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FORMULATION AND EVALUATION OF GOAT MIL TABLET FOR NUTRACEUTICAL PURPOSES

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ABSTRACT:

School children often face challenges in consuming pure goat milk on a daily basis dueto its unpleasant taste and odor, along with its short shelf life. To address these issues, converting goat milk into tablets offers a practical solution. This transformation not only enhances the product's shelf life but also facilitates easier consumption, particularly for distribution in remote areas. The primary focus of this project was formulating goat milk tablet by using direct compression method and also enhance hardness and disintegration of tablet. Direct compression techniques were instrumental in improving the poorly flowing properties of goat milk powder. This method effectively enhanced the flow ability and compressibility of the tablets, resulting in uniform weight, low friability, and optimal hardness. Thus, the development of goat milk tablets represents a significant advancement in making this nutritious product more accessible and appealing to school children.

Keywords- Goat milk, direct compression, tablet dosage, oral forms, nutraceutical, goat milktablets.

I. INTRODUCTION:

Milk is essential for children's growth due to its rich nutrient content, supporting the development of cells and organs. There is scientific investigation by the FDA that 15%-20% of the energy is come from protein and it produce almost 800-1000kcal.[1] Goat milk is rich in calcium and phosphate, containing about 1.2g of calcium and 1g of phosphate per liter, similar to cow milk. This makes it a valuable source of these minerals, especially compared to humanmilk, which contains much less. The soft curd of goat milk is advantageous for adults with gastrointestinal issues and ulcers, and its high buffering capacity can aid in treating gastric ulcers. Goat milk is often recommended as a substitute for cow milk for patients allergic to cow milk proteins, with many patients tolerating it well. [3]However, challenges arise in daily milk

consumption, especially with goat milk, due toits unpleasant taste and odor, short shelf life, and the need for refrigeration.[1] To address these challenges, transforming goat milk into chewable tablets offers a viable solution. By formulating goat milk into tablets, its shelf life is extended, making it convenient for storage and distribution, even in remote areas. Moreover, tablet form enhances ease of consumption and eliminates the need for refrigeration. This innovation provides a practical way to ensure children's daily milk intake.[1]Developing goat milk tablets involves optimizing formulations through direct compression methods to improve flow properties, making tablet production more efficient. Studies emphasize the importance of sensory acceptability to ensure children willingly consume the tablets. [1]Goat milk offers nutritional advantages over cow milk, including higher levels of calcium, phosphorus, potassium, magnesium, chloride, selenium, vitamins A and D, and lower sodium and sulfur contents. Despite its benefits, goat milk's goaty odor and limited availability hinder widespread consumption. Producing goat milk tablets addresses these challenges, offering a convenient, palatable, and nutrient-rich alternative. In conclusion, goat milk tablets provide a practical solution to promote regular milk consumption among children, addressing taste preferences, storage limitations, andaccessibility barriers. By leveraging goat milk's nutritional benefits in a convenient and appealing form, these tablets have the potential to improve children's dietary intake and overall health.

Figure 1: Goat Milk

II. AIM & OBJECTIVE:

1. Formulation Optimization: Determine the optimal formulation of the goat milk tablet by selecting suitable excipients, concentrations, and processing parameters.
2. Process Optimization: Evaluate various direct compression techniques to determine the most efficient method for producing uniform, high-quality tablets with desirable physical and chemical properties.
3. Physical Characterization: Characterize the physical properties of the goat milk tablet, including hardness, friability, disintegration time, and uniformity of dosage, to ensure consistent product quality and performance.
4. Chemical Characterization: Assess the chemical composition of the goat milk tablet,.
5. Sensory Analysis: Conduct sensory evaluation tests to assess the organoleptic properties (e.g., taste, Odor, texture) of the goat milk tablet and optimize its palatability and consumer acceptance.

Figure 2: Goat Milk Tablet

III. MATERIAL:

For formulating goat milk tablet goat milk powder is required. So, we had ordered this powder.

