

Sallyso[®]

Croscarmellose Sodium (CCS)

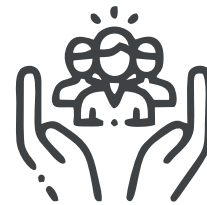
About Us

Gangwal Healthcare Pvt. Ltd., part of the prestigious Gangwal Group, has been a pioneer in the Pharmaceutical industry since 1987. Driven by the sense of social wellbeing and the steely determination to make a difference through technology and expertise, Gangwal Healthcare continues to be at the forefront of Pharmaceuticals, Nutraceuticals and Personal Care sectors in India. Nutraceutical industry globally, is a fastest growing market. As per the recent reports, India has remained 2% of the global nutraceutical industry of USD 400 billion and has potential to be a USD 50 billion by 2025 and USD100 billion by 2030. Our people are our core asset. Their vision, their ideas, their formulations, all connected at the core of Gangwal's success. The team turn our formulations into reality. A reality that has made Gangwal's name synonyms with INNOVATION & QUALITY



Mission

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



Vision

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

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.

Benefits 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 (0.5-3.0% only)

Sallyso® (CCS) provides excellent dissolution properties in tablet formulations. Standard use levels are between 0.5-3.0% in tablets, capsules and granules for disintegration and dissolution improvement.

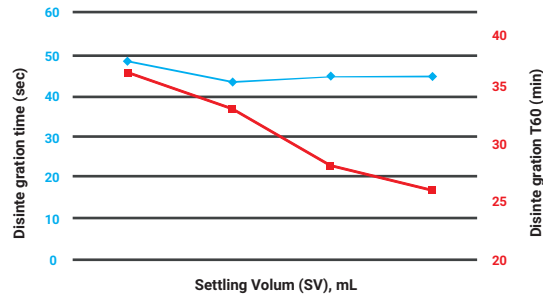
Effect of Sallyso® on Tablet Disintegration

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

Effect of Settling Volumes in Sallyso[®] in Dissolution

Products having Sallyso[®] with higher settling volume has faster drug dissolution. It helps in faster drug release rate



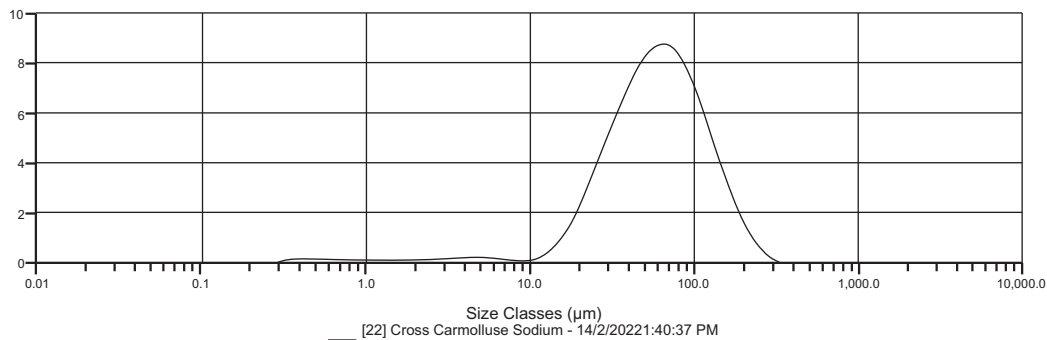
Physical properties

Croscarmellose Sodium (CCS) is an effective superdisintegrant used in tablet and capsule formulations at 0.5–3.0% w/w concentration.

Physical Properties	Result
Bulk density (g/mL)	0.51
Tapped density (g/mL)	0.56
Settling Volume	13 - 18 ml/g

Particle size (by Malvern):

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



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	26.6
Croscarmellose Sodium	2.1
Sodium Stearyl Fumarate	0.5
Total	100.0

