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Original Article

FORMULATION AND EVALUATION OF CHEWABLE MULTIVITAMIN TABLET

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ABSTRACT

Objective: The overall objective of the present study was to formulate the chewable multivitamin tablet prepared by direct compression method.

Methods: The excipient used in this study are mannitol, sucrose, starch, talc, magnesium stearate, vanilla powder for the effective formulation. As it is multivitamin, ascorbic acid, riboflavin, nicotinamide, thiamine HCL are used and evaluated for precompression parameter. The chewable tablets were better presented using sweetener sucrose and vanilla powder as a flavouring agent. The formulated tablet was evaluated for post compression parameter. The chewable tablet are prepared to ensure that they are easily crushed by chewing. The tablet was evaluated for weight variation, hardness, thickness, friability, drug content. Their dissolution properties were assessed using USP (paddle apparatus).

Conclusion: From the above study, we conclude that the chewable tablets were prepared by direct compression method and gave the satisfactory and acceptable result. The tablet shows immediate drug release due to direct compressed tablet

Results: All the parameter were found within the specification. Drug content of ascorbic acid (103.62%-108.84%), riboflavin (99.88%-112.02%), nicotinamide (93.44%-100.31), thiamine Hcl (105.94%-108.5%) were found.

Keywords: Multivitamin, Ascorbic acid, Riboflavin, Nicotinamide, Thiamine HCL, Direct compression, Chewable tablet

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INTRODUCTION

Vitamins are organic compounds which are essential for normal growth and nutrition and are required in small quantities in the diet because they cannot be synthesised by the body. The importance of vitamins as drugs is primarily in the prevention and treatment of deficiency diseases. As these vitamins are not synthesised naturally in the human body a balanced diet is mandatory to keep the amount of vitamins at the required level. However, at times dietary habits can create a deficiency of these vitamins. For these conditions, multivitamins tablets are available in the market for the adequate supply of vitamins. Vitamin deficiencies occur due to inadequate intake, malabsorption, increased tissue needs, increased excretion, certain genetic abnormalities and drug-vitamin interaction [1-3].

Vitamin B1 (Thiamine Hydrochloride) is chemically, 3-((4-Amino-2-methyl-5-pyrimidinyl) methyl)-5-(2-hydroxyethyl)-4-methylthiazolium chloride. It is the hydrochloride salt form of thiamine, a vitamin essential for aerobic metabolism, cell growth, transmission of nerve impulses and acetylcholine synthesis. Upon hydrolysis, thiamine hydrochloride is phosphorylated by thiamine diphosphokinase to form active thiamine pyrophosphate (TPP), also known as cocarboxylase [1, 7].

Vitamin B2 (Riboflavin) is chemically, 3, 10-dihydro-7, 8-dimethyl-10-[2S, 3S, 4R)-2, 3, 4, 5 tetrahyroxypentyl]-benzopteridine-2, 4-Dione. It is yellow to the orange-yellow crystalline compound. Action and physiological role of vitamin B2, flavin adenine dinucleotide (FAD) and flavin mononucleotide (FMN) are coenzyme for flavoproteins involved in many oxidation-reduction reactions [1, 6].

Vitamin B3 (Nicotinamide) is chemically, pyridine-3-carboxylic acid. It is a colourless crystal or a white crystalline compound. Physiological role and actions of nicotinic acid is readily converted to its amide which is a component of the coenzyme Nicotinamide-adenine-dinucleotide (NAD) and its phosphate (NADP) involved in oxidation-reduction reactions [1, 6].

Vitamin C (Ascorbic acid) is chemically, (R)-5[(S)-1, 2-dihydroxyethye]-3, 4-dihydroxy-5(H)-furan-2-one. It is a white to the very pale yellow crystalline compound. Vitamin C plays a role in many oxidations and other metabolic reactions e. g. conversion of folic acid to folinic acid, biosynthesis of adrenal steroids [1, 7].

MATERIALS AND METHODS

Material

Ascorbic acid, Thiamine Hydrochloride, Riboflavin and Nicotinamide purchased from Merck Specialities Pvt. Ltd. Mumbai-400018; mannitol, sucrose, starch purchased from Thangshu Yngyuan Chemical, China; talc, magnesium stearate, vanilla powder purchased from Psychotropic India Ltd. Haridwar, Uttarakhand-249403.

Method

All powder compounds were accurately weighted, passed through a standard sieve (sieve no 80) and thoroughly blended for 5 min. After being mixed powders were evaluated for bulk density and tapped density, compressibility index (Carr's index), Housner ratio and angle of repose. Chewable tablets were prepared by direct compression using rotary tablet compression machine (Shakti, 9001:2000 Company. Six batches (F1, F2, F3, F4, F5, and F6) of white-yellowish tablets with an average mass of 500 mg were obtained. Completed composition of the tablets of six batches [8-12].