IV. METHODOLOGY:

1. Formulation of Goat Milk Tablet:

Goat milk tablet is formulated in 4 batch such as batch A, batch B, batch C, batch D.

a. **Batch A**- In this batch, goat milk tablets per 500 mg includes whole milk powder (55%), microcrystalline cellulose (15%), polyvinylpyrrolidone (4%), talc (10%), sucrose (15%), and magnesium stearate (1%).

b. **Batch B-** In this batch, same ingredient is used except Sodium Starch Glycolate are used as disintegrant instead of Microcrystalline cellulose.

c. **Batch C**- In this batch, Hydroxypropyl Methylcellulose have used instead of Polyvinylpyrrolidone as binder.

d. **Batch D**- In this batch, both Sodium Starch glycolate and Hydroxypropyl Methylcellulose are used instead of Microcrystalline cellulose (disintegrant) and Polyvinylpyrrolidone (binder).

Table 1: Formulation table for 500 mg tablet

Excipients	Weight of the excipients in 500mg(for 1 Tablet)				Uses
	Batch A	Batch B	Batch C	Batch D	
Goat milk powder	275	275	275	275	API
Microcrystalline cellulose	75	-	75	-	Disintegrant
Sodium Starch glycolate	-	75	-	75	Disintegrant
Polyvinylpyrrolidone	20	20	-	-	Binder
Hydroxypropyl Methylcellulose	-	-	20	20	Binder
Sucrose	75	75	75	75	Sweetener
Talc	50	50	50	50	Glidant
Magnesium stearate	5	5	5	5	Lubricant

Figure 2: Batch A

Figure 3: Batch

Figure 4: Batch C

Figure 5: Batch D

2. Manufacturing process flow chart:

Weighing- Weigh all ingredients properly by using weighing balance accordingto formulation table.

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Sieving- All ingredient was passing through Sieve to obtain fine powder.

↓

Mixing- All ingradients were mix continuously for 15 minincluding magnesium stearate as a lubricant

↓

The mixed powder was then transferred to a polybagfor powder characteristic evaluation.

↓

Compression-The well-mixed excipients were compressed intotablet using a single punch tableting machine.

Figure 6: Manufacturing process flow chart

Figure 7: Single punch tablet machine

Figure 8: Punch and die of tablet machine

Figure 9: Goat Milk Tablet

V. EVOLUTION OF GOAT MILK POWDER CHARACTERISTICS-

- **Bulk Density:**

Bulk Density is a weight of powder or granules divided by its volume. It is used to check uniformity of powder. Bulk density measurements were conducted using a Measuring Cylinder. To determine the bulk density of the powder, 25g of the powder was carefully poured into a 100ml measuring cylinder. The bulk density was then calculated by dividing the weight of the sample by its volume.

$$\text{Bulk Density (g/ml)} = \frac{\text{Weight of Powder (M)}}{\text{Bulk Volume (V)}}$$

- **Tapped Density-**

The sample was mechanically/ manually tapped at 50-100 times. Tapped density also was measured by using Measuring Cylinder. 25g powder was slowly poured into the 1000ml measuring cylinder. Tapped density was calculated by dividing the sample weight by its final volume at 50- 100 times.

$$\text{Tapped Density (g/ml)} = \frac{\text{Weight of Powder (M)}}{\text{Tapped Volume (V)}}$$

Figure 10: Bulk Density

Figure 11: Tapped Density

- **Carr's Index:**

Compressibility Index is calculated by following equation

$$\text{Carr's Index (\%)} = \frac{\textit{Tapped Density} - \textit{Bulk Density}}{\textit{Tapped Density}} \times 100$$

Table 2: Flow character of Carr's index and Hausner's ratio

Carr's Index	Flow Character	Hausner's Ratio
Less than 10	Excellent	1 to 1.11
Less than 11 to 15	Good	1.12 to 1.18
16-20	Fair	1.19 to 1.25
21-25	Passable	1.26 to 1.34
26-31	Poor	1.35 to 1.45
32-37	Very Poor	1.46 to 1.59
More than 38	Very Very Poor	Greater than 1.60

