TECHNICAL PRODUCT BOOKLET

DAVAMED™ C1 Tablet Excipient

Premium Direct Compressible Partially Pregelatinized Corn Starch

SMS Corporation

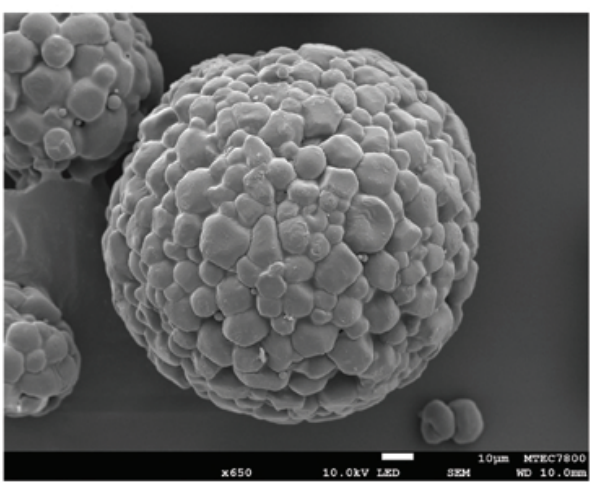
Direct Compressible

Partially Pregelatinized Corn Starch

DAVAMED™ C1, a partially pregelatinized starch excipient, is specially designed for the direct tablet compression process and also for wet and dry granulation processes. DAVAMED™ C1 provides superior flowability, excellent compressibility, and desirable disintegration. As a multi-function excipient, DAVAMED™ C1 may be conveniently manufactured without flow aid, compression aid, and disintegrant. The optimal cost-effectiveness of your tablet manufacturing will be achieved. Finding out more about benefits of DAVAMED™ C1 in this paper.

01 Advantages of DAVAMED™ C1

- Time & Cost Effectiveness
- Low Dusting
- Efficient Disintegration
- Excellent Flowability
- Good Compactability & Low Friability



Physical properties:

Parameters	Value
Average particle size (μM)	110
Bulk density (g/cm^3)	0.55
Tapped density (g/cm^3)	0.80
Carr index	7
Hausner ratio	1.08
Angle of repose (°)	24.7

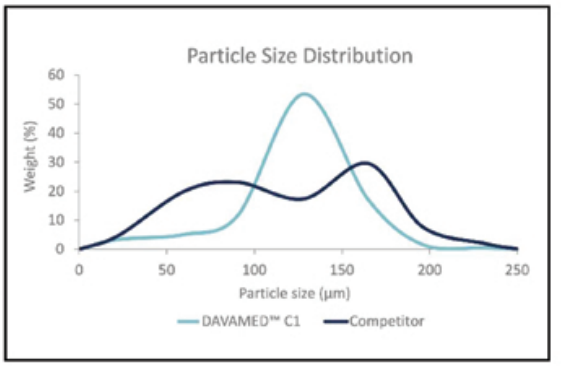
▸Scanning Electron Microscopy (SEM) micrographs of agglomerated particles of DAVAMED™ C1

02 Applications of DAVAMED™ C1

Wet Granulation

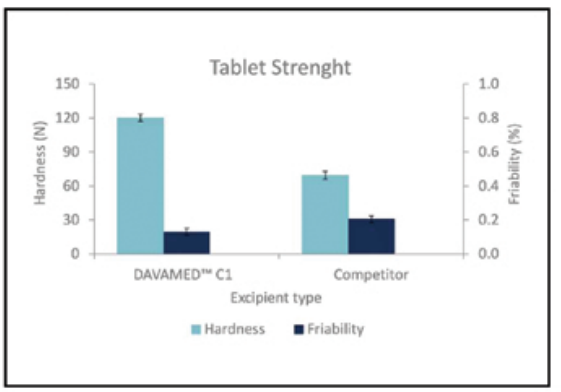
Dry Granulation

Direct Compression



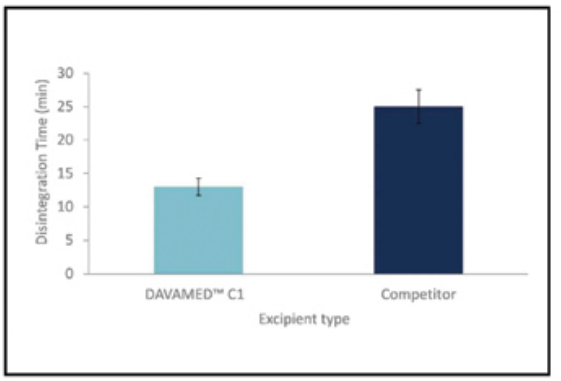
Tablet weight consistency

DAVAMED™ C1 has the unique desirable spherical particle of about 100 µm. The agglomerated spherical shape along with a narrow particle size distribution contributes to the excellent flowability. Consequently, the low tablet weight variation within an acceptance range is achieved.



Compactability

- Optimal tablet hardness
- Robust tablets with low friability
- Ability to withstand coating, packaging, and shipping processes



Disintegration

DAVAMED™ C1 has a fast hydration rate and promotes efficient disintegration properties. It has a shorter disintegration time comparing with commercial corn starch excipient.

Versatile Excipient

DAVAMED™ C1 shows many competitive attributes described above, thus, it can replace a number of various single-function excipients in direct compression, dry or wet granulation while resulting the cost-effectiveness and optimum tablet quality.

