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Formulation and Evaluation of Tablets from *Amrita Guduchi* Churna by Wet Granulation Method

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Abstract

Amrita guduchi churna is a well-known polyherbal Ayurvedic preparation used to treat indigestion, constipation, diarrhea, liver disorders, diabetes mellitus, immunity booster,anaemia, liver disorders, skin diseases, dyspepsia and piles. The objective of this study was to improve patient compliance, dosage uniformity and reduce adulteration of churna by formulating it into a tablet. Granulation was necessary in order to improve flow properties and organoleptic characteristics of churna. Tablets were prepared by wet granulation. Starch solution was used as binding agent, sodium benzoate as preservative, crospovidone as superdisintegrant, talc as glidant and magnesium stereate as lubricant. Pre formulation studies showed that churna is having poor flow property. Hence wet granulation technique was adopted for tablet preparation. Tablets were evaluated for hardness, friability, weight variation, tensile strength and disintegration time. From the results it can be concluded that patient compliance of churna can be improved by suitable formulation strategies. And the quality of Amrita Guduchi Churna tablets prepared by the wet granulation method using different binders, namely, polyvinyl pyrrolidone (PVP), and Starch solution. Hardness, tensile strength, and disintegration time evidenced that the Starch solution appeared to be the best for Amrita Guduchi Churna tablet than PVP. It was found that the strength of inter- and intra granular forces plays key role in maintaining quality of tablets. All parameters are dependent on the type, quality, concentration and degree of spreading of a binder.

Keywords: Granulation, Patient compliance ,Amruta Guduchi Churna tablet.

Introduction

Churnas are preparations comprising of fine powders of drugs and may be simple or compound. Amrita guduchi churna is a Ayurvedic herbal formulation mentioned in the Ayurvedic Formulary of India with the reference of Charakasamhita (Chikitsasthanaadhyaya 16; 70-71)1. It has some main chemical constituents like Vayasthapana, daha-prashamana, trishna nigraha, triptighna, stanyashodhana, bhavanrakasha, guduchyadi, patoladi, vali, panchamoola, kakplyadi, Antioxidants like ascorbic acid, lycopene, caratene. Alkaloids like berberine, choline, tinosporine, tembetarine. Glycosides like tinocordisides, syringin, pregane glycosides and beta sitosterol . Amrita guduchi churna is used to treat indigestion, constipation, diaareha, immunity booster, diabetes mellitus, anaemia, liver disorders, skin diseases, dyspepsia and piles. Patients show less interest in administering churna as they stick on to throat and tongue and also because of their bitter and pungent taste. In addition to that, it is difficult to carry them while travelling, dosage uniformity is poorly regulated and rate of adulteration is high[4]. In order to overcome these

problems, Amrita guduchi churna was formulated into tablets in different concentrations of superdisintegrant and binders.Tablet was prepared by wet granulation technique. Granulation was performed to improve flow properties and organoleptic characteristics of churna. Starch solution was used as binding agent, sodium benzoate as preservative, crospovidone as super disintegrant, talc as glidant and magnesium stereate as lubricant.

A tablet is a pharmaceutical dosage form which comprises of a mixture of active substance known as drug and excipients, usually in powder form, which is pressed or compacted into a solid dose. The excipients can include diluents, binders or granulating agents, glidants (flow aids) and lubricants to ensure efficient tableting, disintegrants to promote tablet break-up in the digestive tract; sweeteners or flavors to enhance taste, and pigments to make the tablets visually attractive. The compressed tablet is by far the most widely used dosage form, having advantages for both producer and user.[1, 2]

The properties of the tablet (e.g. mechanical strength, disintegration time and drug release characteristics) are affected by both the properties of the constituent materials and the manufacturing process. Excipients such as diluents, binders and lubricants are generally needed in a formulation in order to facilitate the manufacturing process, but also to ensure that the resulting tablets have the desired properties. For instance, tablets should be sufficiently strong to withstand handling during manufacturing and usage, but should also disintegrate and release the drug in a predictable and reproducible manner. It is hence important to choose the appropriate excipient and manufacturing process when developing a new tablet formulation.[3- 4]

Material and Method:

Amrita Guduchi Churna was purchased from local Ayurvedic medical shop. Cross povidone, starch, sodium benzoate, talc, magnesium stearate was purchased from S.D Fines Chem. Ltd., Mumbai. All other ingredients, reagents and solvents were of analytical grade.

