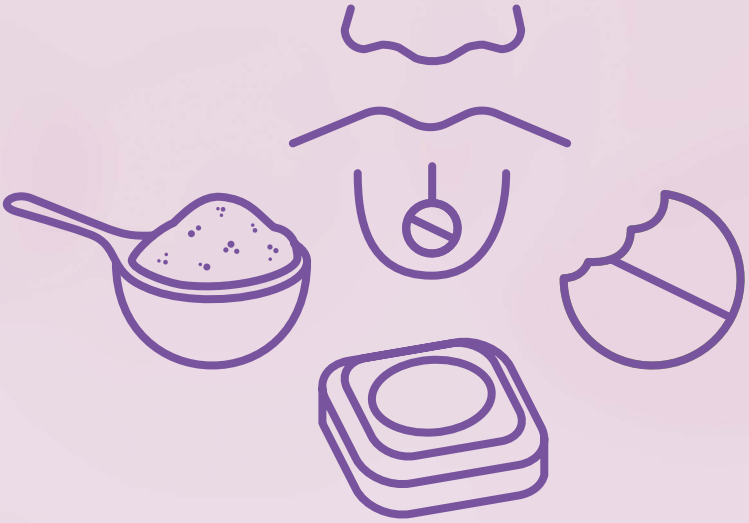
# DELIVERING
## ADAPTIVE SOLUTIONS WITH THE RIGHT PARTNER



# FILLER AND FILLER-BINDER SOLUTIONS

ROQUETTE
*Offering the best of nature™*

AN UNWAVERING COMMITMENT TO ENABLING
**LIFE-SAVING PHARMACEUTICALS**

# Enable effective drug manufacturing and enhance patient compliance with our expansive range of reliable fillers and filler-binders.

Final dosage forms come in all shapes and sizes, and our focus is providing formulators and manufacturers with flexible, high-quality ingredients that enable cost-effective production. No matter your formulation, dosage or process constraints, Roquette offers a diverse range of adaptable filler and filler-binder products and the technical expertise to ensure the right excipient solution is selected.

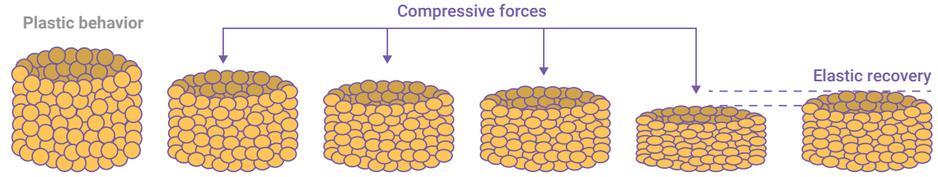
Our commitment to consistency is what sets us apart. Each of our excipients is manufactured under Roquette quality control systems, ensuring consistent product performance for optimum productivity. From laboratory to industrial scale production, rely on Roquette to help solve your process and formulation challenges with flexible filler and filler-binder solutions.

## FILLERS AND FILLER-BINDERS: A BALANCING ACT

The ideal formulation delivers a defect-free dosage form in the widest range of manufacturing conditions possible, which is obtained by balancing the brittle, plastic and elastic behavior exhibited by the deformation of the excipients and API under compaction.

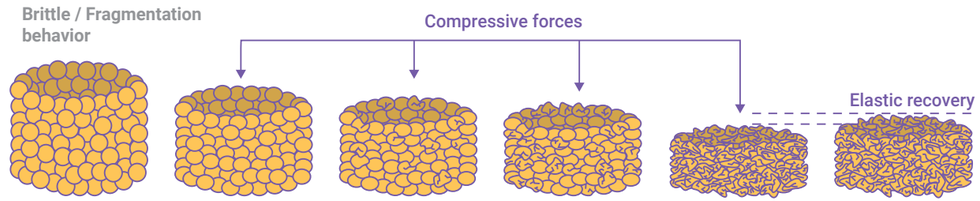
### Plastic behavior

- Fewer surfaces generated during compaction, which makes ingredients sensitive to lubrication
- Higher mechanical strength
- Higher propensity to cap, higher sensitivity to turret speed



