



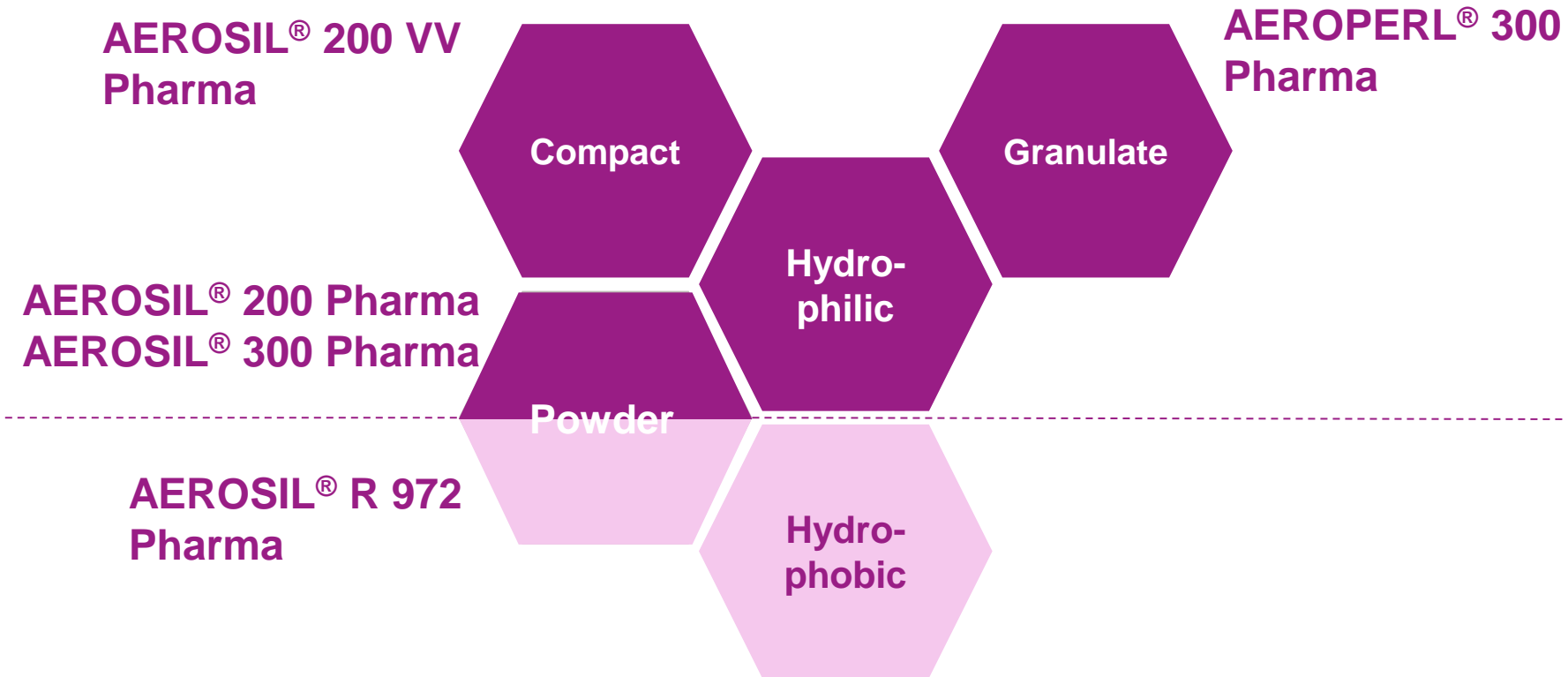
AEROSIL® Pharma

Differences and similarities to
other pharma silica products



EVONIK
INDUSTRIES

AEROSIL® Pharma: A full range of pharma silica



AEROSIL® Pharma offers the full choice of pharmaceutical silica grades:

- hydrophilic / hydrophobic products
- powders / compacts / granulates

AEROSIL® Pharma

Full pharmacopeia compliance



AEROSIL® Pharma*

Silica Colloidal Anhydrous

Ph. Eur.

+

USP/NF

+

JP

+

ChP

+

IP

+

Silica Colloidal Hydrated**

+

+

No monograph

+

No monograph

* Data based on AEROSIL® 200 Pharma, AEROSIL® 300 Pharma

** e.g. Syloid® 244 FP, Syloid® AL-1 FP

AEROSIL® Pharma products are recognized by all major pharmacopeia as suitable for pharmaceutical manufacture and produced according to IPEC-GMP guidelines.

