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Assessment of Vitamin D3 In Different Pharmaceutical Dosage Forms

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Table of Contents

Abstract

Vitamin D is a secosteroid that is synthesized endogenously when human skin is exposed to UV-B. At insufficient sun exposure, such as during winter at higher latitudes, the compound is a true vitamin that needs to be taken up by diet, such as fatty fish or fortified milk, or direct supplementation.

Introduction

Vitamin D one of the fat-soluble vitamins, which has It has a very important role as it is acting as a regulator for some minerals as the Calcium and phosphorus as; calcium and Vit. D modulates bone and intestine absorption to regulate calcium plasmatic concentration. These substances are called micronutrients which are considered the cornerstone in bone health

Although vitamin D is called a “vitamin” (a required nutrient obtained from the diet), it is not truly a vitamin. It acts more like a hormone since the body can synthesize it from cholesterol after the skin is exposed to UVB rays from the sun.

<u>There are few foods that naturally contain vitamin D</u>

The major source of vitamin D for both children and adults is exposure to natural sunlight. The major cause of vitamin D deficiency is lack of sun exposure.

Food Sources include:

- Oily fish – such as salmon, sardines, herring and mackerel.
- Red meat.
- Liver.
- Egg yolks.
- Fortified foods – such as some fat spreads and breakfast cereals.

A level of 20 nanograms/milliliter to 50 ng/mL is considered adequate for healthy people. A level less than 12 ng/mL indicates vitamin D deficiency

Consequences of Vitamin D Deficiency :

Vitamin D deficiency results in abnormalities in calcium, phosphorous, and bone metabolism. Severe and prolonged deficiency can cause bone mineralization diseases, such as rickets in children and osteomalacia in adults. Vitamin D deficiency has also been associated with fractures, falls, and functional limitations, some types of cancer, diabetes, cardiovascular disease, and depression.

Mechanism of Action

The hormonal form of vitamin D, 1,25 (OH)2D, is the ligand for a transcription factor, the vitamin D receptor (VDR). Most if not all effects of 1,25(OH)2D are mediated by VDR acting primarily by regulating the expression of genes whose promoters contain specific DNA sequences known as vitamin D response elements (VDREs). There are thousands of VDREs throughout the gene, often thousands of base pairs away from the coding portion of the gene regulated. However, some actions of 1,25(OH)2D are more immediate, and may be mediated by a membrane bound vitamin D receptor that has been less well characterized than the nuclear VDR or by the VDR acting outside of the nucleus. On the other hand, some actions of VDR do not require its ligand 1,25 (OH)2D. Our understanding of the mechanism by which VDR regulates gene expression has increased enormously over the past few years.

Disposition in the Body

Once vitamin D is absorbed into the body, it undergoes several metabolic processes. It is first transported to the liver, where it is converted to 25-hydroxyvitamin D [25(OH)D], also known as calcidiol. This form of vitamin D is the main circulating form in the body and is commonly measured in blood tests to assess vitamin D status.

Afterward, if needed, 25(OH)D is further converted to its active form, 1,25-dihydroxyvitamin D [1,25(OH)2D], also known as calcitriol, primarily in the kidneys. Calcitriol plays a crucial role in maintaining calcium and phosphorus homeostasis, bone health, and overall bodily functions.

Pharmacodynamics Properties

Comparative pharmacodynamics (PD) analyses on different dosing schedules for cholecalciferol supplementation are limited. This was an open-label, randomized, parallel-group study involving 75 healthy individuals deficient in vitamin D (baseline 25OHD < 20 ng/mL) receiving oral cholecalciferol with three different dosing regimens: Group A: 10,000 IU/day for 8 weeks followed by 1000 IU/day for 4 weeks; Group B: 50,000 IU/week for 12 weeks and Group C: 100,000 IU every other week for 12 weeks. Regulators of calcium and phosphate homeostasis, bone turnover markers and Wnt inhibitors were measured at baseline, Day 28, 53, 84, and 112. The 1,25OH2D increased at each time point. The increase was greater ($p < 0.05$) for group A vs. B and C at Day 28, and vs. group B at Day 56. No significant difference among groups was observed for the other biomarkers. The 24,25OH2D remained stable over time. PTH decreased at Day 84 and FGF-23 increased at all-time points. CTX-I and PINP increased slightly at Day 28. BALP decreased from Day 56 onward. Dkk-1 increased from Day 56 onward, while sclerostin did not show significant changes. In healthy individuals deficient in vitamin D, vitamin D supplementation exerted effects on multiple regulators of calcium, phosphate and bone metabolism, without marked differences using the three regimens.

