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Research Article

FORMULATION AND EVALUATION OF SIDDHA FORMULATION OF *THIRIPHALA* TABLET USING *THIRIPHALA* DECOCTION AS A NATURAL SYNERGISTIC BINDER

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ABSTRACT

The objective of the present study was conversion of *Thiriphala* chooranam into *Thiriphala* chooranam Tablet 500mg stable, palatable and patient convenient in swallowing and transportation by wet granulation method using *Thiriphala* decoction as a binder. Three formulations F1, F2, F3 were developed and evaluated for both precompression and post compression parameters. Among the formulations, F3 was shows the best results and all are within the limit as per Ayush guideline. Dissolution studies showed Maximum drug Release of 45.7% @ 60minutes in Phosphate Buffet PH 6.8. It indicates Maximum drug Release taken place in the intestine.

Key words: *Thiriphala* chooranam tablet, Siddha formulation, *Thiriphala* Kudineer, *Thiriphala* Decoction

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INTRODUCTION

Siddha system is one among the ancient system of Indian medicine (International Diabetes Federation, 2008). This system focuses on leading a healthy life style based on physical, emotional, psychological and social wellbeing. In AYUSH systems, the promotion of preventive approach to achieve the goal of being healthy is attained through holistic treatments.

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A pre-diabetic state (IFG, IGT and both) of dysglycemia is defined as IGT which has a strong association with insulin resistance and increased risk of cardiovascular pathology. IGT may precede type 2 diabetes mellitus by many years. It is also a risk factor for mortality (Engberg *et al*., 2009). *Thiriphala* chooranam tablet is a potent Kayakalpam drug rich in antioxidants and polysaccharides used in the ancient Science of Siddha. It consists of equal parts of the *Terminalia chebula* Retzr., *Emblica officinalis* Gaerth, *Terminalia bellerica* Linn. Kayakalpam herbs of Siddha possess natural antioxidants which play a vital role in preventing free radical formation and thus preventing NCD's like Pre-diabetes, Diabetes, Hypertension, Cancer and so on. Polysaccharides can have number of potential effects like anti-inflammatory, immune-stimulating, complement activation, anti-thrombotic, antidiabetic and infection protectant activity and many more (Thakur *et al*., 2009 & 2009; Xiao *et al*., 2002; Yeaman *et al*., 2001; Zjawiony *et al*., 2004). Many medicinal properties are attributed by *Thiriphala* such as anti-aging, antimutagenic, anti-cancerous, anti-inflammatory, antibacterial, antiviral, antioxidant, anti-anemic, antidiabetic, antiparasitic, anti-diarrhoeal, cardio protective, hepatoprotective, hypocholesterolaemic, radio protective, colon cleanser and gas distentioner (Sabu MC & Kuttan R, 2002; Ahmad *et al*., 1998; Jose *et al*., 2000; Naik *et al*., 2004; Sandhya *et al*., 2006; Kaur *et al*., 2005).

The most used and popular dosage form of *thiriphala* is chooranam (herbal powdered form) which meet several disadvantages such as low shelf life, deliquescence or hygroscopic nature, difficulty to swallow and misunderstanding of the correct dose, etc (Yeaman *et al*., 2001; Zjawiony *et al*., 2004). In recent days chooranam is formulated into tablets in order to fix the dose easily (Sabu MC & Kuttan R, 2002). Since, tablets are the most widely preferred solid dosage forms of medication that ensure rapid onset of action, increased bioavailability and good stability, (Ahmad *et al*., 1998; Jose *et al*., 2000) it was thought worthwhile to develop tablets of this formulation. Although an effort has already been made in past in this direction. The present study was focused into the formulation of *Thiriphala* chooranam tablet was planned using *Thiriphala* Kudineer as a natural synergic binder & its evaluation parameters to be investigated.

MATERIALS & METHODS

All the ingredients for the preparation of *Thiriphala chooranam* tablet (Figure 1, Table 1) were procured from the local market of of Chennai, Tamil Nadu, and India. The collected drugs were identified and authenticated at Department of Pharmacognosy, Siddha Central Research Institute (SCRI), Chennai, Tamil Nadu, and India.

