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Comparative Evaluation of Flow of Pharmaceutical Powders and Granules of Triphala Churna

Ms. Chetana D. Patil[1], Mr. Anil A. Aldar[2], Ms. Swati R. Devkar[3]

[1]Principal, Jaywant Institute of Pharmacy Wathar, Karad, Maharashtra, India
[2]Department of Chemistry, GIPER, Limb, Satara, Maharashtra, India
[3]Lecturer, Jaywant Institute of Pharmacy Wathar, Karad, Maharashtra, India

ABSTRACT

The objective of this work was the conversion of Triphala churna into stable, palatable and patient acceptable granules to swallow conveniently by dry granulation methods, using suitable binding agents. The formulations of churna granules were optimized on the basis of acceptable flow properties of granules. These properties of developed herbal churnas are compared with corresponding marketed product. Developed churna granules were tested for organoleptic evaluation and physiochemical evaluation such as moisture content, total ash, Acid insoluble ash, water soluble ash, Alcohol soluble extract, water soluble extract by human volunteers. Dry granulation process will improve flow and compression characteristics, reduce segregation, improve content uniformity, and eliminate excessive amounts of fine particles. The dry granulation technology that gives good results based on evaluation of different granule properties, namely the Carr‟s index, Angle of repose and tapped bulk density.

KEYWORDS: *Triphala churna, granules, organoleptic studies, Flow properties*

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INTRODUCTION

Powder flow is a key requirement for pharmaceutical manufacturing process. Tablets are often manufactured on a rotary multi-station tablet press by filling the tablet die with powders or granules based on volume. Thus, the flow of powder from the hopper into the dies often determines weight, hardness, and content uniformity of tablets. In case of capsules manufacturing, similar volume filling of powders or granules is widely used. Understanding of powder flow is also crucial during mixing, packaging, and transportation. And thus, it becomes essential to measure the flow properties of these materials prior to tabletting or capsule filling There are various methods available to measure the powder flow. The measurement of angle of repose[1], bulk density, tapped density[2] ,Carr‟s compressibility index[3], or Hausner ratio[4] . Churnas are fine powder of Ayurvedic drug or drugs. Among all Ayurvedic dosage forms churnas are most prescribed dosage forms. Some of the churnas are having large dose, which makes inconvenience to the patients to swallow. Some of the churnas stick to the tongue and oral cavity due to inherent adhesive nature. Patients are showing less interest to take herbal churnas orally because of their astringent, bitter and pungent taste. Churnas being in powder form also suffer stability due to their hygroscopicity. Triphala churna is a powder preparation of three myrobalan fruits, (i) Amalaki (EmblicaofficinalisGaertn) (ii) Haritaki (Terminaliachebula Retz) and (iii) Bibhitaki (Terminaliabelerica, Roxb) in equal proportions [5].

It is widely prescribed as a bowel regulator, purgative, and as an immunity booster. Triphala formulation is traditionally prescribed in the form of powder or churna, a powder of equal proportions of dried fruits of all the three ingredients mentioned above. Ayurvedic formulary of India specifies the dose of Triphala powder to be 3-6 gm per day. But swallowing such large amounts of powder is difficult to the patients.[6] Bulkiness of herbal formulations

shall be reduced by converting the herbal powder into granules by slugging or compaction methods; hence their density can be improved. Dry granulation is energy efficient and suitable for processing pharmaceutical agents that are sensitive to moisture and heat. Slugging technology is to compact the dry powder into large size tablets (called slugs) using heavy duty compression machines under higher force. The slugs so prepared without any wet granulating agents are then size reduced to obtain granules of higher density than original powder.