- **HausnerRatio:**

$$\text{Hausner Ratio} = \frac{\textit{Tapped Density}}{\textit{Bulk Density}}$$

- **Angle of Repose:**

The internal angle between the surface of pile and the horizontal surface is known as the angle of repose. The angle of repose was calculated using the following equation.

$$\text{Angle of Repose } (\tan\theta) = \frac{h}{r}$$

Where, θ = Angle of Repose, h = Height of pile, r = Radius of Circle **Table**

8: Flow properties of powder

Angle of Repose	Type of Flow
< 20	Excellent
20-30	Good
30-40	Passable
>40	Very Poor

Figure 12: Angle of Repose

VI. EVOLUTION OF GOAT MILK POWDER CHARACTERISTICS:

Hardness:-

Tablet need to be strong enough or having specific amount of hardness during transportation and handling. We measure this strength, called hardness, to make sure the tablets don't break easily. If it's too hard, it might not be disintegrated properly when administered them, and if it's too soft, it could cause problems during handling or packaging.There are different type of hardness testers and they are used to determine hardness of tablet.

a) **Monsanto Hardness tester**: To measure the hardness of a tablet, we use a device with a spring, a screw knob, and a scale. First, we set the scale to zero. Then, we put the tablet between two parts called the spindle and the anvil. We start turning the screw knob, whichpushes against the tablet. As we turn the knob, we check the scale to see how much force,measured in kilograms, is needed to break the tablet. Generally, a hardness of around 4 kilograms is good for handling the tablet safely. If it's harder, like 6 kilograms or more, thetablet might be too compact, which could cause issues.

b) **Pfizer Hardness tester**: To measure the hardness of a tablet, we use a device that looks like pliers. First, we put the tablet between two jaws on the device. Then, we check the pressure dial, which starts at zero. Next, we squeeze the handles of the device with our hands. As we squeeze, the pressure dial

shows how much force, measured in kilograms or pounds, is needed to break the tablet. That tells us how hard the tablet is.

Figure 13: Monsanto Hardness Tester

Figure 14: Pfizer Hardness Tester

Table 3: Hardness of Tablet

No. of Tablet	Batch A	Batch B	Batch C	Batch D
Hardness (Kg/ cm^2)	4.06	5.03	5.4	5.75

Weight Variation Testing:

The tablet weight variation was calculated by weighing 20 tablets separately. The average weight of 20 tablets was calculated. The percentage difference of each tablet wasalso calculated and compared to the limit set by USP.

$$\textbf{Average Weight} = \frac{\textit{Weight of 20 tablet}}{20}$$

Average Weight of Tablet	Variation Allow
80 mg or less	10%
80 mg or less than 250 mg	7.5%
250 mg or more	5%

a. **Limit** = = $\frac{\%}{100}$ Deviation × Average Weight

b. **Upper Limit** = Avg Wt. + Limit

c. **Lower Limit** = Avg Wt. – Limit

Table 4: Weight Variation of tablet

Batch A										
Upper Limit = 0.52					**Lower Limit** = 0.47					
No. of Tablet	1	2	3	4	5	6	7	8	9	10
Weight (gm)	0.50	o.46	0.50	0.49	0.51	0.49	0.50	0.49	0.51	0.53
Pass/Fail	Pass	Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Fail
No. of Tablet	11	12	13	14	15	16	17	18	19	20
Weight (gm)	0.50	0.49	0.50	0.51	0.52	0.50	0.51	0.50	0.51	0.50
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Batch B										
Upper Limit = 0.52					**Lower Limit** = 0.47					
No. of Tablet	1	2	3	4	5	6	7	8	9	10
Weight (gm)	0.53	0.52	0.51	0.52	0.52	0.51	0.50	0.49	0.52	0.52
Pass/Fail	Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
No. of Tablet	11	12	13	14	15	16	17	18	19	20
Weight (gm)	0.50	0.48	0.50	0.50	0.53	0.47	0.49	0.47	0.47	0.50
Pass/Fail	Pass	Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass	Pass

