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DEVELOPMENT OF A POLY HERBAL SOLID DOSAGE FORMULATION USING AMLA WITHANIA AND TULSI EXTRACT IN DIFFERENT RATIO

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ABSTRACT

The aim of present study was to develop a polyherbal solid dosage formulation using Amla Withania and Tulsi extract in different ratio. Polyherbal formulation was developed by using well documented medicinal plants like Amla fruit, Withania root and Tulsi aerial part. The extracts were prepared by using solvents like 60% ethanol for Amla fruit, 50% ethanol for Withania root and pure ethanol for Tulsi aerial part. After extraction granules were prepared with help of extracts and excipients by using wet granulation technique and granules were evaluated by different methods i.e. Physical appearance of granules, Flow property, Fines, Loss on drying, Bulk density, Tap density, Hausner ratio, Carr's index and Angle of repose. Finally polyherbal tablet was formulated and evaluated by using different methods like Physical appearance of tablets, Thickness of tablets, Weight variation, Hardness, Friability and disintegration.

KEYWORDS: Amla fruits, Withania roots, Tulsi aerial parts, Extract, Formulation, Evaluation.

INTRODUCTION

Emblica officinalis Gaertn. Also known as *Phyllanthus emblica linn.*, Family- Euphorbiaceae. It is found both in the wild and cultivated state, Common in the mixed deciduous forests in India. Fresh fruit is globose, depressed, shining yellowish green when ripe. Six vertical furrows are distinct. Taste sour and astringent followed by delicately sweet. Major constituents are Vitamin C (ascorbic acid-2%); Tannins (5%) viz., gallic acid, ellagic acid, phyllemblic acid and emblicol. Others: Alkaloids viz., phyllantidine and phyllantine;[1,2] Pectin and Minerals. The fruits are useful in diabetes, cough, asthma, bronchitis, cephalalgia, ophthalmopathy, dyspepsia, colic, flatulence, hyperacidity, peptic ulcer, erysipelas, skin diseaes, leprosy, haematemesis, inflammations, anaemia, emaciation, hepatopathy, jaundice, strangury, diarrhoea, dysentery, haemorrhages, leucorrhoea, menorrhagia, cardiac disorders, intermittent fevers and greyness of hair.[3,4]

Withania somnifera, also known as Ashwagandha, Indian ginseng, Winter cherry, belongs to the family- Solanaceae. Whose roots are commonly used in various traditional formulations for adaptogenic properties. It grows as a stout shrub that reaches a height of 170 cm. It bears yellow flowers and red fruit, though its fruit is berry-like in size and shape. Ashwagandha grows prolifically in India, Nepal, Pakistan, Sri Lanka and Bangladesh. It is commercially cultivated in Madhya Pradesh. The main constituents of *Ashwagandha* are alkaloids and steroidal lactones. Among the various alkaloids, withanine is the main constituent. The other alkaloids are somniferine, somnine, somniferinine, withananine, pseudo-withanine, tropine, pseudo-tropine, 3-a-gloyloxytropane, choline, cuscohygrine, isopelletierine, anaferine and anahygrine. Two acyl steryl glucoside viz. sitoindoside VII and sitoindoside VIII have been isolated from root. It is used as immunomodulatory,[5] adaptogen, aphrodisiacs, diuretics and for treating memory loss.[6]

Ocimum sanctum linn. Also known as Tulsi belongs to the Family- Lamiaceae (Labiateae). A herbaceous plant found throughout India. It is much branched small herb and 30 to 75 cm in height. All parts of tulsi are used in medicine, especially fresh and dried leaves. Leaves are oblong, acute with entire or serrate margin, pubescent on both sides and minutely gland-dotted. The leaves are green in colour with aromatic flavour and slightly pungent taste. Volatile oil (0.4 – 0.8%) containing chiefly eugenol (21%) and β- caryophyllene (37%) (Eugenol content reaches maximum in spring and minimum in autumn).[7] Other: A number of sesquiterpenes and monoterpenes viz., bornyl acetate, β-elemene, methyleugenol, neral,

β-pinene, camphene, α-pinene etc.: ursolic acid, campesterol, cholesterol, stigmasterol, β-sitosterol and methyl esters of common fatty acids. It is used as antioxidant, stomachic and expectorant, in treating coughs, bronchitis, skin diseases, and diarrhea.

