

SallysoTM

Croscarmellose Sodium (CCS)

USP/BP/EP/US-DMF No: 037309

About Us

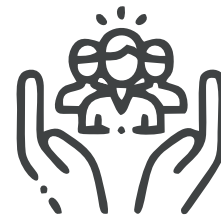
Gangwal Healthcare is a efficacious solution provider and manufacturer that combines innovative research and smart, seamless technology that can tackle the complex challenges of the healthcare system through novel formulations that enhance the quality of life.

Today, as we see newer health challenges cropping up day after day, at Gangwal Healthcare we strive to resolve these by plugging in our rich knowledge and working alongside industry experts who have a strong foothold in pharmaceuticals and nutraceuticals. To give the optimum solution and produce products of the highest quality begins with understanding your needs and concerns and extracting those insights. Promptly followed by bringing in the raw materials that promise the best outcome and blending them with our latest technologies and processes to manufacture a product that can simplify your complications.



Mission

To become a global healthcare company through Innovation, Quality and Competence.



Vision

To build healthier society - Driven by innovation to serve with quality.

Quality

We keep quality as the highest priority when it comes to the products manufactured at Gangwal along with processes deployed or technologies adapted. We firmly believe that nothing can supersede a product or a service that is backed by excellent quality. As solution providers, we strive to have a global footprint through each phase of our journey.

Innovation

Modern medicine is seeing the traces of ancient sciences blend with it effectively, thanks to technology and innovation. Our highly dedicated task forces keep innovation at the center of their activities so that the world can truly reap the optimum benefits of what we create or source. Innovations aid us to challenge the most complex health concerns, thereby addressing your prominent issues.

Consistency

Nothing can make an impact in its entirety unless it comes with consistency. Be it our top management or other teams within the organization, we thrive on consistency at work, in order to see the bigger reforms in health that we are aiming for. Whether it's our external or internal stakeholders we are strongly driven by persistent efforts towards improving the quality of lives that people lead.

Our Quality Certificates



Introduction

Sallyso™ - Croscarmellose Sodium (CCS)

The effective superdisintegrant

Sallyso™ - Croscarmellose Sodium (CCS) is a cross-linked Carboxymethylcellulose-Sodium, and it is water-insoluble, yet rapidly swelling and absorbing in water. As a result, it provides excellent tablet disintegration and dissolution of the APIs, thus ensuring better bioavailability.

Sallyso™ provides consistent disintegration performance which helps to the low use level of CCS for excellent disintegration and dissolution.

Cas No.: 7811-65-7

Advantages of Sallyso™

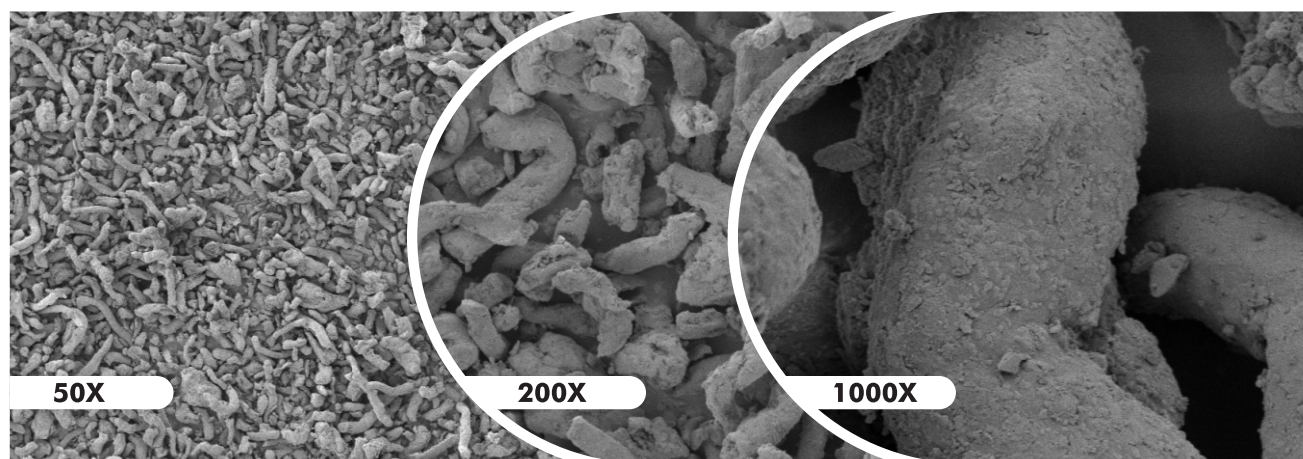
- ✧ Fast disintegration
- ✧ Better dissolution
- ✧ Excellent bioavailability of active ingredient
- ✧ No effect on the compression and flow
- ✧ Cost-effective as it is used in less percentage 2.0–6.0% (w/w) only

