



## FORMULATION AND EVALUATION OF TABLET IN TABLET OF MAGNESIUM GLYCINE COMPLEX AND VITAMIN D<sub>3</sub> TABLET

Urvashi Virakt\*

Dr. Shri R.M.S. Institute of Science & Technology College of Pharmacy, Bhanpura, Mandsaur, M.P.



\*Corresponding Author: Urvashi Virakt

Dr. Shri R.M.S. Institute of Science & Technology College of Pharmacy, Bhanpura, Mandsaur, M.P.

DOI: <https://doi.org/10.5281/zenodo.17747867>



**How to cite this Article:** Urvashi Virakt\*. (2025). Formulation And Evaluation Of Tablet In Tablet Of Magnesium Glycine Complex And Vitamin D<sub>3</sub> Tablet. World Journal of Pharmaceutical and Life Science, 11(12), 152–156.

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Article Received on 16/10/2025

Article Revised on 06/11/2025

Article Published on 01/12/2025

### ABSTRACT

The present study is investigated for formulation development and evaluation of Vitamin D<sub>3</sub>. Research is focused to improve the stability of the drug by changing the production process meant for the treatment of rickets, familial hypophosphatemia and hypoparathyroidism, and in the management of hypocalcemia and renal osteodystrophy in patients with chronic renal failure undergoing dialysis, calcium in the management and prevention of primary or corticosteroid-induced osteoporosis.

**KEYWORDS:** Tablets- in-tablet, hypoparathyroidism, hypocalcemia, osteoporosis.

### INTRODUCTION

Tablets are indeed the most popular solid dosage form for oral administration. One category of tablet formulations that has gained remarkable importance in drug therapeutics owing to various benefits it offers is controlled or modified release formulations. Although less popular, tablet- in-tablet technology gained increased interest in the recent years for creating modified released products. It involves the compaction of granular materials around a preformed tablet core using specially designed tableting equipment. Compression coating is a dry process. This type of tablet (compression coated tablet) has two parts, internal core and surrounding coat. The core is small porous tablet and prepared on one turret. After tablet core manufacture it is transferred (centrally positioned) to another slightly larger die that is partially filled with coating powder. More coating powder is filled on the top of the core and compressed again resulting in tablet with in tablet. Mechanically, it is a complex process, as the tablet may be tilted when transferred to the second die cavity. Mostly, the coat is water soluble and disintegrates easily after swallowing, in order to achieve immediate release product. This tablet readily lend itself in to a repeat action tablet as the outer layer provides the initial dose while the inner core releases the drug later on. But, when the core quickly releases the drug, entirely different

blood level is achieved with the risk of over dose toxicity.<sup>[1]</sup>

To avoid immediate release of both the layers, the core tablet is coated with enteric polymer so that it will not release the drug in stomach while, the first dose is added in outer sugar coating. Even so, coating operation requires interpretation while manufacturing and dawdling the manufacturing process. The tablet coating have number of advantages like masking odor, taste, color of the drug, providing physical and chemical protection to drug, Protecting drug from the gastric environment. Tablets are usually coated in horizontal rotating pan with coating solution is either directly poured or sprayed on to them. The amount of coating on the surface of a tablet is critical to the effectiveness of the oral dosage form.<sup>[2]</sup>

### METHODOLOGY

#### a) Pre compression parameters

##### i) Angle of repose

Angle of repose was determined using funnel method. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the heap of the blends. Accurately weighed blend is allowed to pass through the funnel freely on to the surface. The height and diameter of the powder cone was measured and angle of repose was calculated.<sup>[3]</sup>

**ii) Bulk density**

Bulk density is ratio of given mass of powder and its bulk volume. Bulk density was determined by measuring the volume of known mass of powder sample that has been passed through the screen in to granulated cylinder or through volume measuring apparatus into cup.<sup>[4]</sup>

**iii) Tapped density**

A known quantity of powder was transferred to a graduated cylinder and volume V<sub>0</sub> was noted. The cylinder fixed to a density determination apparatus, tapped for 500 times then reading was observed. The density is achieved by mechanically tapped by a measuring cylinder containing the powder sample. After observing the initial volume the cylinder is mechanically tapped and volume reading were taken until little further volume changes is observed.<sup>[5]</sup>

**iv) Compressibility index and Hausner ratio**

The compressibility index and Hausner ratio may be calculated using measured values of bulk density and tapped density as follows,<sup>[6,7]</sup>

Compressibility index =  $100 \times \text{tapped density} / \text{bulk density}$   
 Hausner ratio =  $\text{tapped density} / \text{bulk density}$ .

