

A scanning electron micrograph (SEM) showing numerous spherical particles of varying sizes. The particles have a porous, textured surface. One large particle is prominently featured in the center-right, surrounded by many smaller particles. The background is dark, making the light-colored particles stand out.

AEROPERL® 300 Pharma

A versatile excipient for
pharmaceutical applica-
tions



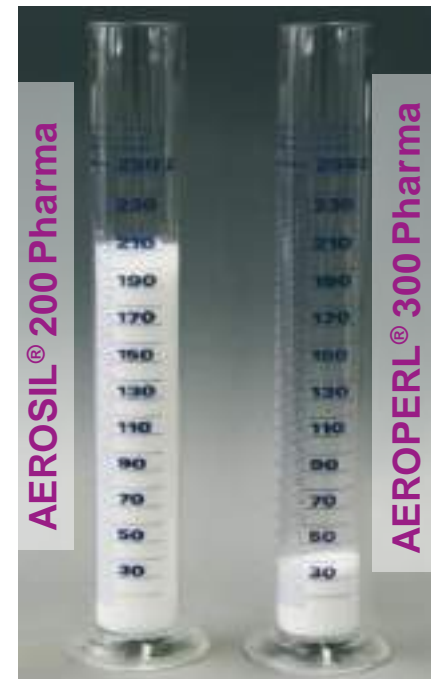
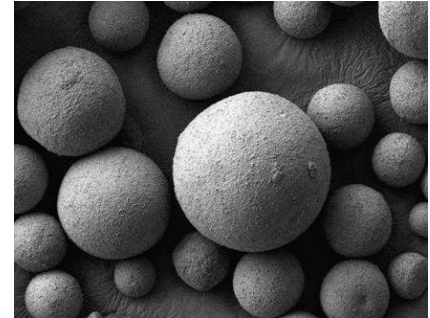
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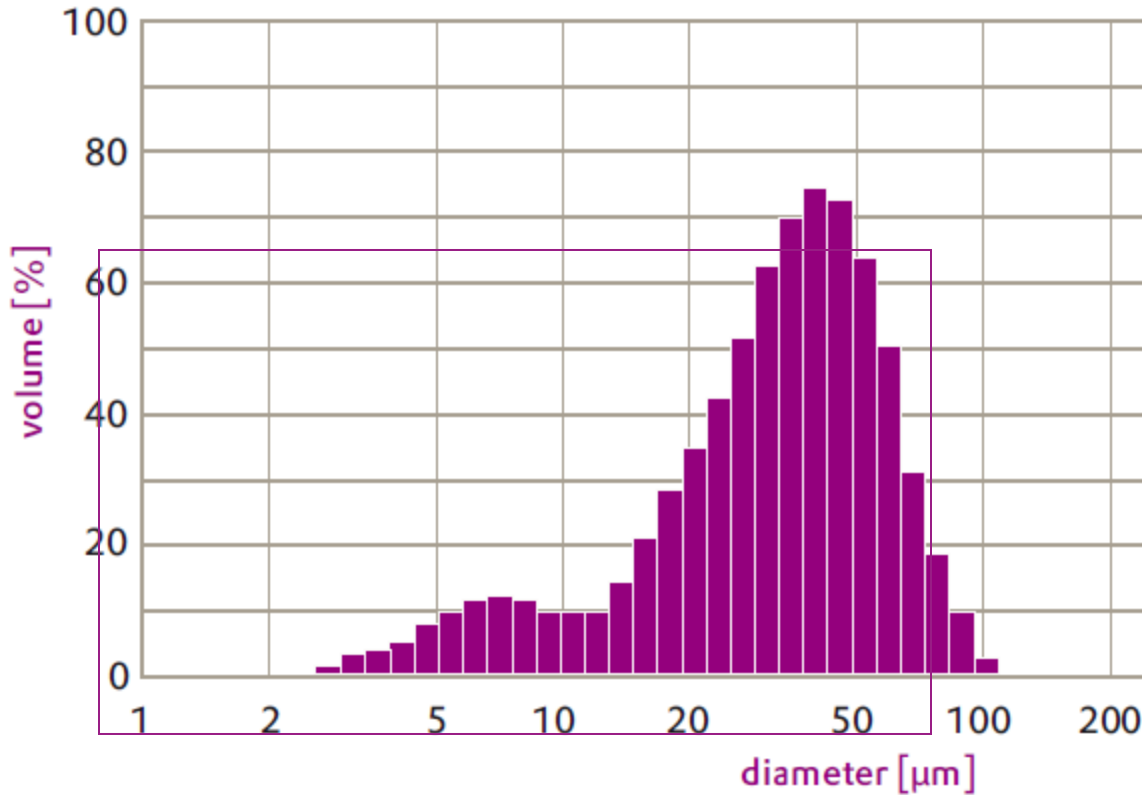
AEROPERL[®] 300 Pharma

– a granulated form of AEROSIL[®]

AEROPERL[®] 300 Pharma ...

