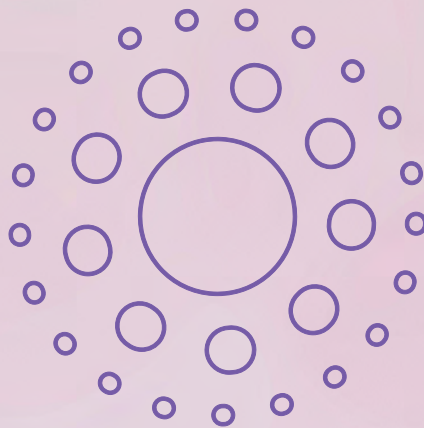




**DELIVERING
CONFIDENCE
WITH THE RIGHT PARTNER**



DISINTEGRANT AND SUPERDISINTEGRANT SOLUTIONS



ROQUETTE

Offering the best of nature™

A consistent disintegration and dissolution profile is critical for the delivery of your medications' active ingredients.

Roquette understands this, and offers an extensive range of disintegrant and superdisintegrant solutions designed to fit your needs in a variety of formulation, manufacturing process and dosage forms.

We don't just provide more disintegrant solutions than anyone else – we also offer peace of mind through product traceability from extraction of raw materials to final product. Our ability to manufacture disintegrants exhibiting consistent performance and reliability you can trust means you can focus on your product, and not have to worry about its untimely breakdown.

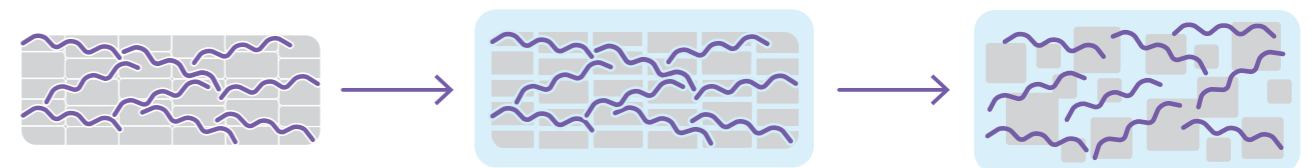


For disintegration, no one size fits all

Our wide range of disintegrant offerings reflects our customers' diverse formulation challenges. As no two formulations are the same, no one disintegrant or superdisintegrant is suited to maximize performance for every formulation. Disintegration is achieved through three main mechanisms, and your products' specific disintegration will involve each of the three mechanisms to a different extent.

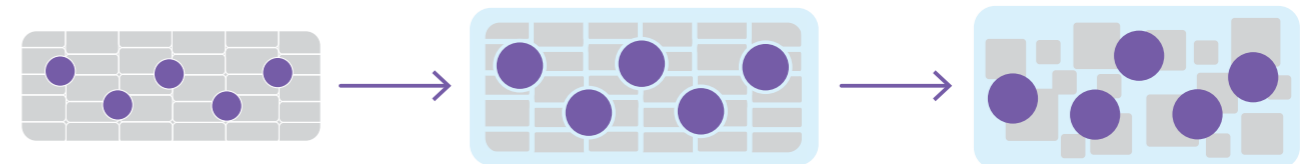
WICKING

Material will draw in water, establishing a capillary network for liquid to penetrate within the tablet. Water will then produce disintegrant swelling and/or dissolution of soluble particles.



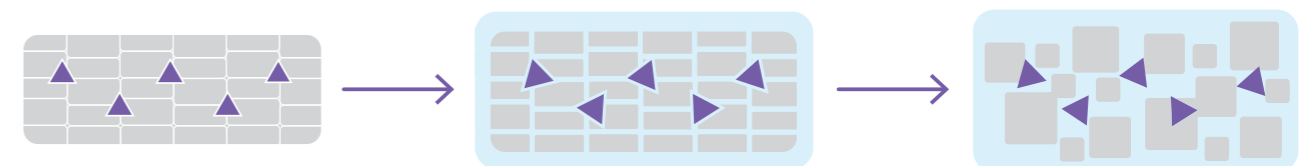
SWELLING

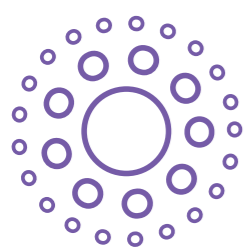
Material swells with water upon contact, exerting pressure within tablet that overcomes tablet cohesiveness.