**b) Post Compression parameters****i) Weight Variation**

Twenty tablets were selected randomly and the average weight determined by electronic balance. Tablets are weighed individually and compared with average weight.<sup>[8,9]</sup>

**ii) Thickness test**

Ten tablets were selected randomly and thickness was assessed using a Vernier caliper/screw gauge.<sup>[10,11]</sup>

**iii) Diameter**

It also dimensionally described & controlled. Tablet diameter can be measured for six tablets by Dial caliper.<sup>[12,13]</sup>

**iv) Friability test**

Friability of the tablets was determined using Roche friabilator at 25 rpm/min for 4 min. the device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at I height of 6 inches in each revolution. Pre weighted sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. Twenty tablets were weighed and loss in weight (%) was calculated.<sup>[14,15]</sup>

**v) Disintegration study**

The disintegration test determines whether dosage forms such as tablets, capsules, suppositories disintegrate with in prescribed time when placed in a liquid medium under the prescribed experimental conditions. Disintegration is defined as the state in which no residue of the unit under test remains on the screen of the apparatus or if a residue remains it consists of fragments of disintegrated parts of tablet component part such as insoluble coating of tablets.<sup>[16,17]</sup>

**Formulation development****Table 1: Formulation For Inner Tablet.**

S.No	Ingredients	F – 1	F – 2	F – 3	F – 4	F – 5
1.	Cholecalciferol	75.00	75.00	75.00	75.00	75.00
2.	Mannitol	0.165	0.165	0.165	0.165	0.165
3.	Micro crystalline Cellulose	0.065	0.075	0.025	0.045	0.035
4.	Povidone	0.015	0.015	0.015	0.015	0.015
5.	Iso Propyl Alcohol	0.15	0.15	0.15	0.15	0.15
6.	Crospovidone	0.0075	0.0175	0.0325	0.0125	0.0225
7.	Colloidal silicon di oxide	0.004	0.004	0.004	0.004	0.004
8.	Talc	0.004	0.004	0.004	0.004	0.004
9.	Magnesium Stearate	0.003	0.002	0.004	0.004	0.004
10.	Instacoal white	0.0139	0.0139	0.0139	0.0139	0.0139
11.	Erythrosine lake	0.0004	0.0004	0.0004	0.0004	0.0004
12.	Brilliant blue lake	0.00025	0.00025	0.00025	0.00025	0.00025
13.	Iso propyl alcohol	0.095	0.095	0.095	0.095	0.095
14.	Methylene chloride	0.178	0.178	0.178	0.178	0.178

**Table 2: Formulation for outer tablet.**

S. No	Ingredients	F – 1	F – 2	F – 3	F – 4	F – 5
1.	Magnesium glycine complex	6.25	6.25	6.25	6.25	6.25
2.	Micro crystalline cellulose	0.4	0.7	0.2	0.4	0.5
3.	Sodium starch glycolate	0.225	0.225	0.225	0.225	0.225
4.	Povidone	0.25	0.25	0.25	0.25	0.25
5.	Iso propyl alcohol	3.1875	3.1875	3.1875	3.1875	3.1875
6.	Crospovidone	0.255	0.305	0.295	0.275	0.265

8.	Colloidal silicone dioxide	0.05	0.06	0.02	0.03	0.04
9.	Talc	0.03	0.03	0.03	0.03	0.03
10.	Magnesium stearate	0.08	0.08	0.08	0.08	0.08
11.	Instacoat white	0.2706	0.2706	0.2706	0.2706	0.2706
12.	Erythrosine lake	0.012	0.012	0.012	0.012	0.012
13.	Brilliant blue lake	0.006	0.006	0.006	0.006	0.006
14.	Iso propyl alcohol	1.4375	1.4375	1.4375	1.4375	1.4375
15.	Methelene chloride	2.67	2.67	2.67	2.67	2.67

