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Research Article

Formulation and Evaluation of New Dosage Form of Calcium and Vitamin D

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A B S T R A C T

The aim of the research work was to develop a new dosage form (tablet in tablet) of calcium and vitamin D. In this research work vitamin D3 was used as vitamin D. This type of dosage form is very useful for elder people and children who have a week swallowing reflex. They have difficulty in swallowing tablets with water. In the present research work, pre-formulated and evaluated chewable tablets of calcium and vitamin D3 (from Formulation and Evaluation of Chewable Tablets of Calcium and Vitamin D) were taken and then moulded into a jelly like material under specified conditions of temperature and humidity and a new dosage form was developed which is sweet, flavored and chewable dosage form (tablet in tablet). The new dosage form was subjected to various tests for evaluation of the new dosage form.

Keywords: Calcium, vitamin D, pectin, tablet in tablet.

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INTRODUCTION

Calcium is very essential in muscle contraction, building strong bones and teeth, blood clotting, nerve impulse transmission, regulating heart beat and fluid balance within the cells. Eating a well balanced diet can provide all the necessary nutrients and help to prevent calcium deficiency. Calcium plays an important role to maintain some important body functions. Calcium controls nerve excitability. It is necessary for maintaining the tone and contractility of heart. It is essential for clotting of blood, It is necessary in the prevention of postmenopausal osteoporosis [1].

Vitamin D refers to vitamin D2 (ergocalciferol) or vitamin D3 (cholecalciferol). Vitamin D plays an important role in the intestinal calcium absorption, muscle functions, potentiate immune system, prevents risk of type I and type II diabetes mellitus and also prevents the risk of cancer [2].

MATERIALS AND METHODS

Following materials were used in the research work which were received as gift samples from a pharmaceuticals manufacturing company. Pectin [3,4], gellan gum [5], corn syrup, sugar, sodium citrate, citric acid, black carrot juice concentrate colour, strawberry flavour liquid and self prepared and evaluated chewable tablets of calcium and vitamin D3 were used in the present research work.

METHOD

Weigh, sieve, blend and dissolve pectin, gellan gum, sodium citrate, sugar and corn syrup in hot DM water, heat to get a mixture of brisk level 78%. Add colour, flavour and mix well. Prepare citric acid solution in hot DM water and add in above mixture. Stirr well. Heat to get brisk level 75%. Fill the selected and pre-oiled moulds with above hot mixture to approximately one-fourth capacity and then put one tablet of calcium and vitamin D3 in the mould, Then fill the remaining empty space of mould with the hot

mixture. Similarly fill other all moulds with hot mixture and tablets. Cool the moulds in cool place for 20 minutes. Demould the resulting product from moulds into a pre-oiled tray. Cure the product at a specific temperature and humidity for 24-36 hours to get a brisk level of 80-82%. Remove the product from curing chamber. Steam the product and coat with fine sugar. Remove the excess sugar and keep aside for 2 hours. The resulting product is new dosage form i.e. tablet in tablet. Take the sample of new dosage form for evaluation.

Table: 1 Formulation Tablets

Amount of Ingredients per Dosage Form		
S. No.	Ingredients	Qty. per unit dosage (mg)
1.	Calcium and Vitamin D3 Chewable tablet	600
2.	Pectin	100
3.	Gellan Gum	20
4.	Corn Syrup	1400
5.	Sugar	1200
6.	Sodium Citrate	32
7.	Citric Acid	60
8.	Black Carrot Juice conc. Colour	40
9.	Strawberry Flavour Liquid	80
10.	DM Water	1068
	TOTAL	**4600**

Evaluation of New Dosage Form (Tablet in Tablet)
The new dosage form i.e. tablet in tablet was evaluated by using pharmacopoeial and non- pharmacopoeial tests.

Organoleptic properties:
Colour, taste and flavour of product was checked manually by seeing, chewing and smelling the product.

Weight variation test:

20 pieces of the product were used to carry out the weight variation test. All were weighed individually on a digital balance and average weight was calculated. Individual weights were compared with average weight.

Length, width and thickness Test:

Micrometre screw guage was used to determine the length, width and thickness. Random sample of 10 pieces was selected and their length, width and thickness were calculated in mm.

Brisk level test:

10 pieces of the product (tablet in tablet) were randomly selected and brisk level of individual piece was calculated with the help of briskometer.

Assay:

Assay for Calcium: Titrimetric Method [6]

Reagents:

Ammonia buffer pH 10.9: Prepared by dissolving 67.5 gm. of ammonium chloride in sufficient 10 M ammonia to produce 1000 ml.

Mordant black II triturate: Prepared by mixing 1 part of mordant black with 99 parts of sodium chloride.