Sallyso™ (CCS) provides excellent dissolution properties in tablet formulations. Standard use levels are between 2.0–6.0% (w/w) in tablets, capsules and granules for disintegration and dissolution improvement.

Applications of Sallyso

- ✧ Wet Granulation
- ✧ Dry Granulation
- ✧ Direct Compression

SEM images of Sallyso™



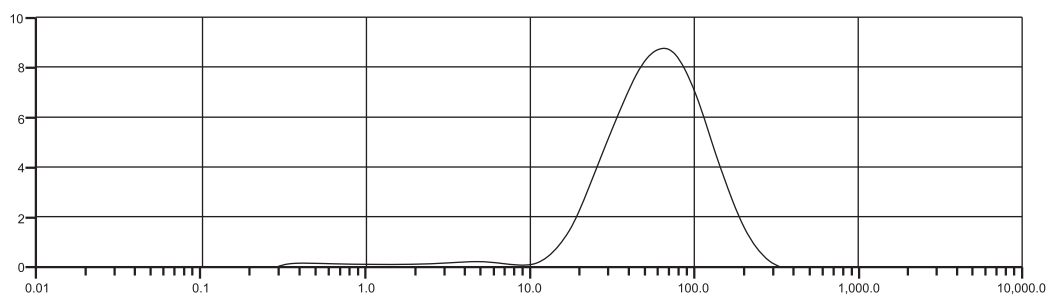
Physical Properties

Croscarmellose Sodium (CCS) is a effective superdisintegrant used in tablet and capsule formulations at 2.0–6.0% (w/w) concentration.

Physical Properties	Result
Bulk density (g/mL)	0.51
Tapped density (g/mL)	0.56

Settling Volume	Result
High	12ml to 18ml
Medium	17ml to 23ml

Parameters	Specification
d10	<25 μm
d50	25-55 μm
d90	>60 μm



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Specification

Test	Specification
Appearance	White or greyish-white, powder
Solubility	Partially soluble in water, Insoluble in acetone, anhydrous ethanol, toluene, alcohol, ether and in other organic solvents.
Identification	Complies as per A, B, C, D Chemical test.
Sulfated Ash	14.0% - 28.0%
Residue on Ignition	14.0% - 28.0%
Sodium Chloride and Sodium Glycolate	NMT 0.5%
Content of Water Soluble Material	NMT - 10.0%
Degree of Substitution (on dried basis)	0.60 - 0.85
Loss on Drying	NMT - 10.0%
pH	5.0 - 7.0
Settling Volume	10.0 ml - 30.0 ml
Heavy Metals	NMT: 20ppm
Microbial Enumeration Tests	
Total Aerobic microbial count	NMT 1000 cfu/g
Total combined molds and yeasts count	NMT 100 cfu/g
Escherichia coli	Absent
Pseudomonas aeruginosa	Absent
Salmonella abony	Absent

Experimental Section

Sallyso™ can be used in wet granulation, dry granulation or direct compression. It is compatible with most of APIs and excipients. Sallyso™ give superior performance compared to many other Croscarmellose Sodium brands.

Metformin Direct Compression formulation

Name of Ingredient	Quantity (% w/w)
Metformin	70.8
ProBlend HD (Silicified Microcrystalline Cellulose)	26.6
Sallyso (Croscarmellose Sodium)	2.1
Lubristar (Sodium Stearyl Fumarate)	0.5
Total	100.0