- is based on traditional AEROSIL[®] excipients well known in the industry as glidants for direct compression processes
- consists of spherical granules with a medium particle diameter of 30 – 40 µm
- Features the advantages of AEROSIL[®] ...
 - high purity precursors, thus extraordinary low heavy metal content
 - no organic or biogenic materials used in production
 - purely amorphous, inert to most chemicals
- ... without the inherent challenges of a fine powder
 - low density, thus challenging storage
 - dust generation on handling





Particle size distribution (laser action):

50 appr. 30 µm

90 appr. 55 µm

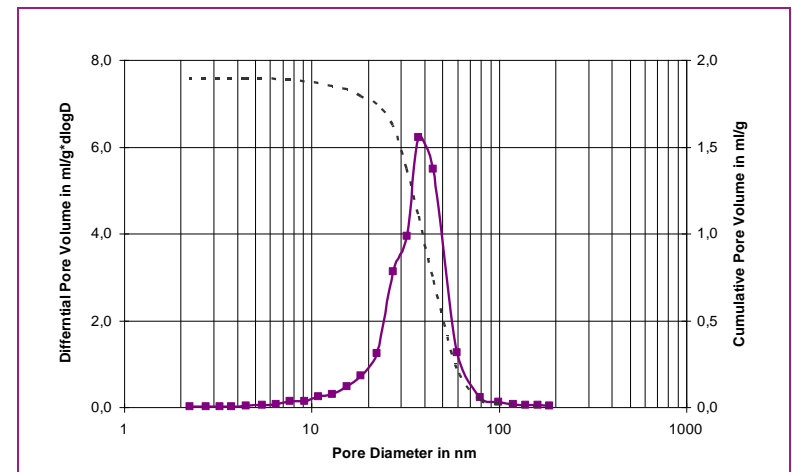
Specific surface area (BET):

appr. 300 m²/g

Apparent density: appr. 280 g/l

- Porous particles, featuring meso- and macropores
- Mesopore volume appr. 1,6 ml/g
- Adsorbates may contain as little as 40 weight -% of the carrier

▶ **More physico-chemical data**



AEROPERL® 300 Pharma meets the requirements of pharma excipients

GMP production

- IPEC-GMP guidelines are followed in production, ensuring
 - validated process
 - full traceability of all raw materials and process parameters
 - high hygiene standards in production and bag filling

Compendial compliance

- Pharm. Eur.
 - complies to monograph “silica colloidal anhydrous”
- USP/NF
 - complies to monograph “colloidal silicon dioxide”
- JP
 - complies to all parameters of monograph “light anhydrous silicic acid”, except the “volume test”
 - currently not tested



AEROPERL® 300 Pharma a versatile carrier for API's



Applications

- Absorption of liquid active pharmaceutical ingredients transforms liquid API's in free flowing powders, enabling processing into solid dosage forms (e.g. vitamins, dimethicone)
- AEROPERL® 300 Pharma may help to isolate pure but hard to crystallize API's and transfer them into a processable form

Model formulations

AEROPERL® 300 Pharma 42 g

Liquid:
dimethicone or vitamin E acetate
(60°C)

- Mixture 1 : 1 42 g
- Mixture 2 : 3 63 g

Mixing conditions

- Somakon MPL-1 mixer
- Fill mixing chamber with AEROPERL®
- Addition of liquid in 1 min (vitamin E acetate @ 60°C)
- 30 s mixing
- 10 min standing
- 10 s mixing