METHODS

Pre formulation and post compression parameter testing is an investigation of physical and chemical properties of a drug substance and its formulation. It involves physical characterization, bulk characterization, drug excipient compatibility study, weight variation, thickness, hardness and friability.

LIST OF EQUIPMENTS:

Table 1. List of Equipments

S.No	Equipment	Manufacture Name
1.	Moisture Analyser	Sartorius
2.	Tapped Volumeter	Erweka
3.	Hot air oven	Remi
4.	Compression Machine	Erweka
5.	Hardness tester	Pfizer
6.	Thickness Apparatus	Vernier caliper
7.	Friabilator	Electrolab
8.	Electronic Weighing Balance	Shimadzu
9.	Disintegator	Electrolab
10.	Bruker	FTIR spectrophotometer

PRE-FORMULATION STUDIES

Pre-formulation activities range from supporting discovery's identification of new active agents to characterizing physical properties necessary for the design of dosage form. Critical information provided during pre-formulation can enhance the rapid and successful introduction of new therapeutic entities for humans. Pre formulation testing is an investigation of physical and chemical properties of a drug substance.

Physical Characterization of drug

Organoleptic properties

Colour: A small quantity of drug powder was taken in butter paper and viewed in well-illuminated place.

Taste and odour: Very less quantity of drug was used to get taste with the help of tongue as well as smelled to get the odour.

BULK CHARACTERIZATION LUBRICATED BLEND

a) Bulk Density: It refers to a measurement to describe packing of particles. Bulk density is used to determine the amount of drug that occupies the volume in mg/mL. It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weighed powder in to a measuring cylinder and the initial volume was noted. This initial volume is called bulk volume. From this, the bulk density is calculated according to the formula mentioned below. It is expressed in g/mL and is given by

$$\text{Bulk density } \left(\frac{\text{g}}{\text{mL}}\right) = \frac{\text{Weight of sample (g)}}{\text{Volume occupied by the sample (mL)}}$$

B) Tapped Density: Weighed quantity of drug was taken in a graduated cylinder. Volume occupied by drug was noted down. Then the cylinder was subjected to 500, 750 & 1250 taps in tap density tester According to USP, the blend was subjected for 500 taps. The percentage volume variation was calculated and subjected for additional 750 taps. The percentage variation was calculated and recorded.

$$\text{Tapped bulk density (g/cc)} = \frac{\text{Mass of powder (g)}}{\text{Tapped volume of the powder (cc)}}$$

c) Compressibility Index: Weighed amount of drug was transferred to 100ml graduated cylinder and subjected to 500,750 & 1250 taps in tap density tester. The difference between two taps should be less than 2%. The percentage of compressibility index was calculated using formula

$$\text{Compressibility Index (CI)} = \frac{V_i - V_t}{V_i} \times 100$$

Where, V_t = Tapped volume; V_i = Untapped volume

d) Hausner's ratio: It provides an indication of the degree of densification which could result from vibration of the feed hopper.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Table 2. Compressibility index& Hausner's ratio

S.No.	Compressibility Index (%)	Flow Character	Hausner Ratio
1.	≤10	Excellent	1.00–1.11
2.	11–15	Good	1.12–1.18
3.	16–20	Fair	1.19–1.25
4.	21–25	Passable	1.26–1.34
5.	26–31	Poor	1.35–1.45
6.	32–37	Very poor	1.46–1.59
7.	>38	Very, very poor	>1.60

e) Angle of repose: Angle that can be obtained between the free surface of a powder heap and horizontal plane. The angle of repose was measured by allowing the powders to fall over a graph sheet placed on horizontal surface through a funnel kept at a certain convenient height.

The height of the heap was measured and then circumference of the base of heap was drawn on a graph sheet with the help of a pencil. The radius of the circle obtained was measured. The angle of repose is given as, (United States Pharmacopeia, 2016)

- $\theta = \tan^{-1}\left(h/r\right)$
- θ = angle of repose;
- h = height of the heap;
- r =radius of the base of the heap.