Preparation of Granules from *Amrita guduchi* Churna

Granules from churna was prepared by adding 10% starch solution along with sodium benzoate and mixed thoroughly until a coherent damp mass was obtained. The wet mass was then passed through sieve no.10 to obtain uniform granules. This was then dried in a steam tray drier till LOD is below 5%w/w. The dried mass is again passed through sieve no.10 to obtain granules.[3]

Table No : 1 Composition of *Amrita guduchi* churna tablet

Formulation code	F-1	F-2	F-3	F-4
Amrita guduchi churna (mg)	500	500	500	500
Sodium bezoate (mg)	0.42	0.42	0.42	0.42
Starch (mg)	48.58	39.58	33.58	35.58
Talc (mg)	18	18	18	18
Crospovidone (mg)	12	18	21	25
Magnesium stereate (mg)	21	21	21	21
Total (mg)	**600**	**600**	**600**	**600**

Preformulation Studies

Determination for powder flow property's

a. Angle of Repose

Angle of repose is defined as the maximum angle possible between the surface of the pie of powder and horizontal plane. Angle of repose was determined by funnel method in which the prepared blend was poured through the sides of funnel, the lower tip of which is 2.00cm above

the hard surface. It is performed to determine the flow property of powder done by the funnel method. The powder mass was allowed to flow through the funnel orifice, kept vertically to a plane paper kept on horizontal surface, giving a heap angle of powder on a paper. The diameter of the powder cone was measured. The blend was poured until the upper tip of the heap touched the lower tip of the funnel. Radius of the heap (r) was measured. The study was done three times3

Angle of repose was calculated by the formula:

$\Theta = \tan^{-1}(h/r)$

Where,

Θ is the angle of repose

h is the height of the pile in cm

r is the radius of the pile in cm

b. Bulk density (ρb)

About 50g of blend was weighed and filled into a graduated measuring cylinder. Initial volume was noted. Bulk density was calculated by the formula3, It is the ratio of total mass of powder to the bulk volume of powder. Accurately weighed 5 g of the churna was placed in a 10 ml graduated measuring cylinder. Initial volume was observed. The cylinder was tapped initially 100 times. The tapped volume was measured to the nearest graduated unit. Again the tap volume was measured to the nearest graduated unit. The D_b and D_t were calculated in g/ ml using following formulae,

$D_b = M/V_b$(1)

$D_t = M/V_t$ (2)

Where M = mass of the powder

V_b= bulk volume of powder

V_t = tapped volume of the powder

D_b = bulk density

D_t = tapped density

Bulk density =final Weight of the granule/Initial volume of the granule.

c. Tapped density (ρt)

About 50g of blend was weighed and filled into a graduated measuring cylinder and tapped 100 times. The final volume was noted. Tapped density was calculated by the formula3,

Tapped density = Weight of the granule / Final volume of the granule.

d. Carr's index

The Carr's index denotes the compressibility of a powder. It is determined by measuring bulk density and tapped density of the powder. Carr's index is calculated by the formula3,

Carr's Index = Tapped density – Bulk density X 100 / Tapped density

e. Hausner's ratio

Hausner's ratio is an indication of ease of powder flow. It is calculated by the formula3,

Hausner's ratio = Tapped density / Bulk density

Preparation of Churna tablets from granules

Granules were lubricated with talc and magnesium stearate by blending manually in a polyethylene bag. The lubricated granules were then compressed on a rotary tablet punching machine3.

Determination of organoleptic characters of tablets

Organoleptic characters like colour, odour, taste, shape and texture of the formulations were noted3.

Determination of Post compression parameters

a. Hardness test

Hardness of the tablet of each formulation was determined using Monsanto Hardness tester. It is expressed in kg/cm2 . Three tablets were randomly picked from each formulation and the mean and standard deviation values were calculated3.