Procedure:
20 pieces of the product were selected randomly. Individual tablet was taken out from the product by cutting it with a blade. Tablets were crushed into fine powder. About 71 mg of tablet powder was taken in a conical flask with 5 ml dilute hydrochloric acid and 30 ml of water. Boiled the solution for 2 minutes; allowed for cooling and diluting up to 50 ml with water. 10 ml of ammonia buffer was added. Titration was done with 0.05M disodium edetate (Each ml of 0.05M disodium edetate is equivalent to 2.004 mg of elemental calcium) using mordant black II triturate as indicator until the colour change from pink to blue.

Content of elemental calcium per tablet was calculated by using following equation:

$$= \frac{V \; X \; F \; X \; 2.004 \; X \; W}{WT}$$

$$= \frac{7.5 \times 0.986 \times 2.004 \times 600}{71.3 = 124.7 \text{ mg/ tablet}}$$

Where

V= Volume of 0.05M disodium edetate used in ml (7.5 ml)
F=Factor of titre (0.986)
WT=Weight of sample taken in mg (71.3 mg)
W=Average weight of tablet in mg (600 mg)

Assay for Vitamin D3: HPLC Method [6]

Mobile Phase: Acetonitrile : Methanol= 91:09
Chromatographic system:
Flow rate: 1.5 ml/min.
Column: Octadecylsilyl silica gel for liquid chromatography (C18).(size: 4.6mm 250mm,5 µm)
Detector: 265nm,UV
Injection Volume: 20 µl
Temperature: 40 C

Procedure:

Standard Preparation: Accurately weigh 100 mg of Cholecalciferol was taken in 100 ml volumetric flask. 30 ml of methanol was added and then sonicated to dissolve. Volume up to 100 ml was completed by using methanol and mixed well. About 2 ml of this solution was diluted to 50 ml by using methanol.

Sample Preparation: 20 tablets were crushed into fine powder. 590 mg of fine powder was taken in a 50 ml volumetric flask. 30 ml of methanol was added and sonicated to dissolve. Volume up to 50 ml was completed with methanol.

Chromatographic Procedure: Before injection, filtration was done through 0.2 µ syringe filter. Separately 20 µl of prepared sample was injected in to the chromatograph. Chromatograms were recorded and measure the responses for major peaks. The content of cholecalciferol was calculated by using following equation:

$$= \frac{AT}{AS} \text{ x } \frac{WS}{100} \text{ x } \frac{2}{50} \text{ x } \frac{50}{WT} \text{ x } \frac{Ps}{100} \text{ x } W \text{ mg per tablet}$$

= 28304/28455 x 99.0/100 x 1/50 x 50/590 x 100000/100 x 600 IU per tablet.

= 100.1 IU per tablet

Where

AT=Area of sample preparation (28304)
AS=Area of standard preparation (28455)
WT=Weight of sample in mg (590 mg)
WS=Weight of standard cholecalciferol in mg (99 mg)
Ps=Potency of cholecalciferol standard (100000 IU/gm)
W=Average weight of tablet (600 mg)

RESULT AND DISCUSSION

Moulding method was used to prepare the new dosage form (tablet in tablet) of calcium and vitamin D3 by using different type of excipients. The new product was evaluated by performing various tests. In organoleptic tests - it was found that the product is reddish-pink coloured, sweet and strawberry flavoured. The result of weight variation was +1.04% and -1.51%. The results of length, width and thickness were 16.3 mm, 14.3mm and 7.5 mm respectively. Average brisk level 81% was calculated and brisk level variation was within limits. Content of vitamin D3 was determined by HPLC method and the content of calcium was determined by titrimetric method. Assay of both calcium and vitamin D3 were within limits. All results are shown in the table.

Table: 2 Evaluation of Tablet

S. No.	Tests	Specifications	Result
1.	Average weight	4.370 -4.830 mg	4620mg
2.	Weight Variation	±5 %	within limits
3.	Length	16.2-16.4mm	16.3mm
4.	Width	14.2-14.4mm	14.3mm
5.	Thickness	7.4-7.6mm	7.5mm
6.	Brisk level	80-82%	81%
7	Assay: a) Content of Calcium	112.5 -137.5 mg	124.7 mg
	b) Content of Vitamin D	Not less than 90 IU	100.1 IU

CONCLUSION

In the present work new dosage form of calcium and vitamin D i.e. tablet in tablet was prepared by using compressed chewable tablets which were moulded into a jelly material containing colouring, sweetening and flavouring ingredients, which makes the product elegant and easily acceptable to all especially to children and elders who has difficulty in swallowing. Chewing this new dosage form, children feel like eating toffee/ jelly candy. For diabetic elders, sugar free product can be formulated. This type of study can be done on other therapeutic or nutraceutical agents.

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