Table 3. Angle of Repose

S.No	Angle of Repose (θ)	Type of Flow
1	25-30	Excellent
2	31-35	Good
3	36-40	Fair-aid not needed
4	41-45	Passable
5	>45	Very Poor

DRUG –EXCIPIENT COMPATIBILITY STUDIES

FT- IR Spectroscopy

FTIR spectroscopy method was used to find out the interaction between the drug and excipients used in the formulation. In this method, a physical mixture of *Thiriphala chooranam* and each excipients in the ratio of 1:1 were prepared and analysed the interference by the excipients using ATR method. Spectra were obtained for pure drug, excipients, drug and excipients, Perkin Elmer spectrum two and compared (Felton *et al*., 2007).

FORMULATION AND EVALUATION OF *THIRIPHALA* CHOORANAM TABLET 500MG

Stage: I Formulation and evaluation *Thiriphala* Kudineer or *Thiriphala* Decoction:

Thiriphala coarse Powder: Water 1: 10 ratio were taken and the blend was boiled to reduce the volume ¼ to its original volume. Then this content was filtered using the fibber cloth and the filtrate was collected for the further granulation process. The filtrate showed Pale Brown colour liquid with approximately 9.74% Solid content and freely soluble in water. Triphala decoction is observed to form an oily precipitate in organic solvent like ethanol and Chloroform.

Stage: II Formulation and evaluation of tablets (F1-F3)

Three *Thiriphala chooranam tablet* 500mg formulations were prepared by Direct and wet granulation method using *Thiriphala chooranam* Powder, *Thiriphala* Kudineer (binder). The active ingredients was weighed accurately, passed through sieve 40 mesh and mixed thoroughly with help of poly bag for 15mins. Solutions of the binding agent were prepared by adding *Thiriphala* Coarse Powder into water with boiling, stirring & filtering Process. The powder mass was wetted with the binding solution until the mass has the consistency of damp. The wet mass was passed through a 20 mesh screen. Collected wet granules was placed on large trays and allowed to drying with use of tray dryer. After drying, the granulation was reduced in particle size by passing smaller mesh screen and collected in polybag. The powder blends were evaluated for pre compression parameters like bulk density, tapped density, angle of repose, compressibility index and Hauser's ratio. The blends were compressed into tablets on a 16 station tableting machine and evaluated for post compression parameters.

- In formulation F1, the direct compression tried and it was observed that tablet showed poor compression property. The reason may be due to the lack of binding.
- In formulation F2, tried with Purified water as a Binder and we observed improper granulation
- Finally F3 formulation was optimized with *Thiriphala* Kudineer and the values shown below

Table 4. Formulations of *Thiriphala chooranam tablet*

Materials	F1	F2	F3
Thiriphala chooranam Powder	500mg	500mg	500mg
Purified Water		Q.S	-
Thiriphala Kudineer (ml)	-		0.1
Total weight	500mg	500 mg	500 mg

POST COMPRESSION PARAMETERS:

Hardness:

For all the formulations, the hardness was checked using the hardness tester like Monsanto Tester and recorded.

Thickness:

The thickness of formulations was determined using a Vernier caliper in mm and recorded.

Weight Variation test (U.S.P.):

Weight variation test to evaluate volumetric fill of die cavity. 20 tablets were weighed individually. Calculate average weight and compared the individual tablet weight to the average. The tablet passed the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Table 5. Weight variation limits

S.No.	Average Weight of Tablet	Percentage
1	80 mg or less	± 10%
2	More than 80 mg & less than 250 mg	± 7.5%
3	250 mg or more	± 5%

Friability

In all formulations, tablets were selected randomly and weighed. Tablets were then placed in friability testing apparatus i.e. Roche Friabilator and rotated at a speed of 25 rpm for 4 minutes. Tablets were then weighed and a friability value was determined. The difference in weight was noted and expressed as percentage friability of fabricated tablets was noted the Official limits not more than 1%.

% Friability = (W1 – W2)/W1 * 100

Disintegration Test (U.S.P.):

The disintegration apparatus contains 6 glass tubes that are long; open at the top and 10 mesh screen at the bottom end. To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of distilled water, at 37 ± 2^{0} C such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement. Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet. According to the test the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified. If any residue remains, it must have a soft mass.