DEFORMATION

Material within tablet is deformed during compression step, but once disintegrant interacts with water, material is prone to recover initial shape and volume.





DISINTEGRANT AND SUPERDISINTEGRANT SOLUTIONS

	Native starches	GLYCOLYS® range (Sodium Starch Glycolate)	SOLUTAB® (Croscarmellose Sodium)
Botanical origin	Maize, wheat, potato, pea	Potato	Wood, cotton
Nature	Non-ionic	Ionic	Ionic
Functionality	Disintegrant	Superdisintegrant	Superdisintegrant
Water content	5-18% max	10% max	6-10% max
pH	Slightly acidic	Neutral or Acidic	Neutral or Acidic
Shear sensitive	No	Yes/No*	No
Ethanol	0%	6% max	0.5% max
Primary mechanism	Swelling	Swelling	Wicking, Swelling
Suggested usage (wt %)	3-15.0%	2-8.0%	0.5-5.0%

*Specific grade available that is not shear sensitive

It must not be forgotten that the composition of the tablet (filler, filler/binder, diluent) will also influence the disintegration performance of the disintegrant/superdisintegrant.

DISINTEGRANTS

The ionic nature of disintegrants might influence the dissolution of APIs; therefore, we offer both ionic and non-ionic products to meet your formulation and process needs.

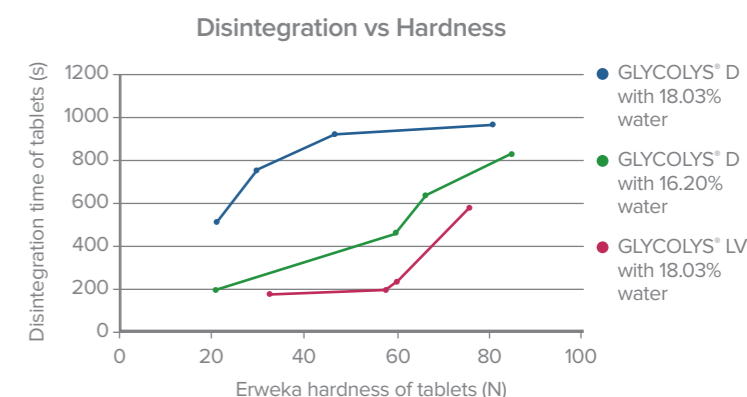
Our non-ionic disintegrants include a selection of native starches, enabling customization potential due to their varied particle size and moisture capacity options.

SUPERDISINTEGRANTS

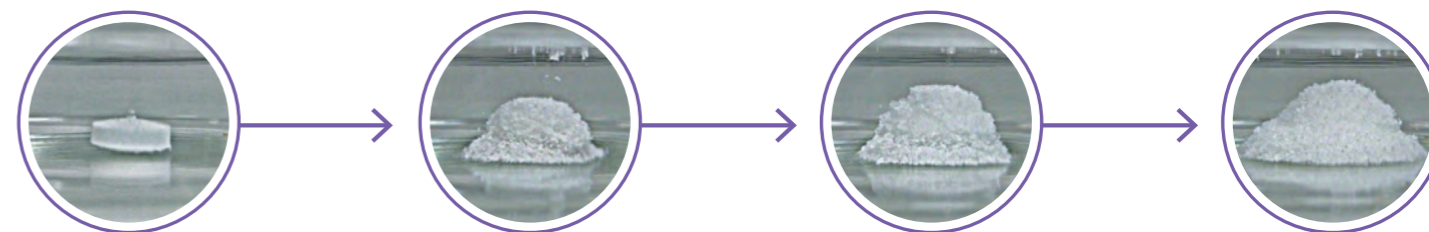
Our superdisintegrant offerings meet the requirements necessary to achieve fast and robust disintegration with minimal amount of disintegrating agent. These properties facilitate the use of any ingredient you need in order to optimize other parameters of your formulation (compactability or drug solubility for example).