### Manufacturing procedure

**Inner part:** Load total sifted quantity of Intra Granular part of Vitamin D3, Mannitol and Microcrystalline Cellulose into the Ribbon Mixer and mix for 10 minutes in Clockwise direction. Add the binder solution slowly for 2-3 minutes into the above Ribbon mixer and granulated. If required add additional quantity of Isopropyl Alcohol and mix it for further 3 minutes to get the uniform wet mass. Collect the above wet mass in a Trays and fixed into Tray Drier. Start drying the granules at 35 - 40°C (inlet temperature) to reach the moisture content of 6.0 to 8.0%. Pass the above semi dried granules through Vibro sifter using 16 # mesh sieve. Collect the sieved granules in Tray Drier trays and fixed into Tray Drier. Start drying at 35-40°C (inlet temperature) to the granules reach the moisture content of 1.0 to 1.5%. Pass the dried granules through Vibro sifter using 20 # mesh and oversized granules are milled through multi mill using 1.5 mm screen at required speed at forward direction and again sifted the milled granules through 30 # mesh Collect the sifted dried granules into IPC bin lined with double poly bag Add Crospovidone, Colloidal Silicon Dioxide and Talc(extra granular) into the Ribbon Mixer containing dried and sized granules and blend for 10 minutes. Add Magnesium stearate (Lubrication part) into the above

Ribbon Mixer and mix for 5 minutes. the bulk lubricated Blend is stored. Set the compression machine and continue the compression after setting all the quality parameters. The core tablets are then transferred to quarantine bulk hold area till reported for Coating. Spray the coating solution over the core tablets at a constant rate.<sup>[18,17]</sup>

**Manufacturing procedure of Outer part:** Load total of Intra Granular part of Magnesium Glycine Complex, Microcrystalline Cellulose and sodium Starch Glycolate into the Rapid mixer granulator and mix for 15 minutes with slow impeller. Add the binder solution slowly for 3-6 minutes with slow impeller, No Chopper into the above Rapid mixer granulator. Pass the above dried granules through Vibro sifter using 16# mesh sieve. Transfer the dried granules & sifted extra granular and lubrication materials into blending area. Add Magnesium stearate (Lubrication part) into the above Octagonal Blender then mix for 5 minutes at 10 RPM. Set the compression machine and continue the compression after setting all the quality parameters. The tablets in tablet are then transferred to quarantine bulk hold area till reported for Coating.<sup>[19,20]</sup>

### RESULT AND DISCUSSION

**Table 3: Preformulation Studies of inner tablet powder.**

Code	Angle of Repose	Bulk density	Tapped density	Carr's index	Hausners ratio
F1	21.87 ± 0.99	0.59 ± 0.18	0.66 ± 0.87	14.99 ± 0.09	1.95 ± 0.34
F2	20.14 ± 0.48	0.51 ± 0.65	0.62 ± 0.23	13.78 ± 0.15	1.80 ± 0.87
F3	22.65 ± 0.11	0.50 ± 0.09	0.66 ± 0.62	13.26 ± 0.65	1.98 ± 0.65
F4	21.09 ± 0.99	0.51 ± 0.98	0.64 ± 0.45	14.76 ± 0.33	1.54 ± 0.23
F5	23.65 ± 0.54	0.53 ± 0.87	0.61 ± 0.54	14.43 ± 0.51	1.33 ± 0.98

**Table 4: Physical Parameters of inner tablet (before coating).**

Formulation	Weight Variation(mg)	Hardness test(kg/cm <sup>2</sup> )	Thickness test(mm)	Diameter (mm)	Friability %
F1	81.23 ± 0.99	3.9 ± 0.14	2.56 ± 0.23	5.40 ± 0.66	0.4%
F2	80.60 ± 0.98	4.1 ± 0.54	2.43 ± 0.87	5.36 ± 0.32	0.5%
F3	81.02 ± 0.54	4.0 ± 0.33	2.54 ± 0.99	5.34 ± 0.87	0.4%
F4	81.99 ± 0.33	4.3 ± 0.21	2.44 ± 0.11	5.45 ± 0.54	0.4%
F5	80.80 ± 0.98	4.7 ± 0.87	2.51 ± 0.66	5.48 ± 0.33	0.5%

