

Wet Granulation of Acetaminophen with Starch 1500[®]

Technical Data

Objective

To demonstrate the combined binding and disintegration properties of Starch 1500 in a low shear wet granulation process. Acetaminophen powder was chosen as the example active due to its high dose, poor flow, and compaction properties. The use of Starch 1500 in the granulation was examined in two ways: As a dry mix with the acetaminophen using water as the granulation binder (Formula A), and with some of the Starch 1500 dispersed in the water to be used as the binder liquid (Formula B). The binding properties of Starch 1500 were also compared to PVP (Polyvidone), a commonly used wet granulation binder (Formula C).

Granulation Process

The granulations were conducted on a laboratory scale using an 8 qt. Hobart Planetary Mixer.

Formulation	A	B	C
Acetaminophen	85.10	85.10	85.10
Starch 1500 (dry)	14.65	11.73	9.65
Starch 1500 (in water)	-	2.92	-
PVP K 29/32 (in water)	-	-	5.00
Magnesium stearate	0.25	0.25	.25
Granulation Conditions	A	B	C
Hobart speed setting	1	1	1
Dry mix time (min.)	4	4	4
Wet mass time (min.)	5	5	5
Binder used	water alone	water alone + Starch 1500	water + PVP
Binder concentration (% solids)	-	20.0	18.2
Wet screening (mesh)	12	12	12
Drying conditions	A	B	C
Glatt GPCG-3 Inlet air (deg.C.)	65	65	65
Drying time (min.)	21	27	35
Final product temperature (deg.C.)	40	40	40
Final granulation % L.O.D.	1.4	1.2	1.2
Blending - 8 qt. "V" blender	A	B	C
Magnesium stearate blend time (min.)	3	3	3

Starch 1500®

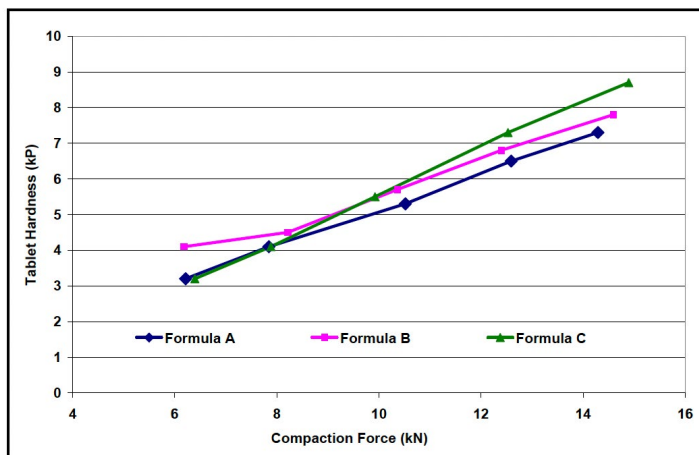
Partially Pregelatinized Maize Starch

Compaction Process

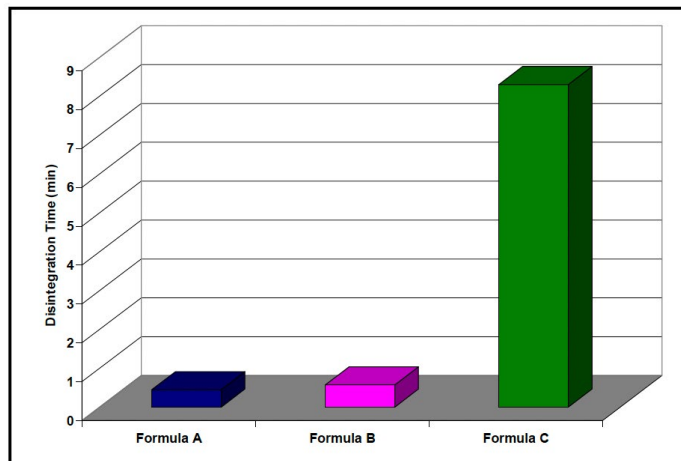
Each of the granulations were compressed on a 10 station rotary tablet press using size B, 3/8" standard concave tooling, to a total tablet weight of 382.0 mg. Tablet samples were taken at 6 different compaction forces between 6 and 15 kN of force.

Compaction Profiles

The compaction profiles for the three granulations were very similar and each of the three formulations produced robust tablets. Adding some of the Starch 1500 to the water for granulation (Formula B) slightly increased the overall tablet hardness. The batch with PVP as the binder (Formula C) produced slightly harder tablets. However, upon disintegration testing in water the clear advantage of Starch 1500 as a binder was seen.



Disintegration Results



Conclusions

Starch 1500 exhibited dual functionality in this formulation. As a wet granulation binder it produced tablets with similar hardness to PVP. As a disintegrant it significantly outperformed PVP, which actually caused a delay in disintegration.

Starch 1500®

Partially Pregelatinized Maize Starch

World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Website: www.colorcon.com e-mail: info@colorcon.com

Locations

United States

Locations	Telephone	Facsimile
Santa Ana, California	714-549-0631	714-549-4921
Indianapolis, Indiana	317-545-6211	317-545-6218
Humacao, Puerto Rico	787-852-3815	787-852-0030

Europe

Dartford, Kent, England	44-1322-293000	44-1322-627200
Bougival, France	33-1-3082-1582	33-1-3082-7879
Idstein, Germany	49-6126-9961-0	49-6126-9961-11
Gallarate, Italy	39-0331-776932	39-0331-776831
Budapest, Hungary	36-1-200-8000	36-1-200-8010
Istanbul, Turkey	90-216-465-0360	90-216-465-0361
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792

Locations

Asia/Pacific

Singapore	65-6438-0318	65-6438-0178
Fuji-gun, Shizuoka, Japan	81-5-4465-2711	81-5-4465-2730
Shanghai, China	86-21-5442-2222	86-21-5442-2229
Goa, India	91-832-288-3434	91-832-288-3440
Seoul, Korea	82-2-2057-2713	82-2-2057-2179

Latin America

Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Bogota, Colombia	571-418-1202	571-418-1257
Caracas, Venezuela	58-212-442-4819	58-212-442-8724
Santa Fe, Mexico	52-55-3000-5700	52-55-3000-5701/02

The information contained herein, to the best of our knowledge is true and accurate. Any recommendations or suggestions are made without warranty or guarantee, since the conditions of use are beyond our control. Any information contained herein is intended as a recommendation for use of our products so as not to infringe on any patent.