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \times 100$$

b. Friability test

The friability of the tablets was measured in a Roche friabilator (Camp-bell Electronics, Mumbai). Tablets of a sample of 20 tablets are dusted in a drum for a fixed time (100 revolutions) and weighed (W) again. Percentage friability was calculated from the loss in weight as given in equation as below. The weight loss should not be more than 1%. Determination was made in triplicate3.it is caluclated by using formula

c. Weight variation test

This test was performed to maintain the uniformity of weight of each tablet, which should be in the prescribed range.20 tablets were selected randomly from the lot and

weighted individually to check for weight variation3.Not more than two of individual weight deviates from the average weight. The weight data from the tablets were analyzed for sample mean and percent deviation.

d. Thickness test

Thickness of the tablet of each formulation was determined using Vernier caliper. It is expressed in mm. Three tablets were randomly picked from each formulation and the mean and standard deviation values were calculated3.

e. Disintegration test

6 tablets from each formulation were randomly selected and disintegration study was carried out in a disintegration test apparatus using 900ml of 0.1N HCl as disintegration medium. The study was continued until all parts of the tablet were passed through the sieve3.

Results

Flow property of churna as well as granules were studied by determining its bulk density, tapped density, angle of repose, carr's index and hausner's ratio and found to be in passable and excellent range respectively. The results are shown in table no 2 and 3 .Organoleptic characters such as colour, odour, taste and shape of the tablet were studied and reported with descriptive terms. The results are shown in table no 4.Post compression parameters such as hardness, friability, weight variation, thickness and disintegration study were carried out using suitable apparatus and tabulated the results in table no 5.

Table No. 2: Flow properties of Amrita guduchi churna

Sl. no	Flow property	Amrita guduchi churna
1).	Bulk density	0.97 ± 0.23 (gm/ml)
2).	Tapped density	1.18 ± 0.19 (gm/ml)
3).	Angle of repose	36.23 ± 0.15

Table no 3: Preformulation studys of granules

Formulation code	F-1	F-2	F-3	F-4
Bulk-density (gm/ml)	0.100	0.102	0.108	0.124
Tapped-density (gm/ml)	0.145	0.144	0.138	0.136
Angle of repose	27.46	28.34	26.19	24.25
Carr's index	24.47	29.46	20.24	18.13
Hausner's ratio	1.34	1.42	1.28	1.22

Table no 4: Organoleptic Character's of churna tablet

Sl. no	Parameter's	Description
1).	Colour	Brown
2)	Odour	Characteristics
3).	Taste	Slightly bitter
4).	Shape	Round

Table no 5: Post compression parameters of churna tablets

Formulation code	Hardness (kg/cm2)	Friability (•\•)	Weight variation (•\•)	Thickness (mm)	Disintegration time (sec)
F-1	3.5 ± 0.33	0.720	600.6 ± 2.20	3.65 ± 0.23	20.50
F-2	5.7 ± 0.38	0.275	600.8 ± 2.42	3.79 ± 0.06	19.80
F-3	4.9 ± 0.26	0.492	599.8 ± 2.90	3.85 ± 0.15	21.45
F-4	4.0 ± 0.35	0.740	600.2 ± 2.38	3.80 ± 0.12	17.20

Conclusion

Most of ayurvedic solid medicines are in form of churnas ,the problems associated with churna such as , dose measurement, difficulty in carrying and disperse during travelling , administration to pediatrics and geriatrics patients can be overcome by formulating into tablets , Initially preformulation studies like Compressibility,Hausners ratio,Angel of repose,carrs index are carried on churna powder to find out the suitability of churna powders for direct compression in to the tablets the preformulation results revealed that churnas are not free flowabel and not fit for direct compression ,to improve the flow properties of churna ,directly compressible diluents like fast flow lactos PVP,starch solution and encompress were included in this formulation however ,incorporation of directly compressible diluents did not show any improvement in the flow properties of churna ,therefore it was decided to use the wet granulation method or technique to prepare Amrita guduchi churna tablet. Navayasa churna was prepared and

Churna showed poor flow properties and so, to improve the flow characteristics churna was converte into granules.For each type of formulation, blends of API and excipients were prepared and evaluated for various parameters. Tablets were developed by wet granulation method and each tablet weighed 600mg.

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