Experimental Section

Direct compression study

Sallyso® In direct compression standard use levels is between 0.5%-3.0%

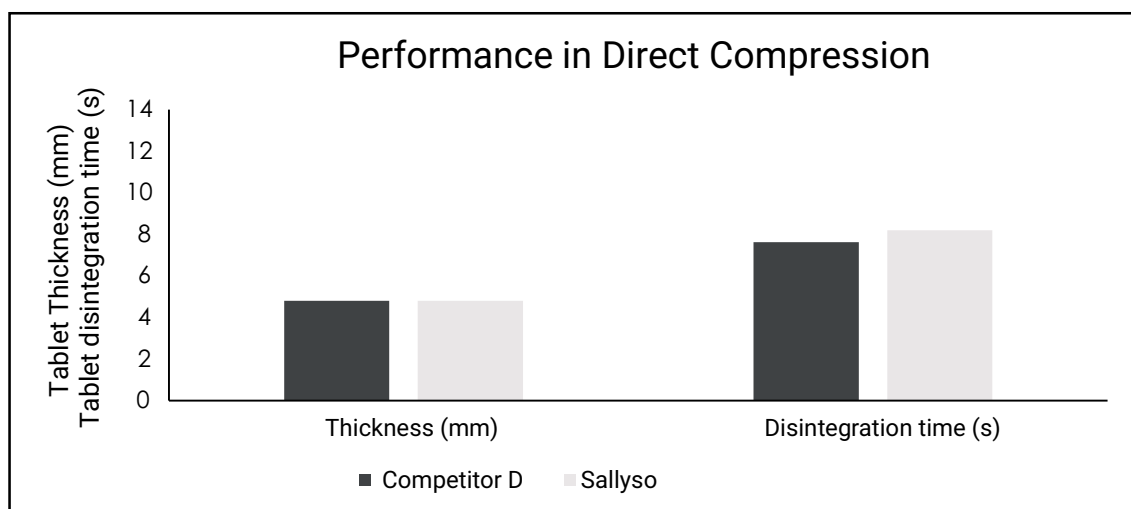
Table 1 shows How the disintegration time of Metformin tablets (850 mg / 15 mm tablets containing 2.1%w/w Sallyso® and 0.5%w/w Sodium Stearyl Fumarate is maintained after storage for 6 months at 40°C / 75% RH in open container. The disintegration of reference tablets is also comparable with leading CCS 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
MCF	4.00-4.3 kgf	4.3-4.8 kgf
DT	7.5 sec	8 sec

Performance & Conclusion



Accreditation & USP

Advantages over overseas product

Customized settling volume, particle size, bulk density & surface area

Cost effective over overseas product.

Easy to access our manufacturing site and less expenses on compliance (Audit, site visit etc).

No need to maintain huge inventory, our product can be delivered to your site within a week.

Customized grade can be provided as per customer's in-house specification

Vocal for Local - Make in India product

Regulatory compliance

Sallyso[®] is manufactured at WHO-GMP and ISO certified facility.

Pharmacopoeia conformity: Sallyso[®] (Croscarmellose Sodium (CCS)) available in USP, BP, IP and Ph. Eur.

Ready tech pack in line with regulatory requirement.

Regulatory Approvals

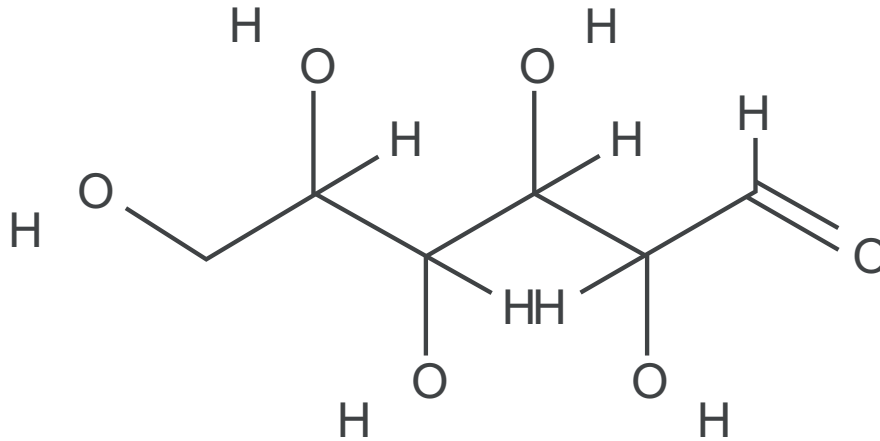
Croscarmellose Sodium is also included in Inactive Ingredient database (IIG) of USFDA for Tablet, Capsule, Pellets, Suspension formulations.

Our manufacturing unit is approved by WHO-GMP and ISO 9001 : 2008

Sallyso[®] is having Type IV Registered US-DMF.

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Croscarmellose Sodium (CCS)



Contact for more information

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