of about 0.5-2 mm. By employing extrusion spheronization, which is primarily meant for oral route, varied sizes of pellets can be created depending on sieve size and speed. Pellets are formed and then placed within a firm gelatine capsule after formulation. A capsule is a solid dosage form that contains the medication inside either a hard or soft dissolving shell, most frequently made of gelatine.

Advantages of pellets: [1, 2]

1) Pellets leads release of drug in controlled manner.
2) Consist of smaller size so they have larger density.
3) Freely disperse in GI tract so the chances of dose dumping get avoided.
4) Shows less peak plasma fluctuation.
5) Prevent local irritation of the drug.

Disdvantages of pellets: [1, 2]

1) Various size of pellets products produced but their size is 0.5 to 1mm.
2) Filling of capsule by using pellets is costly process.
3) Pellets require specialised equipment for their formation.
4) Making of tablet from the pellets this is costly process

TECHNIQUE OF PELLITIZATION:

Technique is used for pellet formulation is extrusion spheronization **[3-5]**. By using this technique, the small spherical pellets formulated which consist of uniform size. It involves following steps:

a. Dry mixing: All the ingredients which are used mix that homogenously by using the twin shell blender, Planetary mixer. b. Wet massing: The homogenous mixture of ingredients gets wetted by using the appropriate solvent in specific proportion which leads to form dump mass. c. Extrusion: The road shaped extrudes get formed by using extrusion machine by inserting the wet mass. For this the appropriate size sieve and speed require so uniform extrude get form. d.Spheronization: The rod shaped extrudes get passed through the spheronization, the appropriate speed and sieve should be selected and the pellets of uniform size get formed.

Figure 1: Extrusion machine

Figure 2: Spheronization machine

MATERIAL AND METHOD OF PREPARATION:

Material and Equipment used:

Table 1: Material used

Sr. no	Material	Manufactured by
1	Liquorice	Research lab fine chem industries
2	Talc	Research lab fine chem industries
3	Starch	Research lab fine chem industries
4	Microcrystalline cellulose	Research lab fine chem industries
5	PEG 6000	Research lab fine chem industries
6	Benzoic acid	Research lab fine chem industries
7	Sodium metabisulphite	Research lab fine chem industries
8	Hydroxy propyl methyl cellulose	Research lab fine chem industries
9	Lemon oil	Research lab fine chem industries
10	Soluplus	BASF Pharma

Table 2: List of Equipment

Sr no	Equipment	Process	Manufactured by
1	Extruder machine	Extrudes form	SHIMADZU
2	Spheronization machine	Spherical shape pellets form	SHAKTI
3	UV	Measure how much a chemical substance absorbs light.	SHIMADZU
4	FTIR	Detect different functional group.	SHIMADZU
5	SEM	Size, Morphology of pellets	Nova Nano SEM NPEP 303
6	Dissolution test apparatus	Dissolution	Electro lab
7	Sonication	Reduces particle size	Dakshin
8	Electronic weighing balance	Weighing	SHIMADZU

Method of preparation: [7-9]

Pellets are prepared by using the extrusion spheronization technique, in which all the ingredients are weighted accurately and mixed together. Then all the mixed ingredients are converted into wet mass by using the appropriate solvent. After the wet mass is formed then passed through the extrusion machine and extrudes get formed. Extrudes after drying at room temperature passed through the spheronization machine so the round pellets get formed.


Figure 3: Solid mass


Figure 4: Extrude


Figure 5: Pellets

SPEED OF SPHERONIZATION: The speed of the spheronizer machine affect the size of the pellets as the speed decreases then the size of the pellets get also decreases and as the speed increases then the pellets size also gets increases. Depending upon the requirement the pellets get formulated.

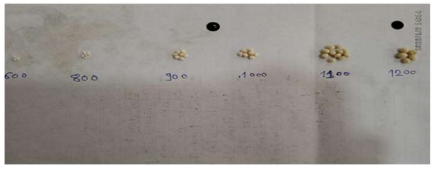

Figure 6: Size of the pellets

DRYING TIME: Drying time of extrudes also affect the formulation of the pellets. As the drying time excide more than essential then the pellets do not form in round shape the extrudes remains as it is. So, the determination of drying time of pellets is more essential. The time period of minimum 30 and maximum 45 min is essential for the formation of proper pellets.


Figure 7: Pellets/Extrude

EVALUATION PARAMETER: [7-13]

Percentage yield of pellets: The percentage yield of garlic and liquorice combination pellets was calculated by using the following formula. Percentage yield= The practical yield of pellets/ The theoretical yield * 100.