CERTIFICATE OF ANALYSIS

Date	21.08.2023
Product	DAVAMED C1
Packing	-
PO No.	PRE-COA
GS Number	30570028-0
Standard	Current USP

Sampling: 20% samples were drawn at random by our inspectors and throughly mixed and analyzed in our laboratory with the following results:

	Lot No.	GS Spec	12203355
Product description		Moderately coarse to fine, white to off white powder. Odorless & has slight characteristic taste	Complies
Solubility		Slightly soluble in cold water, insoluble in alcohol	Complies
Identification		A water slurry of it is colored orange-red to deep blue by iodine	Complies
Loss on drying (%)		7.0-11.0	9.5
pH		4.5-7.0	6.2
Residue on igniton (%)		0.5 Max	0.0
Limit of sulfur dioxide (ppm)		Not more than 80	Not more than 80
Iron (ppm)		Not more than 20	Not more than 20
Oxidizing substances		No distinct blue, brown or purple colour is observed.	Complies
Cold-water-soluble matter (%)		10.0-18.0	15.2
Particle size retained on 8 mesh (%)		0.0-0.0%	0.0
Particle size retained on 40 mesh (%)		0.0-0.5%	0.2
Particle size through 100 mesh (%)		90.0-100.0%	91.0
Particle size through 270 mesh (%)		25.0%-50.0%	26.3
Bulk density (Tapped) (g/mL)		0.8-1.05	0.81
Bulk density (g/mL)		0.55-0.75	0.59
Total plate count (CFU/g)		1,000 Max.	40
Yeast and mold (CFU/g)		100 Max.	0
E.coli (/g)		Absent	Absent
Salmonella spp. (/g)		Absent	Absent
Mfg. Date			07/SEP/2022
Best Before Date			05/SEP/2024

This certificates represents our finding at time of product / loading

QC Department

CERTIFICATE OF ANALYSIS

Date	21.08.2023
Product	DAVAMED C1
Packing	-
PO No.	PRE-COA
GS Number	30570028-0
Standard	Current USP

Sampling: 20% samples were drawn at random by our inspectors and throughly mixed and analyzed in our laboratory with the following results:

	Lot No.	GS Spec	12204164
Product description		Moderately coarse to fine, white to off white powder. Odorless & has slight characteristic taste	Complies
Solubility		Slightly soluble in cold water, insoluble in alcohol	Complies
Identification		A water slurry of it is colored orange-red to deep blue by iodine	Complies
Loss on drying (%)		7.0-11.0	7.2
pH		4.5-7.0	5.8
Residue on igniton (%)		0.5 Max	0.4
Limit of sulfur dioxide (ppm)		Not more than 80	Not more than 80
Iron (ppm)		Not more than 20	Not more than 20
Oxidizing substances		No distinct blue, brown or purple colour is observed.	Complies
Cold-water-soluble matter (%)		10.0-18.0	16.6
Particle size retained on 8 mesh (%)		0.0-0.0%	0.0
Particle size retained on 40 mesh (%)		0.0-0.5%	0.1
Particle size through 100 mesh (%)		90.0-100.0%	92.2
Particle size through 270 mesh (%)		25.0%-50.0%	25.9
Bulk density (Tapped) (g/mL)		0.8-1.05	0.82
Bulk density (g/mL)		0.55-0.75	0.61
Total plate count (CFU/g)		1,000 Max.	230
Yeast and mold (CFU/g)		100 Max.	70
E.coli (/g)		Absent	Absent
Salmonella spp. (/g)		Absent	Absent
Mfg. Date			27/OCT/2022
Best Before Date			25/OCT/2024

This certificates represents our finding at time of product / loading

QC Department

CERTIFICATE OF ANALYSIS

Date	21.08.2023
Product	DAVAMED C1
Packing	-
PO No.	PRE-COA
GS Number	30570028-0
Standard	Current USP

Sampling: 20% samples were drawn at random by our inspectors and throughly mixed and analyzed in our laboratory with the following results:

	Lot No.	GS Spec	12303007
Product description		Moderately coarse to fine, white to off white powder. Odorless & has slight characteristic taste	Complies
Solubility		Slightly soluble in cold water, insoluble in alcohol	Complies
Identification		A water slurry of it is colored orange-red to deep blue by iodine	Complies
Loss on drying (%)		7.0-11.0	7.1
pH		4.5-7.0	5.6
Residue on igniton (%)		0.5 Max	0.3
Limit of sulfur dioxide (ppm)		Not more than 80	Not more than 80
Iron (ppm)		Not more than 20	Not more than 20
Oxidizing substances		No distinct blue, brown or purple colour is observed.	Complies
Cold-water-soluble matter (%)		10.0-18.0	16.3
Particle size retained on 8 mesh (%)		0.0-0.0%	0.0
Particle size retained on 40 mesh (%)		0.0-0.5%	0.2
Particle size through 100 mesh (%)		90.0-100.0%	95.5
Particle size through 270 mesh (%)		25.0%-50.0%	27.0
Bulk density (Tapped) (g/mL)		0.8-1.05	0.85
Bulk density (g/mL)		0.55-0.75	0.62
Total plate count (CFU/g)		1,000 Max.	70
Yeast and mold (CFU/g)		100 Max.	10
E.coli (/g)		Absent	Absent
Salmonella spp. (/g)		Absent	Absent
Mfg. Date			18/JUL/2023
Best Before Date			16/JUL/2025

This certificates represents our finding at time of product / loading

QC Department