These three plants play an important role in major health problems such as rheumatoid arthritis, cataracts, cancer, cardio vascular diseases, Alzheimer's disease[8] Parkinson's disease, and degenerative diseases associated with aging. A great deal of research has been carried out to prepare polyherbal solid dosage formulation as tablet and its evaluation. The herbal formulation contains the extract of *Emblica officinalis*, *Withania somnifera* and *Ocimum sanctum*.

MATERIALS AND METHODS

The crude dried fruits of Amla and dried roots of Withania were procured from *"*jonadumbalaya*"*ayurvedic store, Begumbazar, and fresh aerial parts of the plant Tulsi were collected from Herbal Garden, Sun City, Hyderabad, Telangana. The three plant samples were authenticated by Botanical survey of India, Deccan regional centre Hyderabad-500048, Telangana, India, with reference number BSI/DRC/2015-16/Tech./734.

Preparation of extracts

Procured plant materials Amla, Withania and Tulsi were properly washed with distilled water and finally allowed to dry under shade, and then coarsely powdered in a blender. The coarse powder (500 gm each) were subjected to maceration for 72 hours, followed by exhaustive maceration for 48 hours and 12 hours, by using various solvents like 60% ethanol for Amla, 50% ethanol for Withania and pure ethanol for Tulsi. The solvents were decanted and filtered with help of filter paper and recovered by rotary vacuum evaporator. Finally extracts were dried under desiccators.

Figure: 1 Prepared plant extracts

Preparation of granules by wet granulation method

All the solid fractions and excipients were passed through *SETHI STANDARD SIEVES* (SSS) 80 prior to use. Doses of individual extracts: required quantities of extracts were weighed accurately using an electronic balance (INFRADIGI) and mixed with the diluent microcrystalline cellulose and lactose to make it to dry powder form and then passed through, 44 meshes. Add required quantity of methyl paraben and starch to the above mixture. The Poly vinyl pyrrolidone paste was prepared by adding Isopropyl alcohol (q.s). The wet coherent mass was prepared by using poly vinyl pyrrolidone paste then passed through sieve no. 14 and dried at 40ºC for 30 minutes in tray dryer. The dried granules were passed again through sieve no. 22**.** The granules were finally lubricated with purified talc and magnesium stearate and then evaluated.

Evaluation of granules[9,10]

a) Organoleptic properties

The colour and odour of the fractions were evaluated on visual and sensual basis.

b) Loss on drying

A well mixed granules (1g) was transferred into a dried, glass stopper, shallow weighing bottle. The contents were distributed evenly and placed in the drying chamber, the stopper was removed from the bottle and the contents were dried for a specified time to constant weight. The experiment was repeated for three times and loss in weight (% w/w) resulting from water or volatile matter was then calculated using the following formula.

$$\text{Loss on drying (\%)} = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

c) Fines

A 100 gm mass of the combined granules after lubrication was passed through BSS # 80. The amount of sample passed through was considered to be fines and its weight was noted. The following formula was used for determining the amount of fines in percentage.

$$\text{Fines} = \frac{\text{Weight of fines}}{\text{Total weight of granules}} \times 100$$

d) Tapped density, Hausner ratio & Carr's Index

(Vijay Kumar et al. 2002; Carr 1965, Hansuner, 1967) Weighed quantity of powder was taken in a graduated cylinder and the volume (Vo) was measured. The graduated cylinder was fixed in density determination apparatus and tapped for 250 times and again subjected to 500 steps till the constant reading was obtained (Vf). The volume was then observed and the bulk density, tapped density, hausner ratio and compressibility index were calculated using the following formula

Bulk density = W/ Vo

Tapped density = W/ Vf

Hausner ratio = Vf / Vo

$$\text{Compressibility index} = \frac{Vf - Vo}{Vf} \times 100$$

e) Angle of repose

15 gm of granules were allowed to pass through a funnel from a particular height (2cm) on to a flat surface until it formed a heap, which touched the tip of the funnel. The height and the radius of the heap were measured. The experiment was repeated thrice and the angle of repose (tanθ) was calculated using the formula.