PHSICOCHEMICAL PROPERTIES:-

Cholecalcifero

Formula: C28H44O

- Vitamin D chemistry

▪ Vitamin D-active compounds tend to exist in extended conformations due to the 180° rotation of the A ring about the 6,7 single bond.

▪ The hydroxyl group on C-3 is thus in the B position (above the plane of the A ring) in the closed forms and in the a position (below the plane of the A ring) in the stretched forms.

- Physical Properties

Vitamin D3 is white to yellowish powders that are:

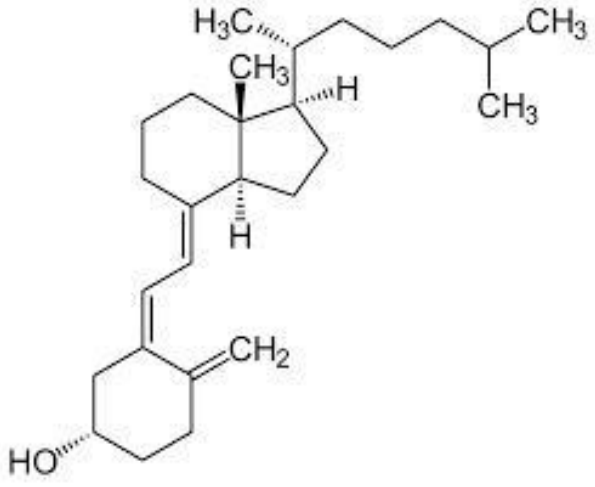
Insoluble in water

Moderately soluble in fats, oils and ethanol

Freely soluble in acetone, ether and petroleum ether

Vitamin D3 show strong ultraviolet (UV) absorption, with a maximum at 264 nm.

Vitamin D is sensitive to oxygen, light and iodine. Heating or mild acidity can convert it to the 5, 6- trans and other inactive forms.



Aim of Study

Assessment of vitamin D3 in different pharmaceutical dosages forms to determine how much the real amount found in gelatine capsules and ampoules.

Materials and Methods

Materials

- 3 soft gelatine capsules of VIT D3 50,000mg (Hidee Kingdom of Jordan)
- 3 soft gelatıne capsules of VIT D3 10,000 (TQ MAX)
- 1 ampoule of VIT D3 300,000 (DEVIT DEVA)
- 1 ampoule of VIT D3 300,000 (DIBASE ABIOGEN)
- Ethanol Solution

Equipment

- Vials
- Volumetric flasks
- Syringes
- Beakers
- Cuvette
- Sensitive Balance
- UV spectrophotometer

Method

1. Weigh each capsule / ampoule on the sensitive balance
2. Weigh the empty beaker we are going to use
3. Weigh the empty capsule / ampoules after aspirating all of the VIT D3 content out by a syringe and place it in a vial
4. Take five drops from the VIT D3 in the vial and weigh the amount after placing the five drops in another vial

5. Dilute the five drops with ethanol in the volumetric flask and shake well
6. Complete the volume to 20ml
7. Place the required amount of the sample in the cuvette
8. Use ethanol to reset the UV spectrophotometer as a blank
9. Set the wave length on 291nm
10. Write down the ABS value for each capsule and ampoule

Calculations

DOSAGE FORM	WEIGHT OF CAP / AMP	WEIGHT OF EMPTY CAP / AMP	WEIGHT OF VIT D3	WEIGHT OF 5 DROPS	ABS
HIDEE CAP	519mg	211mg	308mg	125mg	0.482A
	521mg	219mg	302mg	129mg	1.328A
	506mg	212mg	294mg	120mg	0.300A
TQ CAP	181mg	88.7mg	92.3mg	69mg	0.184A
	187mg	91mg	96mg	20mg	0.155A
	186mg	88.2mg	97.8mg	74mg	0.030
DEVIT AMP	2347mg	1411mg	963mg	130mg	0.556A
DIBASE AMP	2571mg	1726mg	845mg	135mg	0.477A

- ***Weight of empty vial = 13577mg***
- ***Wave length = 291nm***

Results

The amount of vitamin d3 in every dosage form differs from one another leading to different absorbance values regardless the constant value of wave length which show us an idea of why so many different brands do not actually elevate the vitamin d3 inside our bodies for these who suffer from vitamin d3 deficiency even if the patient took the required dose with the proper that confirms that not any pharmaceutical brand uses the required amount of vitamin d3 in their industrial job.

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