Dissolution studies: In vitro dissolution of Tablets was studied in USP XXIV dissolution test apparatus 900 ml Different dissolution medium was used. The stirrer was adjusted to rotate at 50 rpm. The temperature of dissolution medium was maintained at 37 ± 0.5 ºC throughout the experiment. One Tablet was used in each test. Samples of dissolution medium (5 ml) were withdrawn by means of syringe fitted with pre-filter at known intervals of time and analyzed for drug release.

RESULTS & DISCUSSION:

PRE-FORMULATION STUDIES

Organoleptic characters

The organoleptic characters of *Thiriphala* chooranam tablet were studied. The study showed that the drug was a pale brown color and very slight bitter taste with odorless. The results were shown in the table 6.

Table 6. Organoleptic characters of *Thiriphala* chooranam tablet

S.No	Property	Results
1.	Organoleptic character	Color: pale brown Odor: odorless Taste: very slight bitter

BULK CHARACTERIZATION

The bulk density of lubricated blend (F3) was found to be 0.7546 gm/cc and the tapped density was found to be 0. 9122 gm/cc. Both the values were similar to the specific standard. The angle of repose was done as per the procedure and the value was 35°. The value indicated that the powder had good flow property and Excellent Compressibility Index & Hauser's ratio. The results were shown in the table. 7.

Drug - Excipients compatibility study

The FT-IR spectra of the *Thiriphala* chooranam tablet (500mg) and physical mixture of drug– excipient was recorded using FTIR spectrophotometer in order to check interaction between drug and excipient. The characteristic peaks *Thiriphala* chooranam tablet had appeared in the spectra without any markable change in the position in the spectra of drug-excipient. The results indicated that there was no chemical interaction between *Thiriphala* chooranam and excipients and suitability of the excipients in the formulation. The results were shown in the (Fig.1, 2, 3 and Tables 10, 11) (Williams WD, 1986; Stuart B, 2008).

Post compression parameters of optimized formulations of *Thiriphala* chooranam tablet (F3)

The optimized formulations of *Thiriphala* chooranam tablet (F4) was evaluated for post compression parameters like the average weight, thickness, disintegration time, Dissolution, hardness, friability the values were shown in (Fig.2 and Table 8, 9).

Table 7. Bulk characterization of lubricated blends of optimized formulation (F3)

Parameters	Results	Reference value	Flow property
Bulk density (gm/cc)	0.7546	-	-
Tapped density (gm/cc)	0.9122	-	-
Compressibility index (%)	10	≤ 10	Excellent
Hauser's ratio	1.08	1.00–1.11	Excellent
Angle of Repose (θ)	35	20-30	Passable

Table 8. Post compression parameters of optimized formulation (F3)

Average Weight	497.5 mg
Hardness	1.0 kg/cm^2
Thickness	4.52 mm
Friability	0.45%
Disintegration time	5 mins 35 sec
Dissolution studies	45.7 % @ 60 minutes Release in Phosphate Buffer PH 6 .8 26.7% @ 60 minutes Release in Water 28.9% @ 60 minutes Release in acid Medium

Table 9. Post compression parameters of optimized formulation (F4)

Weight Variation studies of *Thiriphala* Tablets						
S.N	**Iw (mg)**	**Aw (mg)**	**Iw-Aw**	**Iw-Aw/Aw**	**Iw-Aw/AwX100**	**Remarks**
1	495	497.95	2.95	0.01	0.59	√
2	509	497.95	11.05	0.02	2.22	√
3	499	497.95	1.05	0.00	0.21	√
4	498	497.95	0.05	0.00	0.01	√
5	491	497.95	6.95	0.01	1.40	√
6	498	497.95	0.05	0.00	0.01	√
7	497	497.95	0.95	0.00	0.19	√
8	492	497.95	5.95	0.01	1.19	√
9	508	497.95	10.05	0.02	2.02	√
10	504	497.95	6.05	0.01	1.21	√
11	498	497.95	0.05	0.00	0.01	√
12	500	497.95	2.05	0.00	0.41	√
13	502	497.95	4.05	0.01	0.81	√
14	494	497.95	3.95	0.01	0.79	√
15	490	497.95	7.95	0.02	1.60	√
16	497	497.95	0.95	0.00	0.19	√
17	495	497.95	2.95	0.01	0.59	√
18	500	497.95	2.05	0.00	0.41	√
19	492	497.95	5.95	0.01	1.19	√
20	500	497.95	2.05	0.00	0.41	√