Batch C										
Upper Limit = 0.53					**Lower Limit** = 0.48					
No. of Tablet	1	2	3	4	5	6	7	8	9	10
Weight(gm)	0.52	0.53	0.52	0.51	0.50	0.50	0.52	0.53	0.52	0.51
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
No. of Tablet	11	12	13	14	15	16	17	18	19	20
Weight(gm)	0.52	0.52	0.52	0.51	0.51	0.48	0.52	0.49	0.50	0.51
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

						Batch D				
Upper Limit = 0.52						**Lower Limit** = 0.47				
No. ofTablet	1	2	3	4	5	6	7	8	9	10
Weight(gm)	0.52	0.51	0.52	0.52	0.52	0.51	0.53	0.52	0.52	0.50
Pass/Fail	Pass	Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Fail
No. ofTablet	11	12	13	14	15	16	17	18	19	20
Weight(gm)	0.53	0.51	0.49	0.50	0.53	0.52	0.49	0.50	0.52	0.50
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

- **Friability Testing:**

This test is used for checking the strength of uncoated tablets. It helps to determine physical strength of tablets when they're handled or during transportation. For this test, we use a machine called a 'Roche's Friabilator'.

Figure 15: Roche's Friabilator

The Friabilator has a drum or round plastic chamber. It's about 28 to 29 centimeters wideand 3.6 to 4 centimeters deep. Inside, there are a smaller ring in the middle that's about 2.5 to 2.55 centimeters wide. To test the tablets, first, we clean off any dust and weigh 10 tablets. Then we put them inside the chamber and spin it for 4 minutes at a speed of 25 rotations per minute. After spinning, we remove the tablets from chamber and weigh them again. The difference in weight indicates friability, and it can be measure in percentage. A good tablet will only lose less than 0.8% of its weight during this test.

$$\% \text{ Friability} = \frac{W1 - W2}{W1} \times 100$$

W1= Initial Weight =4.96

W2 = Final Weight = 4.90

Table 5: Friability of tablet

Batches	Batch A	Batch B	Batch C	Batch D
Friability (%)	4	4.2	2.4	0.5

- **Disintegration Test:**

Disintegration test is used to determine the time required for breaking of tablets when it placed in a liquid medium. The apparatus is used in this test is known as disintegration test apparatus. In this apparatus a water bath is filled with water up to the mark. In which 1000 ml beakers are Place into water bath. Inside these beakers, there's a rack holding six plastic tubes that are open at the top and have a 10mesh screen at the bottom. The bottom is covered with a 10-mesh screen. The basket rack assembly is suspected in liquid medium in 1000ml beakers. We fill the beakers with a liquid kept at 37°C. We place one tablet into each tube, and a clear plastic disk is put on top of each tablet, applying a little pressure. Then, the assembly moves up and down 30 times every minute.

We note down the time it takes for the tablet to completely break apart and fall through the screen.

Figure 16: Disintegration Apparatus

The wire mesh in the beaker place about 2.5 centimeters below the surface of the liquidand about 2.5 centimeters above the bottom of the beaker. The rate of disintegration varies from tablet to tablet.

- **Disintegration test for uncoated tablet**:

Put one tablet into each of the six tubes. We'lluse water as the liquid and kept at a temperature of 37°C. Then, we add a disc on top of each tablet and start the experiment. All six tablets should completely break apart within 15 minutes.

Table 6: Disintegration of tablet

Batches	Batch A	Batch B	Batch C	Batch D
Disintegration	20	18	11	15

- **Dissolution Test for Tablet:**

Dissolution testing is an important test used by pharmacopeias. It helps to predict the time required for a given amount of drug to be released into solution from a solid dosage formunder specified condition. This test gives us information about in-vitro drug release information. There are two main types of dissolution apparatus: USP Apparatus-I, which is the rotating basket type, and USP Apparatus-II, which is the paddle type. The dissolution test apparatus consists of a cylindrical vessel with hemisphere bottom and made of glass or transparent plastic which having 1000 ml volume capacity. The vessel partially immersed in water bath with maintaining the temperature at 37^{o} $^{+-}$05°C. The vessel has a cover with four holes: one for the shaft, another for inserting a thermometer, and the remaining twofor taking samples. The shaft is connected to a motor that can adjust its speed, rotating anywhere from 25 to 150 times per minute.