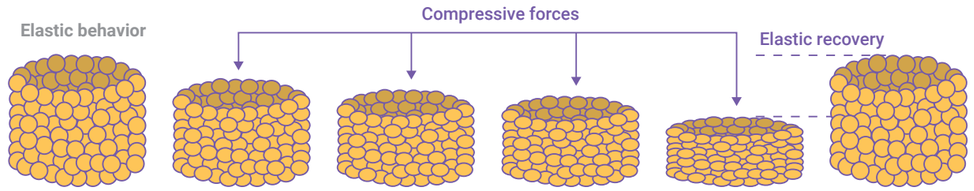

### Fragmentation behavior

- Fragmentation under compression generates new surfaces fresh of lubricants, making ingredients insensitive to lubrication
- Lower mechanical strength
- Lower propensity to cap, lower sensitivity to turret speed




### Elastic behavior

- No new bonds formed between particles during compaction
- No mechanical strength
- Highest capping propensity, insensitive to turret speed



# OPTIMIZED FOR YOUR PROCESS

Our manufacturing technologies allow us to offer various grades within our filler and filler-binder product families that can be differentiated by particle size, density, surface area or moisture content. This diversity allows our customer to formulate and manufacture all types of solid dosage forms with any process (wet or dry granulation, direct compression) ensuring uniformity and stability, and optimal organoleptic properties. Below is an overview of the key features of our various products.

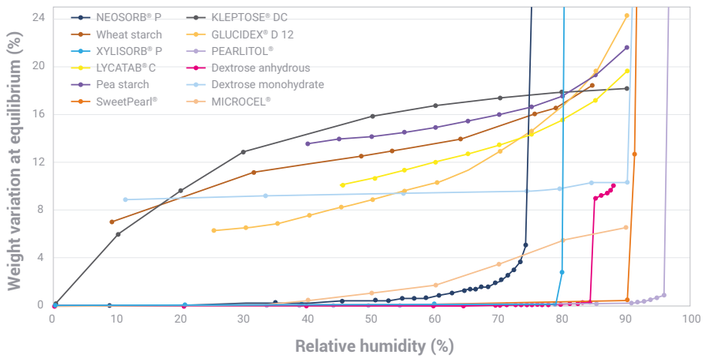



Figure 1: Dynamic vapor sorption plot at 20°C of designated filler/filler-binder offering.

**Dextrose** and **GLUCIDEX®** exhibit filler functionality with the addition of being a carbohydrate source. Of various botanical origin to help alleviate patient-intolerance issues, our **Native starch** excipients provide affordable filler functionality with the addition of disintegration properties.

Ranging from the high hygroscopicity of **NEOSORB®**, to no hygroscopicity of **PEARLITOL®**, our filler product range helps alleviate variable stability and process constraints.

# PATIENT-FOCUSED FORMULATIONS

Our polyol fillers offer sugary sweetness without the drawbacks. Possessing a low caloric and low insulinemic index, these excipients tackle the growing concern of health-conscious patients.

For “tasty” dosage forms, the unique organoleptic properties of **XYLISORB®** combine sweetness and a cooling effect.

**PEARLITOL®** is the all-in-one excipient: a unique combination of solubility, sweetness, chemical and physical stability that makes it fit with any formulation or dosage form.

With its intrinsically high density, **SweetPearl®** allows formulators to pursue smaller dosage forms for ease of intake. As Figure 2 shows, polyols range offers you to design your product sensorial profile to target any patient population.


Figure 2: A ternary plot representing the various terms and definitions relating to sensory analysis, as dictated by NF EN ISO 5492.

# FILLER-BINDERS FOR YOUR DESIRED TABLET PROPERTIES

The combination of organoleptic and tableting properties of our filler-binder range unleashes your formulation capabilities, and facilitates solid dose manufacturing in the form of chewables, suckables, swallowables, effervescents, and orally dispersible tablets (ODT).

Designed specifically for compressed dosage forms like tablets and capsules, our **MICROCEL®** range delivers a solution to your compaction challenges by enhancing tabletability and reducing friability.

**KLEPTOSE® DC** exhibits multi-functionality, helping to improve solubility, dissolution speed, and taste masking.

**PEARLITOL® FLASH** ensures ODT formulation with a fast disintegration time. Contrary to other ODT excipients, the disintegration time is independent of compression force.