Flow properties:

Bulk density: Bulk density is determined by pouring the pellets into the measuring cylinder. So, the bulk volume gets determined and the weight also. Formula used for the determination of bulk density is.

Bulk density (ρb) = $M/V_{b.}$

Were, M- Mass of pellets, V_b- Bulk volume

Tapped density: Tapped density is determined by pouring the pellets into the measuring cylinder and tapped that 100 times and pellets tapped density determined and weight also determined. Formula used for the determination of tapped density is. Tapped density (ρT) M/V_t

Were, M- Mass of pellets, V_t- Tapped volume

Angle of repose: For the determination of Angle of repose funnel is used. In this method the tripod stand is required to this the funnel is held from its tip at the hight of 5cm from the base. Then the accurately weighted pellets poured through the funnel on the surface. Then the diameter or radius of the pellets were measured and so angle of repose was determined. Angle of repose:

$$\tan\theta = h/r$$

Were, h = Height of pill (cm), r = Radius of pellet cone

Standard values of angle of repose.

Hausners ratio: Hausners ration it is used to determine the flow property of the pellet, It is ration of tapped density to the bulk density. When the hausners ration is 1.25 then the flow property is good, 1.25- 1.5 then flow is moderate, 1.5 then the flow is poor. Hausners ration (Hρ): Tapped density (ρt)/Bulk density (ρb)

Carrs index: Carrs index it is ration of tapped density minus bulk density divided by the tapped density multiply by the 100. Carrs index = Tapped density (ρt)- bulk density (ρb)/ tapped density (ρt).

Drug content: Drug content is determined by dissolving 25 mg of drug into the 25 ml of distilled water by sonication for 15 min, and after the sonication that solution get filtered by using Waltman filter paper and after that the UV absorbance of drug get taken.

Particle size: Particle size is determined by using the sieve analysis, it gives us an idea about the particle size of the pellets.

Moisture content: Moisture content is determined by drying the pellets at room temperature. The wet mass of pellet is taken and after the drying of pellets at room temperature their weight is taken so the moisture content of pellet is determined in such a way. Formula for calculation of moisture content is given as follows.

Moisture content. $(M_c) = (m_{w-} m_d)/m_d \times 100$

Were, m_w - wet mass of pellet, m_d - dried mass of pellet

Scanning electron microscopy:

By using the scanning electron microscopy, the morphological characteristic and shape of formulated pellets get observed. Morphological characteristic of the pellets depends upon the composition of the pellet, varying upon the composition of the pellets the morphological characteristic and shape get obtained.

FTIR:

Fourier transfer infrared spectroscopy determine the different types of functional group present in the drug and formulation.

The wavelength of light absorbed it can be seen the FTIR spectra and the chemical bond present also determined.

Drug content of pellets:

The drug content of formulated garlic and liquorice combination pellets was calculated by weighing the accurately 100 mg of pellets and dissolved in 100 ml of phosphate buffer, then dilutions were obtained with phosphate buffer 6.8 and the resulted solutions are analysed spectrophotometrically at 210nm and the drug content were calculated.

In vitro dissolution studies:

Dissolution of the formulated sustain release combination pellets of garlic and liquorice were carried out by using the USP apparatus 2 basket type for 8 Hr by using the phosphate buffer 6.8 as dissolution media (900ml) in each jar as dissolution media at 37±0.50°C at 50 rpm. An equivalent number of formulated pellets were added to 900 ml of dissolution media (jar). The 5 ml of solution was withdrawn from the dissolution media at a time interval up to 4 hr by maintaining sink condition. And the solution was analysed under spectrophotometrically at 210nm. The percent drug release (% CDR) in the dissolution media calculated.

RESULT AND DISCUSSION:

Evaluation of batches:

Flow properties: Flow property are mainly used to know the flowability of the powder material. When the powder shows the angel of repose between the 25-30 then the angel of repose is excellent. And when the hausners ratio is between the 1.00-1.11 then the flow property is excellent.