GLYCOLYS®, one of our sodium starch glycolate (SSG)-based products, offers solutions to specific environments and conditions susceptible to affect disintegrant performance as well as ensuring stability for drugs, like **GLYCOLYS® Low pH** ensures stability to acidic molecules.

GLYCOLYS® LV is designed to withstand stresses involved in high shear granulation processes, while maintaining the effective disintegration properties of sodium starch glycolate.



GLYCOLYS® bolsters our SSG superdisintegrant portfolio. The ingredient induces rapid and important swelling of tablets followed by an intense and subsequent disintegration. **GLYCOLYS®** has an added benefit of low ethanol content.



SOLUTAB® is composed of croscarmellose sodium, an insoluble hydrophilic polymer. The polymers' structure facilitates both capillary wicking and swelling to achieve disintegration, as its long fibers increase the water spreading within the tablet structure and superdisintegrant network, leading to swelling and the rapid breakdown of formulations.

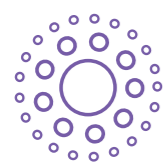




NATIVE STARCHES

	PEA STARCH	MAIZE STARCH B	EXTRA WHITE MAIZE STARCH	MAIZE STARCH 5%	WHEAT STARCH TB	WHEAT STARCH 5%	POTATO STARCH SUPRA NP BACTERIO	POTATO STARCH 8%	POWDERED NF CORN STARCH	400 L NF CORN STARCH
Product description	Pea starch	Corn starch	Corn starch	Corn starch	Wheat starch	Wheat starch	Potato starch	Potato starch	Corn starch	Oxidized corn starch
Color / for uniform tablet color	White to off white	White to off white	White	White to off white	White to off white	White to off white	White	White	White to off white	White
pH	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral	Acidic/Neutral
Not shear sensitive	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Ethanol	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Particle size (µm)	5–45	5–25	5–25	5–25	2–40	2–40	15–100	15–100	5–25	5–25
Loss on drying	16% max	15% max	15% max	5% max	15% max	5% max	20% max	8% max	15% max	15% max

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GLYCOLYS® RANGE

GLYCOLYS®

GLYCOLYS® LV

GLYCOLYS® Low pH

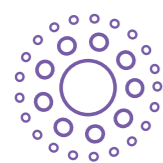
GLYCOLYS® Low Solvent

GLYCOLYS® Corn

Sodium Starch Glycolate

	GLYCOLYS®	GLYCOLYS® LV	GLYCOLYS® Low pH	GLYCOLYS® Low Solvent	GLYCOLYS® Corn
Product description	Potato	Potato	Potato	Potato	Corn
pH	Neutral/Acidic	Neutral/Acidic	Acidic	Neutral/Acidic	Neutral/Acidic
Not shear sensitive / adapted to wet granulation	No	Yes	No	No	No
Ethanol	6% max	6% max	6% max	<0,5% max	<0,5% max
Compliance	EP, NF, JPE	EP, NF, JPE	EP, NF, JPE	EP, NF, JPE	NF





SOLUTAB®

SOLUTAB® A

SOLUTAB® A-IP

SOLUTAB® EDP

Croscarmellose Sodium

Product description	Wood	Wood	Cotton
Nature	Ionic	Ionic	Ionic
Water content	10% max	6% max	10% max
pH	Neutral/Acidic	Neutral/Acidic	Neutral/Acidic
Not shear sensitive	No	No	No
Ethanol	<0,5% max	<0,5% max	<0,5% max
Compliance	EP, NF, JPE	EP, NF, JPE	EP, NF, JPE





LEARN MORE ABOUT ROQUETTE DISINTEGRANT AND SUPERDISINTEGRANT PRODUCTS AT
www.roquette.com | pharma@roquette.com

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