**STARLAC®*** is more than just a lactose and starch combination. The co-processing delivers superior tablet performance (disintegration, low friability) and robustness (low lubricant sensitivity and constant tabletability over time).

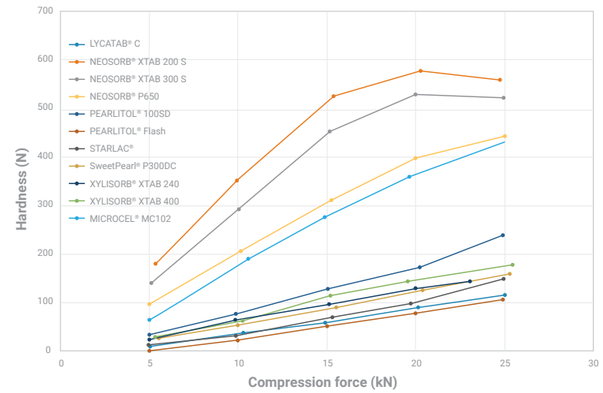



Figure 3: Filler-binder excipient compactability, as measured using Korsch® XP1 with 13mm diameter concave punches at 20 tablet/min rate.

Ideal for capsule filling, our **LYCATAB® C** range delivers consistent performance for customers seeking fast disintegration with the addition of excellent compressibility.

# OPTIMIZED FOR YOUR PRODUCTIVITY

The compactability of these products has been optimized using processes like:

- hot melt extrusion (**PEARLITOL® DC**)
- spray drying (**PEARLITOL® SD**, **NEOSORB® XTAB S**)
- granulation (**XYLISORB® XTAB**, **SweetPearl® P DC**)

in order to provide consistent performance, batch after batch, to maximize productivity.

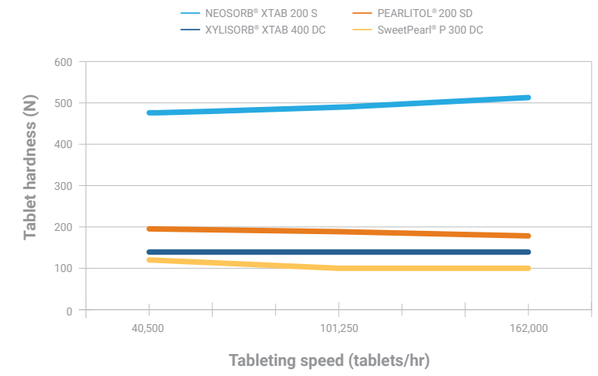



Figure 4: As one example, **PEARLITOL® 200 SD** shows consistent superior hardness independent of turret speed.

*__StarLac®__ is a product co-marketed by Meggle and Roquette.

# FILLER AND FILLER-BINDER SOLUTION OFFERING

| | Native starches range | LYCATAB® C range | Dextrose | GLUCIDEX® | StarLac® | NEOSORB® range | XYLISORB® range | SweetPearl® | PEARLITOL® | PEARLITOL® FLASH | KLEPTOSE® DC | MICROCEL® |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Potato, wheat, maize, pea | Pregel starch | Monohydrate, anhydrous | Maltodextrin dry glucose syrup | Lactose starch | Sorbitol | Xylitol/binder | Maltitol | Mannitol | Mannitol/starch | Betacyclodextrin | Microcristalline cellulose |
| **Main Deformation** | Elastic | Plastic/elastic | Fragmentation | Plastic | Fragmentation/ elastic | Plastic | Fragmentation | Plastic | Fragmentation | Fragmentation/ elastic | Plastic | Plastic |
| **Filler** | X | | X | X | | X | X | X | X | | | X |
| **Filler/binder** | | X | X | X | X | X | X | X | X | X | X | X |
| **Solubility** | Insoluble | Partially soluble | 1000 | >50% (viscosity is a limiting factor) | Partially soluble | 2250 | 1600 | 1500 | 170 | Partially soluble | 18.5 | Insoluble |
| **Self-disintegrating** | Yes | Yes | No | No | Yes | No | No | No | No | Yes | No | No |
| **Maillard reaction** | No | No | Yes | Yes | Yes | No | No | No | No | No | No | No |
| **Hygroscopicity** | High | Medium | Slight | Medium | Slight | High | Medium | Very low | No | Slight | Medium | Medium |
| **Moisture content** | 12% | 5-7% | 8% | 4% | 5% | 0.5% | 0.5% | 0.1% | 0.1% | 2% | 12% | 5% |
| **Organoleptic** | Neutral | Neutral | Sweet | Sweet | Neutral | Sweet | Sweet | Sweet | Sweet | Sweet | Neutral | Neutral |