Table 3: Flow properties

Sr. no	Parameters	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
1	Density	0.62g/cm^{-3}	0.5g/cm^{-3}	0.6g/cm^{-3}	0.5g/cm^{-3}	0.5g/cm^{-3}	0.6g/cm^{-3}	0.5g/cm^{-3}	1g/cm^{-3}	0.6g/cm^{-3}
2	Bulk density	0.62g/cm^{-3}	0.5g/cm^{-3}	0.6g/cm^{-3}	0.5g/cm^{-3}	0.5g/cm^{-3}	0.6g/cm^{-3}	0.5g/cm^{-3}	1g/cm^{-3}	0.6g/cm^{-3}
3	Tapped density	0.77g/cm^{-3}	0.54g/cm^{-3}	0.69g/cm^{-3}	0.53g/cm^{-3}	0.56g/cm^{-3}	0.6g/cm^{-3}	0.6g/cm^{-3}	1.16g/cm^{-3}	0.7g/cm^{-3}
4	Hausners ratio	1.23	1.08	1.15	1.06	1.07	1.08	1.09	1.16	1.1
5	Carrs index	19.4	7.4	13	6.3	7.2	7.9	8.8	13.7	7.14
6	Angle of repose	1.4	1.5	1.6	1.4	1.5	1.5	1.9	1.72	1.72

DRUG CONTENT: Drug content of the formulated pellets were no the how much quantity of drug has been retained in the formulation. In this the 25 mg of pellets dissolved in the 25 mg of distil water and the uv absorbance taken and drug content calculated. When the carrs index is between the 5-10 then the fow property is excellent.

Table 4: Drug content

Sr no	Batches	Drug content
1	F1	73.3%
2	F2	83%
3	F3	91.2%
4	F4	94%
5	F5	90.01%
6	F6	89.7%
7	F7	77.16%
8	F8	94.78%
9	F9	94.09%

DISINTEGRATION STUDY:

Disintegrations of the pellets was performed to know in much interval of time the pellets get disintegrate after intake. So, the pellets disintegrate complete after 15 min when taken in the body.

DISSOLUTION STUDY: Dissolution study was performed to know; in how much interval of time the drug gets dissolved in the body that study in vitro medium.

Dissolution study of F4 and F5 batch:

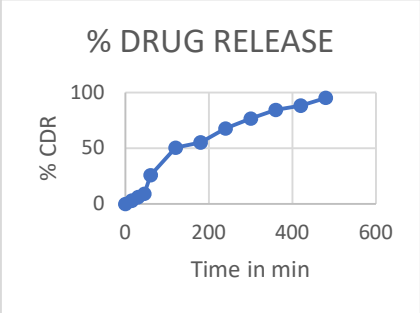

Figure 8: % CDR Release of f4 batch

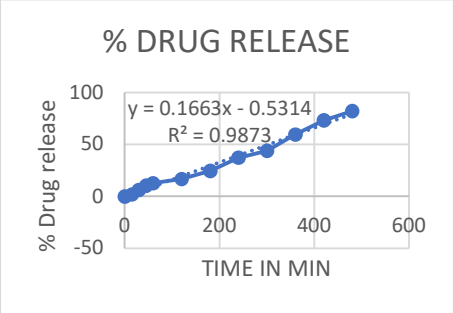

Figure 9: % CDR Release of F5 batch

Comparative Study OF F4 And F5 Batch:

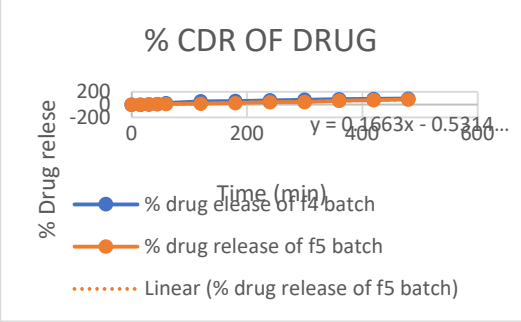

Figure 10: Comparative study of f4 and f5 batch

FTIR DATA: FTIR of the pellets is performed to know the functional group present in the formulation and their bond strength. The infrared spectroscopy act on the principle of that is when the sample is placed for the IR, radiations pass through a sample some of the radiations get absorbed, so the radiations which passes through the sample should be recorded.