Taste is an important factor governing the patient compliance. It has gained importance as the most of the drugs are administered through oral route. Administration of unpalatable churnas has hampered by their unpleasant taste particularly in case of paediatric and geriatrics. Unpleasant taste and odour can be masked by using sweetening and flavouring agent. Hence in the present study, we aimed at conversion of Triphala churna into stable, palatable and patient acceptable granules to swallow conveniently by using dry granulation methods and wet granulation. Granules will also be formulated with permitted sweeteners, flavours and anticaking agents and they will be evaluated appropriately including physical stability studies. Triphala churna was prepared by using different herbal ingredients like Amalaki, Bibhitaki, Haritaki,

Figure No:-1-Dried fruit of Amala Figure No:-2 Fresh fruit of Amala

Figure No:-3 Fresh fruit of bibhitaki Figure No:-4 Dried fruit of bibhitaki

Figure No:-5 Dried fruit of haritaki Figure No:-6 Fresh fruit of haritaki.

Chemical Constituents-

It contain vitamin c, Fat,Phyllemblin,Tannin,Pectin,, B-sitosterol,galic acid, chebulasic acid, mannitol, glucose, galactose, fructose, andramnose, the triterpenes, arjunglucoside I, arjungenin, and the chebulosides I and II. Other constituents include a

coumarin conjugated with gallic acids called chebulin, as well as other phenolic compounds including ellagic acid, 2,4-chebulyl-β-D-glucopyranose, chebulinicacid, gallic acid, ethyl gallate, punicalagin, terflavin A, terchebin, luteolin, and tannic acid [7, 8].

MATERIALS AND METHODS

Raw Materials:

Dried Myrobalan fruits of Amalaki (Emblicaofficinalis, Gaertn), Haritaki (Terminaliachebula, Retz) and Bibhitaki (TerminaliabelericaRoxb). Avicel,, Methyl cellulose, Hydroxyl propyl methyl cellulose, starch paste, calcium carbonate, microcrystalline cellulose. Aerosil, croscarmellose sodium, Sodium Saccharin, Propyl and methyl parabens and Vanillin were used.

Procurement of Herbs:

Three herbal ingredients of Triphala churna were purchased in the local market and the same were authenticated by Deshpande madam, Dept. of Botany, Y.C .Institute of science, Satara.

Preparation of churna:

Formulation of churna was done as per Ayurvedic Formulary of India. Then all the three ingredients are mixed in equal proportion by using planetary mill. Obtained powders of Amla, Bibhitaki and Haritaki passed through sieve no. 60[9]

Organoleptic Evaluation:

Organoleptic evaluation refers to the evaluation of formulation by colour, odour, taste etc.

Parameters	Marketed formulation	Prepared formulation
Appearance	Powder	Powder
Colour	Yellowish	Yellowish
Odour	Characteristic	Characteristic
Taste	Salty	Salty

Table No.1: Organoleptic Properties of TriphalaChurna.

Determination of Physicochemical Properties :

➢ Determination of Moisture Content by LOD

Each ingredient (1 gm) was taken in petridish individually and noted the weight (W1).

Ingredients were dried in a hot air oven at 100 ^{0}C for 3 hours. Final weight (W2) was noted and the loss in weight is considered as moisture content.

Moisture content was determined using the formula = (W1 – W2 /W1)100

➢ Determination of Total Ash

About 1 g accurately weighed Triphala churna was taken in tarred silica dish and incinerated at a temperature not exceeding 450 ºC until free from carbon, then cooled and weighed.

Total Ash %= (Z – X/ Y)100

Where, X=Weight of empty dish, Y=Weight of Triphala churna taken, Z=Weight of empty dish + ash (after completion of incineration).

➢ Determination of Acid Insoluble Ash

To the crucible containing total ash, 25 ml of dilute hydrochloric acid is added. The insoluble matter on an ash less filter paper (Whatman 41) is collected and washed with hot water until the filtrate is neutral. Filter paper containing the insoluble matter is transferred to the original crucible, dried on a hot-plate and ignited to get constant weight in an incinerator. Allowed the residue to cool for 30 minutes and weighed without delay.

Acid Insoluble Ash = (a/y)100

Where, a= weight of acid insoluble residue, y= weight of Triphala churna used.