# FILLER AND FILLER-BINDER SOLUTIONS

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## 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 |
| Particle size (µm) | 5–45 | 5–25 | 5–25 | 5–25 | 2–40 | 2–40 | 15–100 | 15–100 | 5–25 | 5–25 |
| Moisture content | 14% | 12% | 12% | 5% max | 12% | 5% max | 19% | 8% max | 12% | 12% |

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# LYCATAB®

| | LYCATAB® C | LYCATAB® C-LM |
|---|---|---|
| | Pregelatinized starch | |
| Water content | 14% max | 7% max |
| Particle size<br>mean diameter- D4:3 (µm) | 80 | 90 |
| Bulk density (g/mL) | 0.63 | 0.63 |

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## DEXTROSE

| | DEXTROSE MONOHYDRATE F | DEXTROSE MONOHYDRATE M | DEXTROSE MONOHYDRATE GC | DEXTROSE MONOHYDRATE G | ANHYDROUS DEXTROSE CF | ANHYDROUS DEXTROSE C | ANHYDROUS DEXTROSE CG | DEXTROSE MONOHYDRATE GD-SDG |
|---|---|---|---|---|---|---|---|---|
| | | | | Crystalline | | | | Granulated |
| Filler | x | x | x | x | x | x | x | |
| Filler / Binder | | | | | | | | x |
| Moisture content | 9% | 9% | 9% | 9% | 0.2% | 0.2% | 0.2% | 9% |
| Particle size mean diameter-D4:3 (µm) | 120 | 160 | 220 | 300 | 130 | 280 | 400 | 250 |
| Bulk density (g/mL) | 0.6 | 0.6 | 0.56 | 0.65 | 0.77 | 0.82 | 0.83 | 0.5 |
| Application | Pharma/nutra | Pharma/nutra | Pharma/nutra | Pharma/nutra | Pharma/nutra | Pharma/nutra | Pharma/nutra | Nutra |

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## GLUCIDEX®

| | GLUCIDEX® 1 | GLUCIDEX® 2 | GLUCIDEX® 6 | GLUCIDEX® 9 | GLUCIDEX® 12 | GLUCIDEX® 17 | GLUCIDEX® 19 | GLUCIDEX® 21 | GLUCIDEX® 28 | GLUCIDEX® 29 | GLUCIDEX® 33 | GLUCIDEX® 38 | GLUCIDEX® 39 | GLUCIDEX® 47 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Maltodextrin | | | | | | | Dry glucose syrup | | | | | | |
| Sweetness | | | | | | | | | | | | | | |
| Viscosity (60% DS 20°C) | | | 1157 | | 410 | | 129 | 116 | | 58 | | 38 | 37 | 31 |
| Particle size (µm) | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 | 60–100 |
| Bulk density (g/mL) | 0.4 | 0.4 | 0.45 | 0.45 | 0.45 | 0.5 | 0.5 | 0.5 | 0.55 | 0.55 | 0.55 | 0.55 | 0.55 | 0.55 |

For GLUCIDEX IT grades: particle size 250-300µm and density 0.35 to 0.50
For PREMIUM grades: tighter microbial specifications.