Fig 1. FTIR Spectrum of *Thiriphala* Chooranam

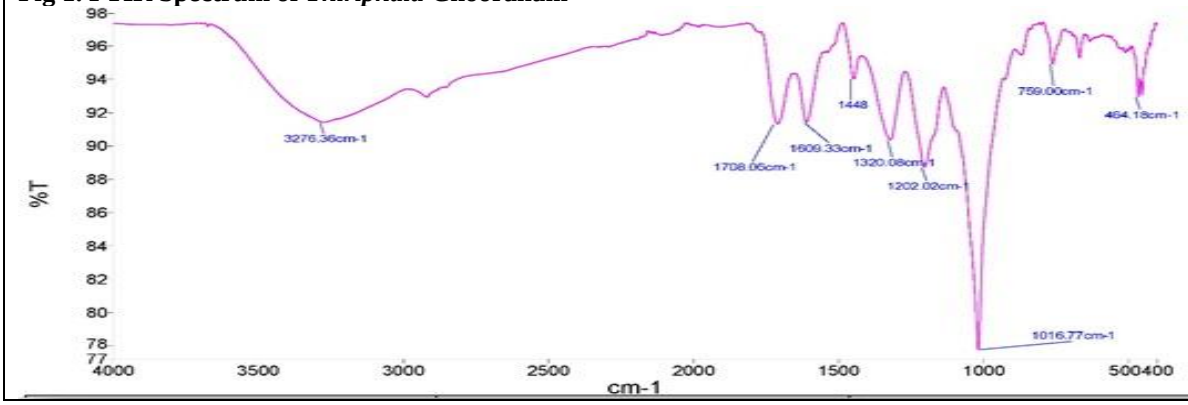

Fig 2. FTIR Spectrum of *Thiriphala* Kudineer

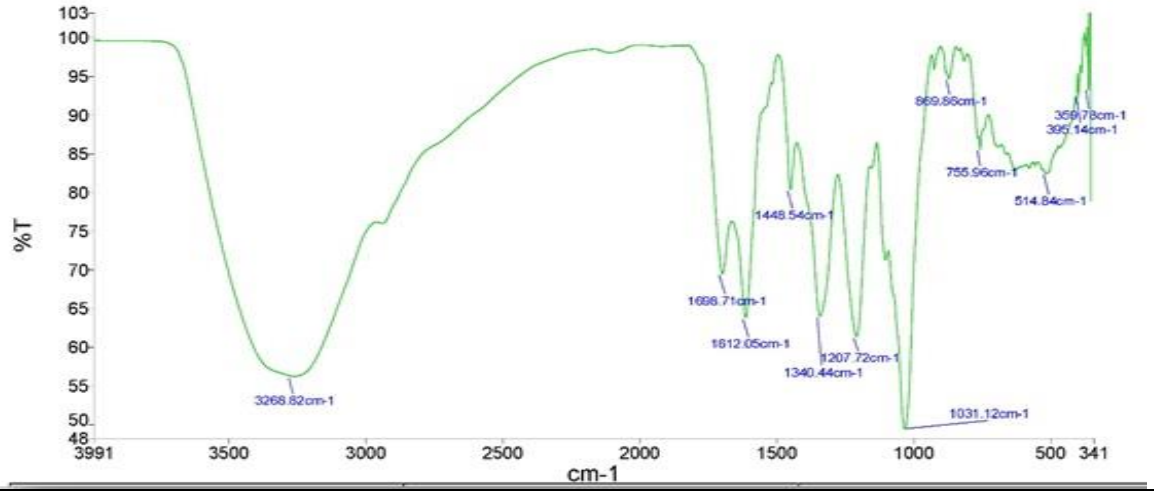

Table 10. The Drug and Excipients compatibility studies

***Thiriphala* choornam**		***THIRIPHALA* KUDINEER**		**COMPATIBLE / INCOMPATIBILE**
Band (cm-1)	**Interference**	**Band (cm-1)**	**Interference**	
3276	Alcohol/Phenol O-H Stretch	3268	Hydroxyl group, H-bonded OH stretch	**COMPATIBLE**
1708	C=O Stretch	1698	C=O Stretch	**COMPATIBLE**
1609	Aromatic C=C Bending	1612	Aromatic C=C	**COMPATIBLE**
1448	OH in-plane	1448	OH in plane	**COMPATIBLE**
1320	Phenol or tertiary alcohol, OH bend	1340	Phenol or tertiary alcohol, OH bend	**COMPATIBLE**
1202	C-N stretch	1207	CN stretch	**COMPATIBLE**
1016	C-O stretch	1031	C-O stretch	**COMPATIBLE**
759	CH out of plane bending	859	CH out of plane bending	**COMPATIBLE**
464	CH out of plane bending	755	CH out of plane bending	**COMPATIBLE**
		514	CH out of plane bending	**COMPATIBLE**
		395	CH out of plane bending	**COMPATIBLE**
		359	CH out of plane bending	**COMPATIBLE**

Fig 3. FTIR Spectrum *THIRIPHALA* KUDINEER + *THIRIPHALA*

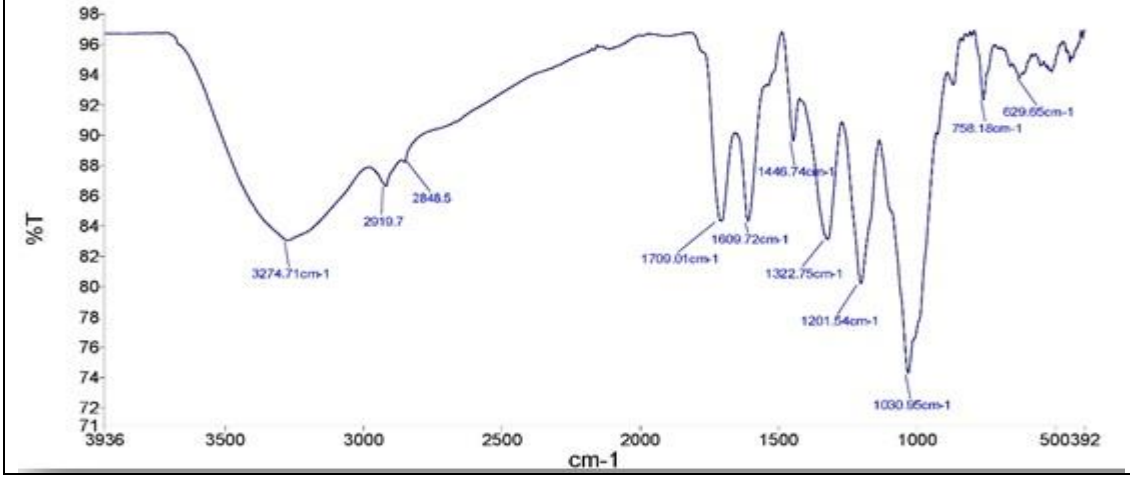

Table 11. The Drug and Excipients compatibility studies (FTIR Spectrum *THIRIPHALA* KUDINEER + *THIRIPHALA*)

S.No.	Band (cm-1)	Interference
1	3274	Hydroxyl group, H-bonded OH stretch
2	2919	C-H stretching vibrations for saturated aliphaticspecies
3	2848	C-H stretching vibrations for saturated aliphaticspecies
4	1709	C=C
5	1609	Aromatic ring stretch
6	1446	bending vibrations
7	1322	bending vibrations
8	1201	Tertiary amine, CN stretch
9	1030	Primary amine, CN stretch
10	758	CH out of plane bending
11	629	CH out of plane bending

DISCUSSION AND CONCLUSIONS

Among three formulation (F3) *Thiriphala* chooranam tablet **(**500mg) showed good pre-formulation and post compression parameters which were well within the limits. Bulk density was tested and free flow property of the powder has been proved. Drug excipient compatibility revealed there were no chemical interaction between the drug and excipients and the excipient is suitable for the formulation. Dissolution studies showed Maximum Release of 45.7% @ 60minutes in Phosphate Buffet PH 6.8. It indicates Maximum drug Release in the intestine also economical for scale up process. This tablets minimize improper drug administration, enhance the therapeutic efficiency and for better patient compliances from previous traditional practice. The study will be extended to *in-vitro anti-diabetic and clinical* evaluation.

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