**Table 5: Physical Parameters of inner tablet: (after coating)**

Formulation	Weight Variation(mg)	Thickness test	Diameter (mm)	Drug content uniformity (%)
F1	82.43 ± 0.18	2.62 ± 0.87	5.48 ± 0.78	91.20%
F2	82.42 ± 0.65	2.54 ± 0.11	5.44 ± 0.11	91.67%
F3	82.41 ± 0.87	2.61 ± 0.24	5.43 ± 0.54	93.80%
F4	82.40 ± 0.77	2.56 ± 0.28	5.51 ± 0.87	97.40%
F5	82.40 ± 0.82	2.59 ± 0.99	5.53 ± 0.65	96.23%

**Table 6: Preformulation Studies of outer tablet Powder.**

Code	Angle of Repose	Bulk density	Tapped density	Carr's index	Ausners ratio
F1	22.91 ± 0.587	0.58 ± 0.06	0.67 ± 0.09	13.32 ± 0.10	1.15 ± 0.11
F2	23.76 ± 0.453	0.58 ± 0.05	0.64 ± 0.11	13.99 ± 0.95	1.10 ± 0.11
F3	21.01 ± 0.867	0.61 ± 0.11	0.67 ± 0.12	14.32 ± 0.47	1.07 ± 0.17
F4	23.81 ± 0.767	0.59 ± 0.07	0.65 ± 0.09	15.56 ± 0.97	1.09 ± 0.15
F5	23.08 ± 0.437	0.58 ± 0.09	0.66 ± 0.04	14.87 ± 0.48	1.11 ± 0.05

**Table 7: Physical Parameters of outer tablet formulation.**

Code	Hardness	Thickness	Diameter	Friability
F1	4.2 ± 0.12	6.81 ± 0.04	10.52 ± 0.14	0.5%
F2	4.1 ± 0.14	6.81 ± 0.05	10.49 ± 0.24	0.4%
F3	4.1 ± 0.54	6.78 ± 0.02	10.50 ± 0.05	0.5%
F4	4.6 ± 0.61	6.80 ± 0.01	10.50 ± 0.62	0.4%
F5	4.7 ± 0.71	6.80 ± 0.03	10.51 ± 0.71	0.5%

**Table 8: Physical Parameters of outer tablet: (after coating).**

Code	Thickness test	Diameter	Disintegration time (min)
F1	4.1 ± 0.04	10.67 ± 0.22	7.43 ± 0.53
F2	4.5 ± 0.05	10.58 ± 0.53	8.87 ± 0.22
F3	4.6 ± 0.14	10.61 ± 0.12	7.53 ± 0.05
F4	4.9 ± 0.62	10.57 ± 0.75	6.32 ± 0.32
F5	4.9 ± 0.71	10.59 ± 0.53	7.76 ± 0.71

**Table 9: Dissolution profile of formulation of Vitamin d3 tablet.**

Time	F1	F2	F3	F4	F5
0	0	0	0	0	0
10	28.25	23.95	28.25	30.21	31.41
20	65.33	47.93	45.33	58.99	55.33
30	84.24	71.65	76.88	78.96	79.25
45	87.23	84.89	85.25	92.47	91.45

## CONCLUSION

The results Vitamin D3 tablet in tablets of evaluation of different batches were done. The HPLC assay study shows that there was drug content final tablet. The weight variation limited tablets was found maximum up to ± 1.2 % RSD. Hardness was found to be within 3.0 to 4.0 kg/cm<sup>2</sup> which limit friability within 0.7% only. The evaluation results of F4 batches were found to be satisfactory within limit and the disintegration time (4min). the same ratio the formulation F4 gave 92.47% drug release at 45 mins time point. The drug Contents was found to be within limits and all tablets were passing the dispersion test.

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