Evaluation of chewable tablets

Pre-compressional studies of powder blend

In the development of new dosage form, the pre-formulation study is the prior step in the potential drug development. It is the principal investigation in the drug development to obtained information on the known properties of the compound and the proposed development schedule. So, this pre-formulation investigation may merely confirm that there are no significant barriers to compound development. Following pre-compressional parameters were studied like the angle of repose, bulk density, tapped density, compressibility indices etc [6, 7].

Table 1: Final composition of chewable tablet formulation (F4)

Ingredients	Amounts	
	mg	%
Ascorbic Acid	50	10
Riboflavin	2	0.4
Nicotinamide	20	4
Thiamine HCL	2	0.4
Zinc Sulphate	15	3
Magnesium Oxide	60	12
Copper Sulphate	2	0.4
Folic Acid	4	0.8
Starch	40	8
Manitol	100	20
Sucrose	194	38.8
Magnesium Stearate	5	1
Talc	5	1
Vanilla Powder	1	0.2
Total	500	100

Angle of repose

It is the maximum angle that can be obtained between the freestanding surface of powder heap and the horizontal plane. It was determined by using fixed funnel method. Specified amount of powder drug was transferred to the funnel keeping the orifice of the funnel blocked by the thumb. When the powder was cleared from funnel then measured its angle of repose and measured in θ [7, 11].

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

Bulk density

It is the ratio of the bulk mass of powder to the bulk volume. It is denoted by ρb. Bulk density is used to find out homogenecity [6, 9].

$$\text{Bulk density } (\rho b) = M/V_b$$

Where M is the mass of the sample,

V_b bulk volume

Tapped density

It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder. Tapped density is determined by placing a graduated cylinder containing a known mass of drug or formulation on a mechanical tapper apparatus which is operated at fixed no. of taps (1000) until the powder bed reached a minimum volume [7, 10].

Tapped density (ρt) = weight of powder blend/Minimum volume occupied by cylinder

Compressibility indices

a. Carr's index

Based on the apparent bulk density and the tapped density, the percentage compressibility of the powder mixture was determined by the following formula [7, 11].

Carr's index = Tapped density-Bulk density × 100/Tapped Density

b. Hausner's ratio

It is an indirect index of ease of measuring of powder flow. Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25)

Hausner's ratio = Tapped density/Bulk density

Post-compressional studies of prepared tablets

The tablets were evaluated for various parameters after consideration of pre-formulation to overcome errors during formulation preparation. These are like appearance, thickness, weight variation, hardness and friability. All the evaluation parameters of all formulations are given in table 3. Physical appearance. The general appearance of the tablet was studied visually in shape, color, texture and odour [5, 6, 9].

Thickness

The tablet thickness was calculated by Vernier callipers. Tablet was put in between two jaws vertically and measured thickness and 6 tablets were used for this test and expressed in mm [9, 13].

Weight variation

Weight variation test is run by weighing 20 tablets individually, calculating the average weight and comparing individual tablet weight to the average. The weight variation test would be a satisfactory method of determining the drug content uniformity of tablets [4, 1].

Hardness

Hardness also termed as tablet crushing strength. The tablet hardness was determined by Monsanto hardness tester. The tablet was placed lengthwise between upper and lower plunger and force applied by turning a threaded bolt until the tablet fractures and measured hardness of tablet in Kg/cm^2 [4, 1].

Friability

It is determined by Roche friabilator, subjects a number of tablets to combined effects of abrasion and shock by utilising a plastic chamber that revolves at 25 rpm, dropping tablet from inches distance operated for 100 revolutions. Pre-weighed tablets were dusted and re-weighed and according to standard limit, friability should be less than 1%. It is calculated by the formula [1, 9].

% Friability = Initial weight–Final weight/Initial weight.

***In vitro* drug release**

The dissolution profile of tablet was determined at 37±0.5 °C at a stirring rate of 75 rpm using the USP dissolution apparatus II in 900 ml of simulated gastric fluid (0.1 N HCl). Various samples were withdrawn with replacement simulated fluid of the same amount at 10, 20, 30, 40, 50 and 60 min respectively. Samples were filtered using Whatman filter paper and taken absorbance in UV spectrophotometer and using calibration curve [6, 7]

RESULTS AND DISCUSSION

The chewable multivitamin tablet of was formulated by direct compression method. This technique was used for a tablet which minimise processing steps and eliminated wetting and drying process. The physiochemical property shows satisfactory results by a tablet which are within the range of prescribed standards required for investigation of the present study. Tablets were examined on the basis of weight uniformity (Denver Instrument), friability (Roche friabilator), hardness (Rolex Tablet hardness tester), and estimation of drug content (UV-Visible spectrophotometer) using calibration curve. The dissolution test was made in accordance with USP (paddle apparatus Varian DS 8000), 75rpm speed, at a temperature of 37 °C, in 0.1M HCL. Amount of drug release was measured in the

intervals of10, 20, 30, 40, 50, and 60 min and determined by UV-Visible Spectrophotometer (Model no: 1800) using calibration curve.

