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Comprehensive evaluation of Cholecalciferol
(Vitamin D3) Dietary Supplement Tablets

Quality Control of vitamin D₃ Tablets

- ▶ Poster presents a simple and sensitive isocratic HPLC method and a dissolution test for a comprehensive quality evaluation of dietary supplement tablets containing cholecalciferol in a wide range of doses, from 10 µg (400 IU; 1 IU = 0.025 µg) to 250 µg (10 000 IU)

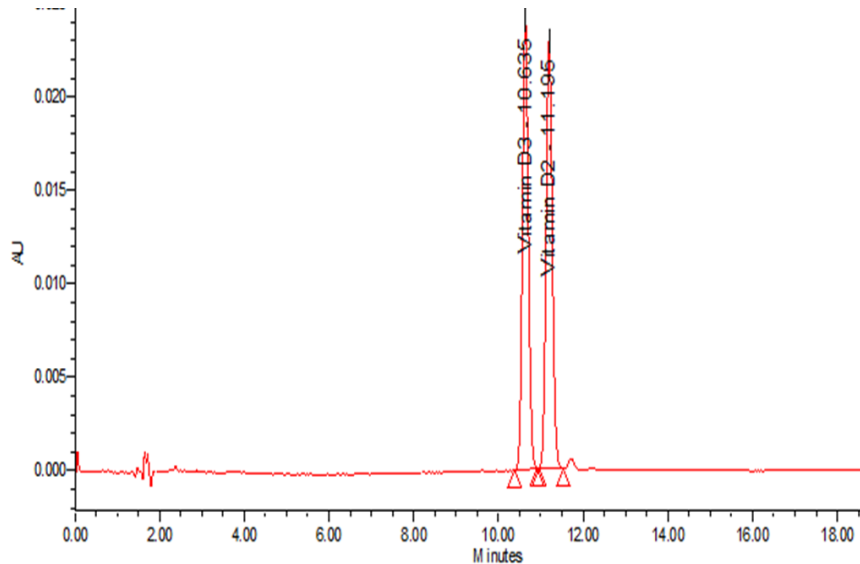


Fig. 1. A typical chromatogram of vitamin D₃ and D₂ resolution solution with concentration of 10 µg/ml

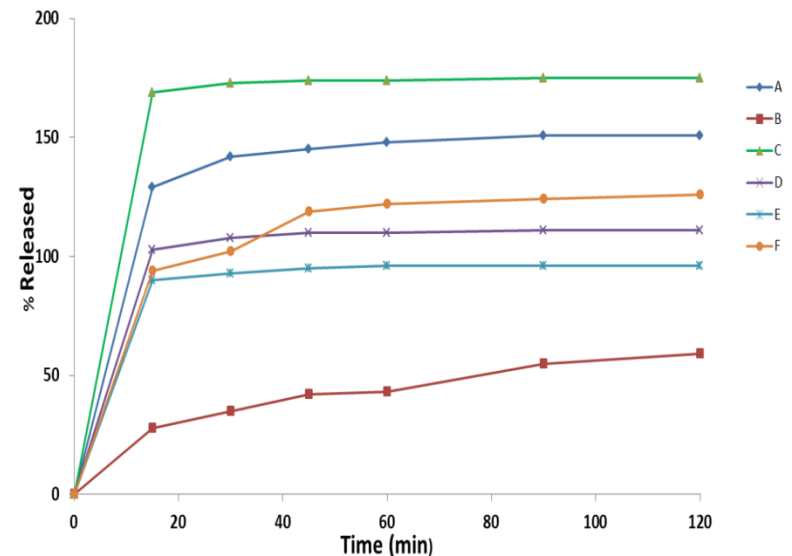


Fig. 2. The mean dissolution profiles (n = 6) of vitamin D₃ in commercial products A-F using USP Apparatus 2 at 75 rpm

Quality Control of vitamin D₃ Tablets

- ▶ It is important to have quality control tools and specifications for vitamin D₃ products quality evaluation

- Cholecalciferol is quite unstable in the presence of oxygen and humidity.
- The majority of finished vitamin D₃ products contain stabilized forms of vitamin D₃ including a protective coating, which could affect the release of vitamin D₃.
- The finished products could contain a considerable overage of vitamin D₃ to meet 100% of the quantity declared on the label through the product shelf life.

Dissolution and Assay results

Product	Label Claim (µg)	Dissolution (% Release)	Assay (% label)
A	10 µg (400 IU)	151	162
B	50 µg (2000 IU)	59	103
C	10 µg (400 IU)	175	181
D	25 µg (1000 IU)	110	125
E	25 µg (1000 IU)	94	101
F	250 µg (10 000 IU)	126	134

- ▶ These methods will be used in the new USP monograph proposal for cholecalciferol tablets and could be used to monitor manufacturing processes, as well as the quality of tablets used in clinical trials, or moving in the market as finished dietary supplements.



Thank You