AEROSIL® Pharma

The quality choice of pharma silica



	AEROSIL® Pharma ¹ Silica Colloidal Anhydrous	Silica Colloidal Hydrated ²
Production	Flame hydrolysis: Gas phase process	Precipitation: Aqueous process
Purity	<ul style="list-style-type: none"> Loss on ignition (LoI)³ ≤ 5.0 w.-% SiO₂ content (after ignition)³ 99.0 – 100.5 w.-% Elemental contamination (ICH Q3D, table 2.1, oral dosage forms) Requirements exceeded: Class 1, 2a: all < 0.5 ppm Class 2 b, 3: not intentionally added 	<ul style="list-style-type: none"> Loss on ignition (LoI)³ ≤ 20.0 w.-% SiO₂ content (after ignition)³ 98.0 – 100.5 w.-% Elemental contamination (ICH Q3D, table 2.1, oral dosage forms) Dependent on product and raw material purity
Physio-chemical data	<ul style="list-style-type: none"> pH³ 3.5 – 5.5 Tamped density 50 – 280 g/l 	<ul style="list-style-type: none"> pH³ 4.0 – 7.0 Tamped density 80 – 470 g/l

¹ AEROSIL® 200 Pharma, AEROSIL® 200 VV Pharma, AEROSIL® 300 Pharma, AEROPERL® 300 Pharma

² E.g. Syloid® 244 FP or Syloid® Al 1 FP by Grace Davison

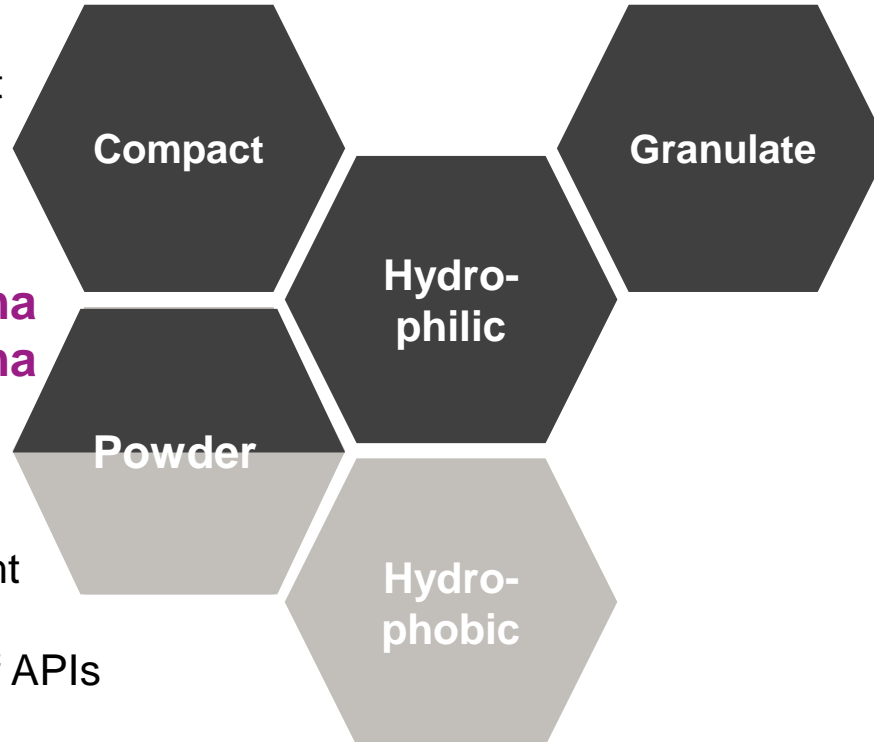
³ Requirements by Ph. Eur. version 8.4

AEROSIL® Pharma Typical applications

AEROSIL® 200 VV Pharma

Glidant:

- Powder flow aid
- Improved tablet weight variation



AEROPERL® 300 Pharma

Pharmaceutical carrier:

- Turn liquids into powders
- Moisture scavenging
- API dissolution and solubilization

AEROSIL® 200 Pharma AEROSIL® 300 Pharma

Glidant:

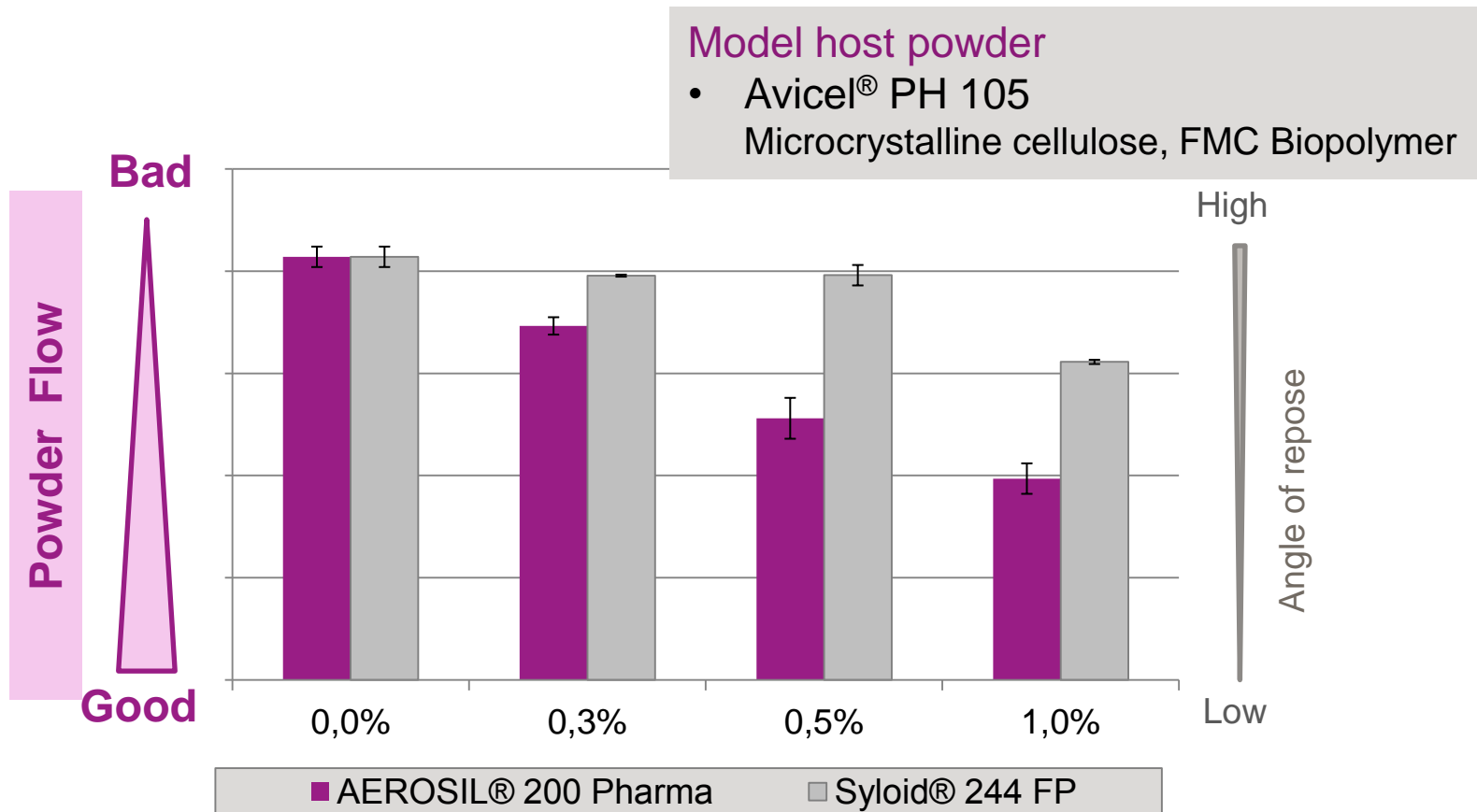
- Powder flow aid
- Improved tablet weight variation
- Moisture protection of APIs

Rheology:

- Gel formation
- Dispersion stabilization

AEROSIL® R 972 Pharma

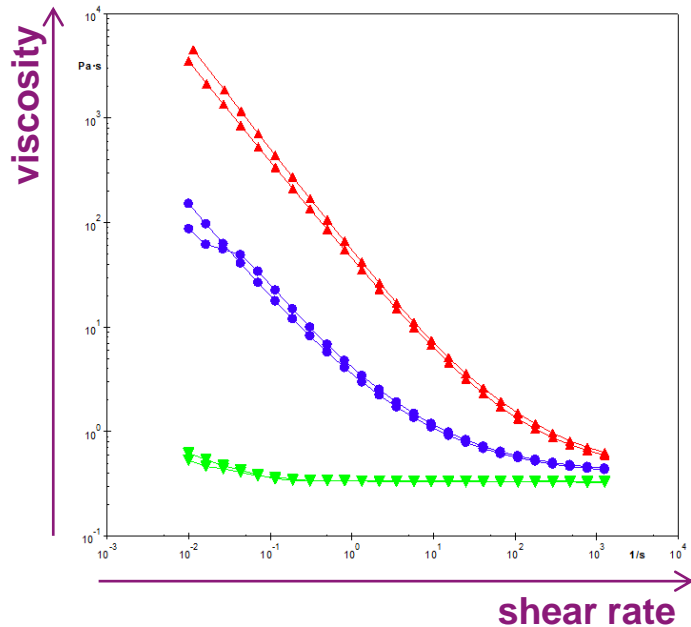
AEROSIL® Pharma Superior powder flowability



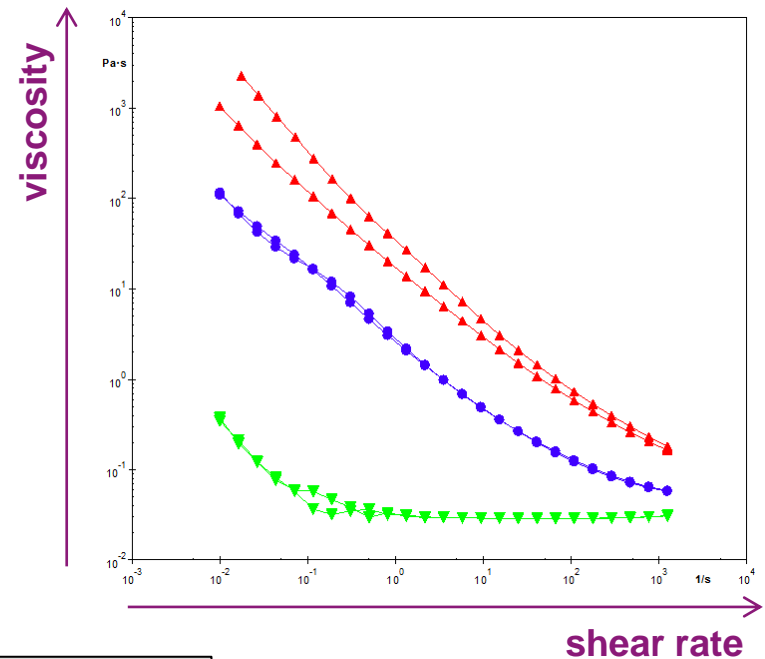
AEROSIL® Pharma excipients are first class glidants, offering more than one product choice.

AEROSIL® Pharma Rheology control

Silicone oil



Paraffin oil



- ▼ Pure Oil
- 3 % Syloid® 244 FP
- ▲ 3 % AEROSIL® 300 Pharma

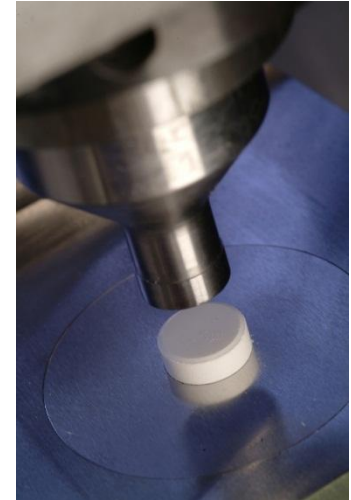
AEROSIL® Pharma products are very efficient thickeners for various oils.

AEROSIL® Pharma

The performance and quality choice



- ✓ **AEROSIL® Pharma products set the quality benchmark in pharma silica:**
 - extremely pure silica: quality requirements of monograph “Silica Colloidal Anhydrous” are exceeded
 - requirements in “Silica Colloidal Anhydrous” more stringent than monograph “Silica Colloidal Hydrated” (e.g. Lol)
 - production according to IPEC GMP guidelines
- ✓ **AEROSIL® Pharma – versatility and high performance:**
 - products for many specific applications
 - highly efficient glidants
 - strong viscosity build in oils
- ✓ **AEROSIL® Pharma provide high supply security:**
 - production in several plants around the globe
- ✓ **AEROSIL® Pharma service package:**
 - regulatory assistance
 - technical assistance by experienced experts in your proximity





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