Direct Compression Study

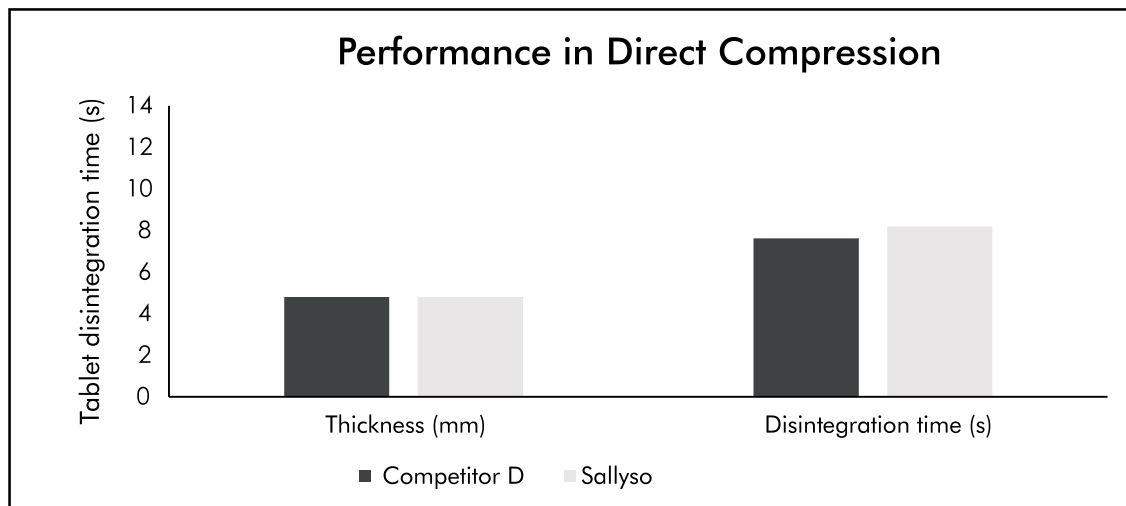
- Sallyso™ In direct compression standard use levels is between 0.5%-3.0%
- Table 1 shows How the disintegration time of Metformin tablets (850 mg / 15 mm tablets containing 2.1%w/w Sallyso™ and 0.5%w/w Sodium Stearyl Fumarate is maintained after storage for 6 months at 40°C/75% RH in open container. The disintegration of reference tablets is also comparable with leading CCS brand.
- This data confirms that Sallyso™ remains an effective super-disintegrant even under the most stressful stability storage conditions when it is compared with leading CCS brand.

Performance & Conclusion

Parameter	Competitor-D CCS	Sallyso™
Punch	15.00 mm	15.00 mm
Hardness	45 N	55 N
Thickness	5.60-5.65 mm	5.60-5.65 mm
Compression force	4.00-4.3 kgf	4.3-4.8 kgf
Disintegration time	7.5 sec	8 sec

Experimental Section

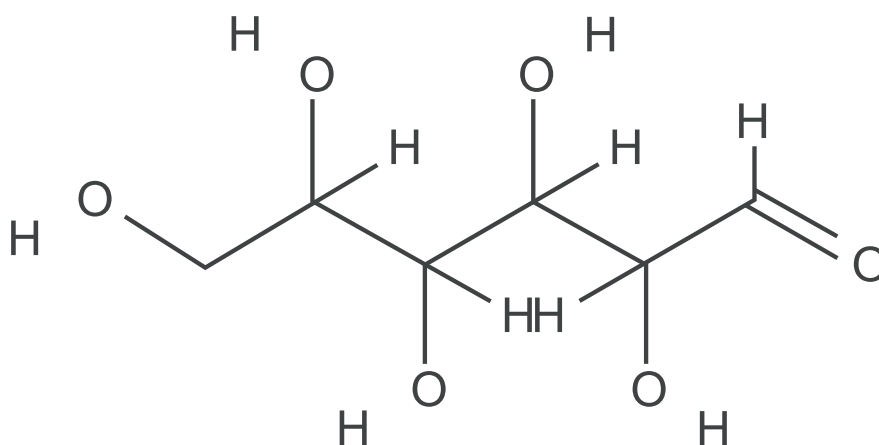
Performance & Conclusion



Effect of Sallyso™ on Tablet Disintegration

Dicalcium Phosphate (DCP) tablets are poorly disintegrating, we have compared different levels of CCS and their effects on disintegration time on DCP tablets as shown below table.

Croscarmellose Sodium%	Disintegration Time
0.10	> 1.8 Hrs
0.25	240 sec
0.50	30 sec
1.00	17 sec
1.50	15 sec



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