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## STARLAC®

| | STARLAC® |
|---|---|
| Product description | Lactose Starch |
| Particle size<br>mean diameter- D4:3 (µm) | 125 |
| Bulk density (g/mL) | 0.6 |

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## NEOSORB®

| | NEOSORB® P 100T | NEOSORB® P 60 | NEOSORB® P 60W | NEOSORB® P 20/60 | NEOSORB® XTAB 200 S | NEOSORB® XTAB 300 S | NEOSORB® XTAB 550 S |
|---|---|---|---|---|---|---|---|
| | Crystalline Sorbitol | | | | Spray dried Sorbitol | | |
| Filler | x | x | x | x | x | x | x |
| Filler / Binder | x | x | x | x | x | x | x |
| Particle size mean diameter- D4:3 (µm) | 130 | 230 | 260 | 400 | 200 | 300 | 550 |
| Bulk density (g/mL) | 0.65 | 0.69 | 0.63 | 0.67 | 0.43 | 0.5 | 0,5 |
| Surface area ($m^2/g$) | Approx. 1 | Approx. 1 | Approx. 1 | Approx. 1 | Approx. 2 | Approx. 2 | Approx. 2 |

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# XYLISORB®

| | XYLISORB® 90 | XYLISORB® 300 | XYLISORB® 700 | XYLISORB® XTAB 240 | XYLISORB® XTAB 400 |
|---|---|---|---|---|---|
| | Crystalline Sorbitol | | | Granulated Sorbitol | |
| Product description | Xylitol | Xylitol | Xylitol | Xylitol/NUTRIOSE® | Xylitol/CMC |
| Filler | x | x | x | | |
| Filler / Binder | | | | x | x |
| Particle size mean diameter- D4:3 (µm) | 90 | 200 | 600 | 240 | 300 |
| Bulk density (g/mL) | 0.61 | 0.78 | 0.84 | 0.6 | 0.6 |
| Application | Pharma/Nutra | Pharma/Nutra | Pharma/Nutra | Nutra | Pharma/Nutra |

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## SweetPearl®

| | SweetPearl® P 35 | SweetPearl® P 90 | SweetPearl® P 200 | SweetPearl® P 300 DC |
|---|---|---|---|---|
| | | Crystalline Maltitol | | Granulated Maltitol |
| Filler | x | x | x | |
| Filler / Binder | | | | x |
| Particle size mean diameter- D4:3 (µm) | 45 | 60 | 200 | 300 |
| Bulk density (g/mL) | 0.45 | 0.48 | 0.84 | 0.6 |

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## PEARLITOL®

| | PEARLITOL® 25 C | PEARLITOL® 50 C | PEARLITOL® 110 C | PEARLITOL® 160 C | PEARLITOL® 100 SD | PEARLITOL® 200 SD | PEARLITOL® 300 DC | PEARLITOL® 400 DC | PEARLITOL® 500 DC |
|---|---|---|---|---|---|---|---|---|---|
| | Crystalline Mannitol | | | | Spray dried Mannitol | | Extruded Mannitol | | |
| Filler | x | x | x | x | | | | | |
| Filler / Binder | | | | | x | x | x | x | x |
| Precompression | | | | | | | x | x | x |
| Particle size mean diameter-D4:3 (µm) | 25 | 50 | 110 | 160 | 110 | 160 | 300 | 400 | 500 |
| Bulk density (g/mL) | 0.43 | 0.49 | 0.6 | 0.63 | 0.4 | 0.5 | 0.7 | 0.7 | 0.7 |

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# PEARLITOL® FLASH

| | PEARLITOL® FLASH |
|---|---|
| Product description | Mannitol/Starch |
| Particle size<br>mean diameter- D4:3 (µm) | 200 |
| Bulk density (g/mL) | 0.48 |

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# KLEPTOSE® DC

| | KLEPTOSE® DC |
|---|---|
| Product description | Beta-cyclodextrin |
| Particle size<br>mean diameter- D4:3 (µm) | 80 |
| Bulk density (g/mL) | 0.55 |

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## MICROCEL®

| Product description | Microcrystalline Cellulose | | | | |
|---|---|---|---|---|---|
| Type | 101 | 102 | 112 | 12 | 200 |
| Particle size (µm) | 50 | 100 | 100 | 160 | 180 |
| Water content | 7% max | 7% max | 1,5% max | 7% max | 7% max |
| Bulk Density (g/mL) | 0,26-0,31 | 0,28-0,33 | 0,28-0,33 | 0,30-0,40 | 0,33-0,40 |

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