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

Compression of poly herbal tablet

Round and biconvex shaped tablets, with average weight of 500mg were compressed using a Rotary tablet punching machine (Cadmack BB3 16) and evaluated.

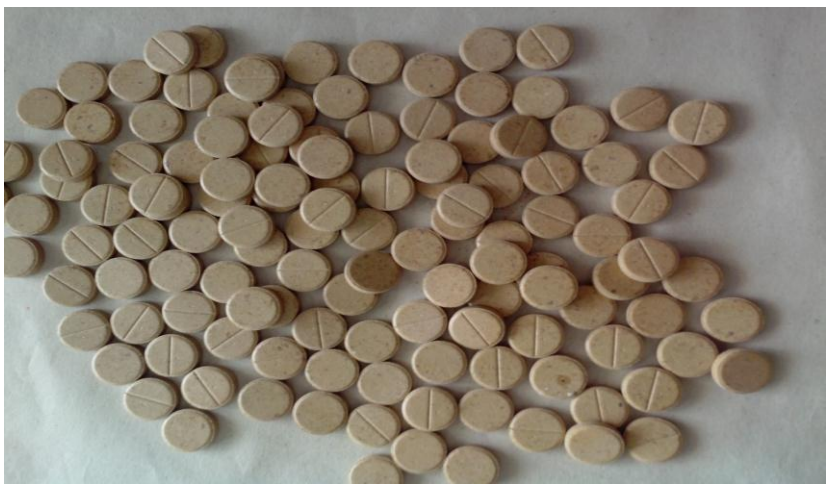

Figure: 2 Prepared poly herbal tablets.

Composition of a poly herbal tablet:

Ingredients	Quantity in mg
Ashwagandha ext.(Withania somnifera)	- 19.6mg
Amla ext. (*Emblica officinalis*)	- 49mg
Tulsi ext. *(Ocimum sanctum)*	- 31.4mg
Microcrystalline cellulose (Diluents)	- 145mg
Lactose monohydrate (filler)	- 145mg
Methyl paraben sodium (antimicrobial agent)	- 0.5mg
Starch soluble (Disintegrating agent)	- 63.5mg
Magnesium stearate (lubricant)	- 05mg
Talc purified (lubricant)	- 40mg
Poly vinyl pyrolidone (Binding agent)	- 1%
Isopropyl alcohol	- q.s

Evaluation of herbal tablets[11,12]

a**) Thickness of tablets**

Randomly 10 tablets were taken and their thickness was measured using vernier callipers. The individual tablet was placed between the anvils and the sliding knob was rotated until the tablet was tightly fitted. The reading was noted. Acceptance limits: ±4-5%

b) Hardness

Hardness of the tablet was determined using the Monsanto hardness tester. The lower plunger was placed in contact with the tablet and a zero reading was taken. The plunger was then forced against a spring by tuning threaded bolts until the tablet fractured. Then the final reading was recorded. The hardness was computed by deducting the initial pressure from the final pressure.

c) Weight variation test

Weight variation test was done by weighing 20 tablets individually, calculating the average weight and comparing the individual tablet weight to the average weight.

d) Friability

Roche friabilator was used to determine the friability. Pre weighed tablets were placed in friabilator and rotated at a speed of 25 rpm for 4 minutes or up to 100 revolutions. The tablets

are dropped from a distance of 6 inches in each revolution. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.

$$\% \text{ friability} = \frac{\text{Weight before friability - Weight after friability}}{\text{Weight before friability}} \times 100$$

e) Disintegration test

Disintegration test performed in vitro using apparatus known as disintegration apparatus (SISCO disintegration apparatus) which consisting of basket and rock assembling containing 6 opened ended glass tubes. These glass tubes are held vertically between the two transparent plastic plates, a stainless steel wire screen is placed below the lower plastic plates. Adjust all the tubes equal distance from each other the upper plastic plates covered with a stainless steel disk with holes of holding glass tubes. Prepared the disintegrating media with help of water and HCl, adjust the PH2 (Gastric fluids) with the help PH paper, put the prepared media or solvent into the glass beaker adjust the volume up to 900ml. Six Tablets is placed in each tube the basket rack is positioned in disintegrating media containing beaker. Switch on the apparatus adjust the temperature 37-40 degrees, Note down the time taken to disintegrate tablet into small particles with help of stop watch.