We started by adding 1000 ml of dissolution medium like distilled water, hydrochloric acid (pH 12), Phosphate buffer (pH 7.4)) into the vessel. Then, we place the vessel in a water bath and keep it at a constant temperature of 37°C. For paddle-type apparatus, we put the tablet directly into the vessel and stir it with the paddle. For basket-type apparatus, we place the tablet into a basket within the vessel. Next, we turn on the motor and set it to rotate at a certain speed, usually 100 rpm or as mentioned in the monograph. At specified times; we are withdrawing asample of the liquid and filter it. We replace the volume of liquid we've withdrawn with freshdissolution medium to keep the volume constant. We test these samples using analytical methods like UV or chromatography to measure how much of the drug has dissolved. The test will be considered acceptable if all 6 tablets are not less than Quantity (Q) specified in monograph + 5%. If it fails, additional 6 tablets are tested. The test will be considered acceptable if average of 12 tablets is equal to or greater than Q and no tablet is less than Q15%. If tablets still fail, additional 12 tablets are tested. The tablets are acceptable if average of 24 tablets is equal to or greater than Q, not more than 2 tablets are less than Q-15%.

Figure 17: Dissolution Apparatus

VII. RESULTS AND DISCUSSIONS:

For Powder Characteristics:

For the powder characteristics of powder, the result of bulk density, tapped density, compressibility index and flow properties of powder is mention in following table. In that experiment, powder having good flowing properties.

Table 7: Flow properties testing result of powder

Preformulation study	Result	Observation
Organoleptic study 1) Color 2) Odour 3) Taste	YellowishMilky Sweet and Milky	YellowishMilky Sweet and Milky
Bulk density	0.31 g/ml	-
Tapped density	0.41 g/ml	-
Carr's index	24.39 %	Passable

Hausner's ratio	1.32	Passable
Angle of repose	56.16	Very Poor

Result of Goat Milk Tablet:

From this experiment following result is obtained that shown in table. According to result Batch D having better result as compare to another batches. Hardness is one of the important criteria for chewable tablets. This tablet was targeted for school children; therefore, the hardness of the tablet cannot be too high resulting hard to consume or too low resulting poor physical properties of the tablet. According to the [1] for children mostly preferred 3-7 kp hardness. Within that experiment Batch D and Batch C having best hardness because in that two batches we had used hydroxypropyl Methylcellulose instead of Polyvinyl Pyrrolidone. Friability is also one of most m\important criteria for handling the tablet by children. So, in thatexperiment friability of Batch D tablet is good as compared to other batches. Disintegration of Batch C is too good as compared to other and batch D is also good.

Result of Goat Milk Tablet:

Batches	Thickness (cm)	Hardness (Kg/ cm^2)	FriabilityTest (%)	Disintegration Test (min)
Batch A	0.3	4.06	4	20
Batch B	0.4	5.03	4.2	18
Batch C	0.3	5.4	2.4	11
Batch D	0.3	5.75	0.5	17

VIII. CONCLUSIONS:

The idea of making goat milk tablets came about because schools childrenneeded a convenient way to provide goat milk to children. In this experiment goat milk tablet is prepared by direct compression method by improving hardness and disintegration.Within that experiment, we have concluded that goat milk tablet can be used as alternativeto the pure goat milk. The hardness and disintegration of goat milk powder can be improved by using direct compression techniques. Batch wise changes of binder and disintegrant also plays important roles to obtaining good hardness, disintegration and friability of the tablet. Based on this study, Batch D shows the best setting to produce the goat milk tablet using direct compression technique. This batch successfully improved thefriability, hardness and disintegration of goat milk tablet.

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