All tests were made in accordance with the Indian Pharmacopeia and the United States Pharmacopeia [5-7, 12].

Pre-compression studies of powder blend

Table 2: The powder blend was evaluated for various parameters and their results

Pre-compression parameter	Formulation code					
	F1	F2	F3	F4	F5	F6
Angle of repose(θ)	22.3	24.5	24.9	23.8	24.1	25.0
Bulk density(g/ml)	0.48	0.47	0.44	0.43	0.42	0.43
Tapped density(g/ml)	0.45	0.44	0.42	0.41	0.40	0.39
Carr's index	12.5	11.9	13.7	13.8	12.9	13.1

Table 3: Post-compression studies of tablet

Post-compression parameter	Formulation cade					
	F1	F2	F3	F4	F5	F6
Thickness (mm)	6	5.8	5.9	6	6.1	5.8
Hardness (kg/cm^2)	6.2	6.1	6.3	6.4	6.3	6.2
% Weight variation	3	4	3.5	2.5	3.4	4.1
Friability (%)	0.5	0.4	0.6	0.2	0.4	0.3

Table 3: Results of assay studies of tablet

Formulation code		Ascorbic acid	Riboflobin	Nicotinamine	Thiamin HCL
F1	Label claim	50	2	20	2
	Amount found	51	1.9	20.1	2.01
F2	Label claim	50	2	20	2
	Amount found	49.5	1.95	19.8	1.98
F3	Label claim	50	2	20	2
	Amount found	49.9	1.99	19.5	1.95
F4	Label claim	50	2	20	2
	Amount found	50.41	1.99	19.97	1.98
F5	Label claim	50	2	20	2
	Amount found	48.5	1.97	19.7	1.94
F6	Label claim	50	2	20	2
	Amount found	51.9	2.1	19.1	1.94

Table 4: Dissolution profile of formulation 4(F4)

Ingredients	% drug release, times in minutes					
	10	20	30	40	50	60
Ascorbic acid	8.1	21.5	40.8	59.8	74.5	89.2
Riboflabin	9.5	25.6	35.8	55.2	65.9	80.5
Nicotinamide	11.5	24.7	45.7	65.8	72.4	91.5
Thiamin HCL	15.2	29.1	49.3	69.2	89.2	95.1

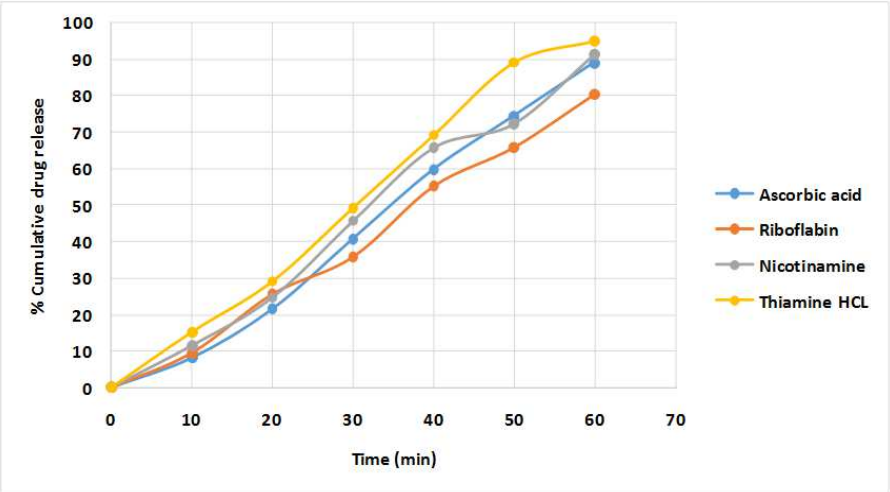

Fig. 1: *In vitro* drug release profile of formulation 4 (F4) of chewable multivitamin tablet

CONCLUSION

From the above study, we conclude that the chewable tablets were prepared by direct compression method and gave the satisfactory and acceptable result. The tablet shows immediate drug release due to the direct compressed tablet. From the above research work, it was concluded that multivitamins tablet prepared in the form of cost effective tablet to minimize patients compliance in regarding suppressing side effects and enhancing positive effects on the body. According to the results obtained from all batches formulation 4 (F4) shows for Carr's index, Hausner ratio and angle of repose, flowability were better compared with other batches. According to the obtained results and our requirements, batch F4 was our choice for further development of the commercially applicable product, because it gave uniform release of more than 80% of all ingredients in a period of 60 min, demonstrated good powder flow ability and complied the pharmacopeial requirement for tablet properties.

CONFLICT OF INTERESTS

Declare none

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