RESULTS AND DISCUSSION

Table: 1 Evaluation of granules.

S.No.	Evaluation	Observation/ Results
1.	Physical appearance of granules	Light brown colour
2.	Flow properties	Free flow
3.	Fines	22%
4.	Loss on drying/ Moisture content	1.4%
5.	Bulk density	0.45gm/cc
6.	Tapped density	0.52gm/cc
7.	Hausner's ratio	1.15
8.	Carr's index	13.46
9.	Angle of repose of granules	27.47

Table: 2 Evaluations of Tablets.

S.No.	Evaluation	Observation/ Results
1.	Physical appearance of tablets	Brownish color
2.	Thickness of tablets	$3.6 \pm 0.01 mm^2$
3.	Hardness	$5.2 kg/cm^2$
4.	Weight variation	500 ± 5 mg
5.	Friability	0.48%
6.	Disintegration time	28 minutes

CONCLUSION

Herbal products may contain combinations of several different herbs or a single herb and believed to have complementary or synergistic effects. Herbal products are sold as either raw plants or extracts of portions of the plant. This herbal formulation contains the extract of *Emblica officinalis*, *Withania somnifera* and *Ocimum sanctum*, was found to be specific and accurate, so this method and can be used for other polyherbal tablet preparation.

REFERENCES

1. Khanna, P. and Bansal, R. Phyllantidine & phyllantine from *Emblica officinalis* Gaertn leaves, fruits, & in vitro tissue cultures, *Indian J. Experimental Biology*, 1975; 13: 82-83.
2. Zhang YJ, Abe T, Tanaka T, Yang CR, Kouno I. Phyllanemblinins A-F, new ellagitannins from Phyllanthus emblica . J Nat Prod, 2001; 64(12): 1527-1532.
3. Scartezzini P, Antognoni F, Raggi MA, Poli F, Sabbioni C. Vitamin C content and antioxidant activity of the fruit and of the Ayurvedic preparation of *Emblica officinalis* Gaertn. *J Ethnopharmacol*, 2006; 104(1-2): 113-118.
4. Parwez Alam, Jyoti Gupta, Seema Firdouse, Evaluation of in vitro antioxidant activity of combined crude extract of *Emblica officinalis, Withania somnifera and Ocimum sanctum* in different ratio, The Journal of Free Radicals and Antioxidants, Photon, 2013; 139: 181-185.
5. Ziauddin M, phansalka N, patki P, Diwanay S, patwardhan B: studies on the immunomodulatory effects of Ashwagandha . J. Ethnopharmacol, 1996; 50: 69.
6. Agarwal R, Diwanay S, Patki P, Patwardhan B. Studies on immunomodulatory activity of Withania somnifera (Ashwagandha) extracts in experimental immune inflammation. J Ethnopharmacol, 1999; 67(1): 27-35.
7. Prakash P, Gupta N. Therapeutic uses of *Ocimum sanctum* Linn (Tulsi) with a note on eugenol and its pharmacological actions: a short review. Indian J Physiol Pharmacol, 2005; 49: 725-31.
8. M Raghavendra, Rituparna Maiti, Shafalika Kumar, SB Acharya Role of *Ocimum sanctum* in the experimental model of *Alzheimer's disease* in rats International journal of green pharmacy Year, 2009: 3(1): 6-15.
9. Gunsel N, Kanig JF. Tablets. In: The Theory and Practice of Industrial Pharmacy, 3rd Ed. ed. by Lachman et al., Lea and Ferbiger, Philadelphia, 1986; 297–303.
10. Indian Ministry of Health and Family Planning. The Ayurvedic Formulary of India. Part I. 1st ed. Delhi, 1978.

11. Allen LV, Popovich NG, Ansel HC. Ansel's pharmaceutical dosage forms and drug delivery systems" in, 8th Edition edn, Lippincott Williams and Wilkins, Philadelphia, 2004; 236.
12. Indian pharmacopoeia, Monographs on dosage forms, The Indian pharmacopoeia commission, Ghaziabad, 2007; 3: 177-178.