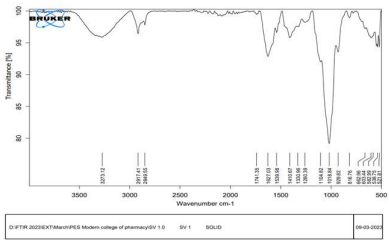

Figure 11: IR spectra of Garlic drug

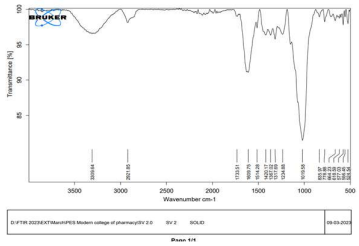

Figure 12: IR spectra of liquorice drug

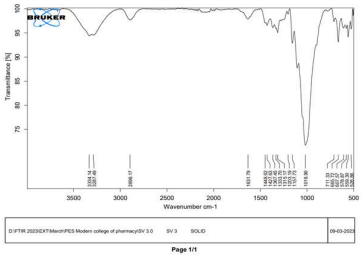

Figure 13: IR spectra of garlic, liquorice and excipient

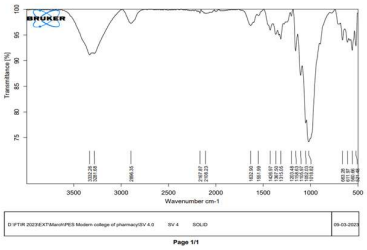

Figure 14: IR spectra of f4 batch

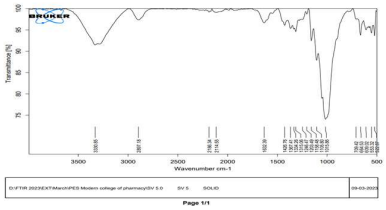

Figure 15: Infrared spectra of f5 batch

FTIR INTERPRETATION:

Table 5: FTIR Interpretation

Functional range	Functional group	Pure drug garlic	Pure drug liquorice	F4 Batch
3200-3600	O-H	3273	3309	3382
1650-1750	C=O	1741	1733	1632
2800-2700	C-H	2849	2729	2739
1700-1725	C=O	1713	1703	1705
2500-3300	O-H	2917	2921	3281
1620-1680	C=C	1627	1609	1632

DLS DATA

DLS of F4 Batch:

Quasi-elastic light scattering, also known as dynamic light scattering (DLS), is a well-known, non-invasive technique for determining the size and size distribution of molecules and other particles, often in the submicron range and, with the most recent technology, down to 1nm. The Dynamic Light Scattering (DLS) method utilises temporal variations in the intensity of scattered light that reflects the diffusion of the particles to determine the size of particles suspended in liquid.

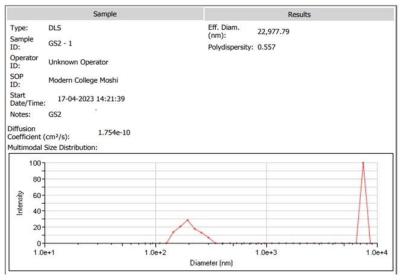

Figure 16: Particle size of f4 batch

FESEM OF F4 AND F5 BATCH:

Particle size of pellets is 1.278mm. The picture of the materials' microstructure is captured using the cutting-edge technology known as field emission scanning electron microscopy (FE-SEM). Because gas molecules have a tendency to affect the electron beam and the produced secondary and backscattered electrons utilised for imaging, FE-SEM is normally carried out in a high vacuum. The main distinction between SEM and FE-SEM is the electron generating mechanism, but FESEM generally adheres to the same principles as SEM. A Field Emission Gun (FEG) is the electron source used by FE-SEMs. While thermionic emission is employed in SEM, a potential gradient is used in FEGs to emit the electron beam.

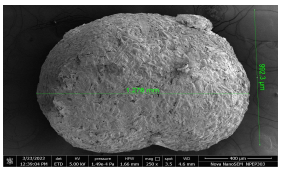

Fig17: FESEM at 250x

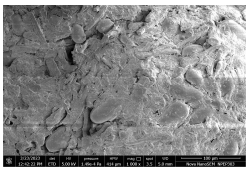

Fig18: FESEM at 1000x

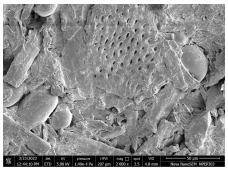

Fig19: FESEM at 2000x

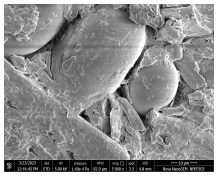

Fig 20: FESEM at 5000x

STABILITY STUDY:

To know the stability of the formulated pellets they were stored in amber coloured glass for 3 to 6 months and after this the sample was evaluated for the colour, surface texture, drug content. In the colour no change was occurred up to 3 months, there was no change in the surface texture of the pellets, the drug content was found to be above 90%.

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CONCLUSION:

The herbal pellets were prepared by using the extrusion spheronization technique how the speed of the spheronization machine, drying time and concentration of the binder affect the physiological properties of the pellets studied.

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