➢ Determination of Water Soluble Ash

Total ash is boiled for 5 minutes with 25 ml of water; insoluble matter is taken on an ash less filter paper, washed with hot water, and ignited for 15 minutes at a temperature not exceeding 450 ºC. The weight of the insoluble matter is subtracted from the weight of the ash; the difference in weight represents the water soluble ash.

Water Soluble Ash = **(a-b/y)100**

Where, a=weight residue after incineration, b=weight of water insoluble residue,

y= weight of Triphala churna used.

➢ Determination of Alcohol Soluble Extraction

Macerated 5 g of the dried Triphalachurna with 100 ml of alcohol in a closed flask for twenty-four hours, shaked frequently during six hours and allowed to stand for eighteen hours. Filtered rapidly, taking precautions against loss of solvent, evaporate the filtrate to dryness in a tarred flat bottomed shallow dish, and dried at 105 ºC, to constant weight and weighed. Calculated the percentage of alcohol soluble extraction

Determination of Water Soluble Extraction

Procedure followed is similar to determination of alcohol soluble extractive, using chloroform-water instead of alcohol.[10]

Physical Characters:

➢ Bulk density and Tapped density :

Bulk density refers to a measure used to describe the packing of particles or granules. It was determined by taking 10g of churna in a graduated measuring

cylinder and tapped on a wooden surface. The initial volume and the tapped volume was noted. The bulk density and tapped density was calculated using the formula.

Bulk density = **M/V0**

Tapped density = **M/V**

➢ **Angle of Repose :**

Angle of Repose has been used as an indirect method of quantifying powder flow ability because of its relationship with interparticle cohesion. It was determined by using funnel method. The powder was allowed to flow through a funnel fixed on a stand to form a heap and the angle of repose was calculated using the formula

Angle of repose = $\theta = \tan^{-1}(h/r)$

Where, h = Height of heap

r =Radius of heap

➢ **Hausner's Ratio :**

Hausner's ratio is related to inter particle friction and as such can be used to predict the powder flow properties. It can be calculated using formula

Hausner's Ratio = **Tapped density/Bulk density**

➢ **Compressibility/Carr's Index :**

Carr's index is an indirect method of measuring the powder flow from bulk density. It was calculated using the formula

Carr's Index = **Tapped density-Bulk density/Tapped density.**

Dry Granulation Technique:

Dry granulation processes create granules by light compaction of the powder blend under low pressures. The compacts so-formed are broken up gently to produce granules (agglomerates). This process is often used when the product to be granulated is sensitive to moisture and heat. Dry granulation can be conducted on a tablet press using slugging tooling or on a roll press called a roller compactor. Dry granulation equipment offers a wide range of pressures to attain proper densification and granule formation. It is simpler than wet granulation, therefore the cost is reduced. However, this method often produces a higher percentage of fine granules, which can compromise the quality or create yield problems for the tablet. Dry granulation requires drugs or excipients with cohesive properties, and a 'dry binder' may need.

Ingredients	Quantity (gm)
Triphala churna	50
Calcium carbonate	5
Croscarmellose sodium	1
Vanillin	5
Saccharin sodium	0.5
Propyl paraben	0.05
Methyl paraben	0.05
Magnesium stearate	0.5
Talc	2.5
Mannitol	0.5
Aerosil	1

Table No.2: Ingredients of Triphala Churna Granules by Dry granulation

Wet Granulation Technique:

Wet granulation is a process of using a liquid binder to lightly agglomerate the powder mixture. The amount of liquid has to be properly controlled, as over-wetting will cause the granules to be too hard and under wetting will cause them to be too soft and friable. Aqueous solutions have the advantage of being safer to deal with than solvent-based systems but may not be suitable for drugs which are degraded by hydrolysis.

