

VITAMIN E – Direct Compression with PROSOLV® 730

4282-073

Aim of the study

Solid dose formulations of Vitamin E, an oily active ingredient, are typically produced as soft-gel capsules in the pharmaceutical and nutraceutical industry. The manufacturing process of these soft-gel capsules is labor-intensive and costly. The goal of this study was to create directly compressible 100 IU (67 mg) Vitamin E tablets with minimal effort.

Vitamin E

Vitamin E is a fat-soluble vitamin with potent antioxidant properties found in many foods, including poultry, eggs, fruits, and vegetables. Research shows that Vitamin E protects cells from oxidative stress, regulates immune function, maintains endothelial cell integrity, and balances normal coagulation.^[1]

Vitamin E supplements can help prevent coronary heart disease, support the immune system, prevent inflammation, promote eye health, and lower the risk of cancer.^[2]



Formulation

The tablet formulation consisted of Vitamin E, the high functionality adsorbent binder PROSOLV® 730, VIVASOL® croscarmellose sodium as disintegrant, and PRUV® sodium stearyl fumarate as lubricant.

Grade	mg/Tablet	Contribution [%]
Vitamin E	67.0	19.1
PROSOLV® 730	268.2	76.4
VIVASOL® Croscarmellose Sodium	14.0	4.0
PRUV® * Sodium Stearyl Fumarate	1.8	0.5
Total	351.0	100.0

*Can be substituted by LUBRI-PREZ magnesium stearate, if required by local food regulations.



Fig. 1A Vitamin E,
Fig. 1B Tablets Made with PROSOLV® 730 and 67 mg (100 IU) of Vitamin E

Vitamin E (DL- α -Tocopherol Acetate >98 %) was obtained from TCI America, Inc. (Figure 1).

Excipients

PROSOLV® 730 is a high functionality excipient composite that was specifically designed to adsorb oily Active Pharmaceutical Ingredients (APIs), resulting in a free flowing powder, capable of being compressed into tablets or encapsulated. Combining PROSOLV® 730 with liquid APIs and additional excipients, such as VIVASOL® CCS as disintegrant, and PRUV® SSF or LUBRI-PREZ magnesium stearate as a lubricant, conveniently enables direct compression of tablets, avoiding costly soft-gel encapsulation processes.

Procedure

Blending

Vitamin E was added to PROSOLV® 730 via high shear mixing for 10 minutes. The oil-loaded PROSOLV® 730 was then transferred to a low shear mixing vessel and blended with the disintegrant VIVASOL® CCS for 5 minutes. PRUV® SSF was sieved through a 20 mesh screen, then added to the low shear mixer, and blended for an additional 5 minutes. The blend was immediately used for direct compression tableting.

Equipment

High Shear Mixer	Braun Multiquick 3 Mixer
Low Shear Mixer	Glen Mills Turbula
Tablet Press	Piccola Rotary Instrumented Tablet Press
Hardness Tester	Sotax Model HT10 Hardness Tester
Disintegration Tester	Dr. Schleuniger Pharmatron DISI-2 Disintegration Apparatus

Tablet Characteristics

Tablet Weight	351.0 mg
Tablet Diameter	9.6 mm
Tablet Height	4.6 mm

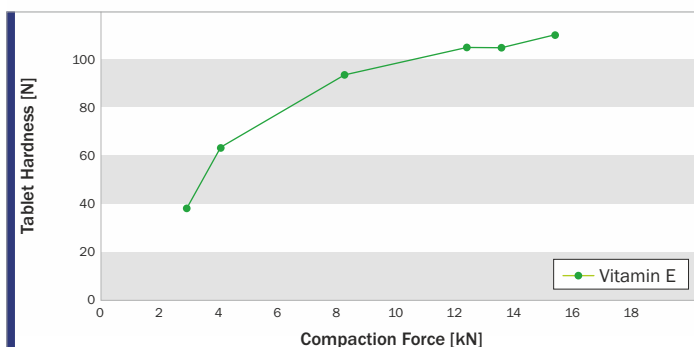


Fig. 2 Tablet Hardness vs. Compaction Force of Vitamin E Tablets made with PROSOLV® 730

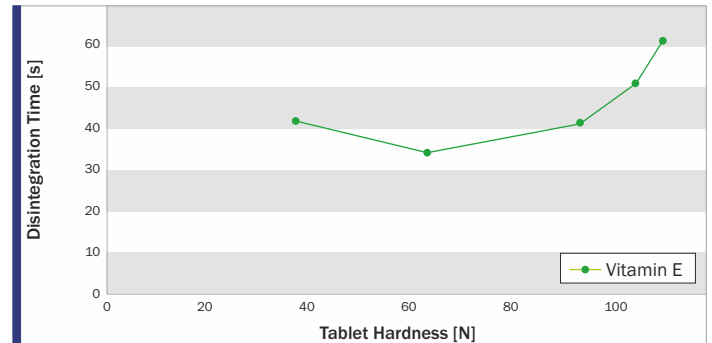


Fig. 3 Disintegration Time vs. Tablet Hardness of Vitamin E Tablets made with PROSOLV® 730

Conclusion

PROSOLV® 730 was found to be perfectly suited for the production of Vitamin E tablets by direct compression. The tablets showed sufficient hardness – obtained by moderate compression force – and fast disintegration.

PROSOLV® 730 enables simple, direct compression formulation of oily APIs, thus offering time and cost savings compared to soft-gel encapsulation.

References

- [1] PubChem, National Library of Medicine - Vitamin E <https://pubchem.ncbi.nlm.nih.gov/compound/Vitamin-E>
- [2] Ten benefits of Vitamin E oil - Medical News Today <https://www.medicalnewstoday.com/articles/318168>

Find out more about **PROSOLV® 730** on https://www.jrspharma.com/pharma_en/products-services/prosolv-730.php

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