Procedure:

The active ingredient and excipients were weighed and mixed. The wet granulate was prepared by adding the liquid binder–adhesive to the powder blend and mixing thoroughly. Examples of binders/adhesives include aqueous preparations of corn-starch, natural gums such as acacia, and cellulose derivatives such as methyl cellulose, gelatine, and povidone. The damp mass was Screened through a mesh to form pellets or granules. Granules were dried by conventional tray-dryer or fluid-bed dryer. Dried granules were passed through a screen of smaller size than the one used for the wet mass to create granules of uniform size. Low shear wet granulation processes use very simple mixing equipment, and can take a considerable time to achieve a uniformly mixed state. High shear wet granulation processes use equipment that mixes the powder and liquid at a very fast rate, and thus speeds up the manufacturing process. Fluid bed granulation is a multiple-step wet granulation process performed in the same vessel to pre-heat, granulate, and dry the powders. It was used because it allows close control of the granulation process.[12]

Ingredients	Quantity (gm)
Triphala churna	50
Starch paste	5
Croscarmellose sodium	1
Vanillin	5
Saccharin sodium	0.5
Propyl paraben	0.05
Methyl paraben	0.05
Magnesium stearate	0.5
Talc	2.5
Mannitol	0.5
Aerosil	1

Table No.3: Ingredients of Triphala Churna Granules by Wet granulation

RESULTS AND DISCUSSION

Moisture content, Total ash value, water soluble ash, acid insoluble ash, water soluble extract and alcohol soluble extract of Triphala churna are determined and their values are mentioned in table no.4. Precompression parameters of triphala churna values are shown in Table no.5

Sr. No	Parameters	Formulated Value (%)	Marketed Value (%)
1	Moisture content	0.12	0.77
2	Total ash	0.41	0.42
3	Acid insoluble ash	0.05	0.06
4	Water soluble ash	0.22	0.24
5	Alcohol soluble extract	0.17	0.18
6	Water soluble extract	2.01	2.04

Table No.4: Pre-Compression Physical evaluation of Triphala churna

Sr. No	Parameters	Formulated Result	Marketed Result
1	Bulk density(gm/ml)	0.58	0.66
2	Tapped density(gm/ml)	0.76	0.90
3	Angle of repose	43.68	39.69
4	Hausner's ratio	1.31	1.36
5	Carr's index(%)	25.71	26.73

Table No.5: Pre-Compression Parameters of Triphala Churna

Figure No:-7 Triphala churna powder, slugs and granules (left to right) by dry granulation

Figure No:-8 Granules by wet granulation

Sr. No	Parameters	Dry granulation	Wet granulation
1	Bulk density(g/ml)	0.66	0.52
2	Tapped density(g/ml)	0.76	0.62
3	Angle of repose	22.77	19.64
4	Hausner's ratio	1.15	1.18
5	Carr's index(%)	10.26	15.84

Table No. 6: Comparative Evaluation

DISCUSSION:

Triphala churna is converted into its granules by using dry granulation and wet granulation method by using binding agents such calcium carbonate and starch paste Starch. Croscarmellose sodium is used as disintegrating agent. Saccharin sodium and Vanillin are used as sweetening and flavouring agents, respectively. Propyl and methyl parabens are added for the purpose of preservation. Magnesium stearate and talc are served as lubricants, mannitol is a cooling agent. Aerosil functions as anti-caking agent to stabilize the formulation. Formulations of Triphala churna are mentioned in the Table no.2 and Table no.3 Dry granulation process will improve flow and compression characteristics, reduce segregation, improve content uniformity, and eliminate excessive amounts of fine particles. Dry granulation technology that gives good results based on evaluation of different granule properties, namely the Carr's index, Angle of repose and tapped bulk density as compared to wet granulation. Comparative evaluation of Triphala churna granules by dry and wet granulation was determined and the results are mentioned in the Table no.6.

CONCLUSION:

Thus it is concluded that present study confirms the use of dry granulation method to convert Triphala churna into granules. Dry granulation method improves the flow properties of the Triphala churna granules. Among the binding agents used calcium carbonate produced granules with suitable hardness and good flow properties. Therefore, suitable formulation strategy can overcome the unacceptability of Triphala churna by consumers.

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