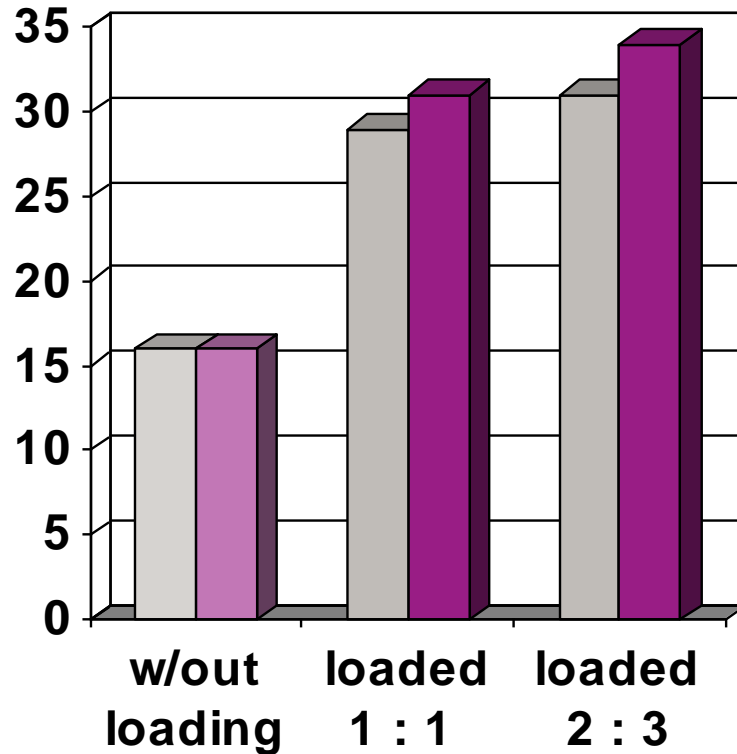
AEROPERL® 300 Pharma

Absorbates with good flowability

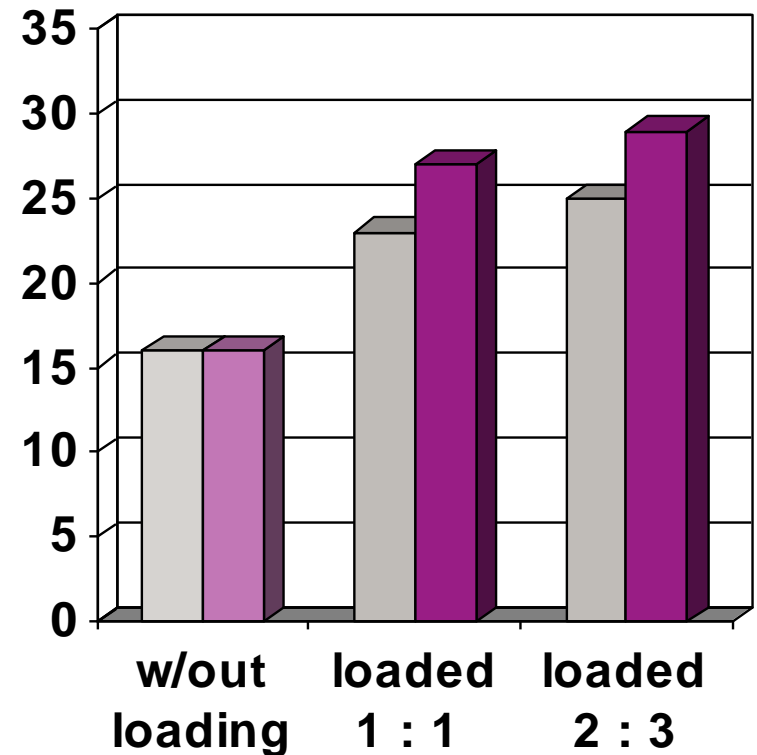


Shortly after production

↑
Angle of Repose (°)



24 h storage



■ Dimethicone

■ Vitamin E acetate

AEROPERL® 300 Pharma a highly absorptive desiccant



- AEROPERL® 300 Pharma can be used to absorb and distribute water more evenly in moisture assisted dry granulation (MADG) processes
- Compared to conventional wet granulation MADG offers several advantages:
 - MADG uses only 2 – 4 weight-% water compared to up to 50 % in wet granulation
 - no drying step is necessary
 - granules are produced in the desired size range, so sizing of the prepared granules can be avoided
- AEROPERL® 300 Pharma can help to run pharmaceutical production more economically



Literature:

I. Ullah et al., Pharmaceut. Technol. 2009(11) 62, Pharmaceut. Technol. 2009(12) 42, Pharmaceut. Technol. Europe 23 2011(3) 22.

AEROPERL® 300 Pharma Performance in MADG formulations



Model formulation

1. Lactose monohydrate	65,0 weight-%	Simulating API
2. Polyvinyl pyrrolidone (Povidone K-12)	7,0 weight-%	Granulation binder
3. Microcrystalline cellulose (Avicel PH 200)	20,0 weight-%	Filler
4. Crospovidone	4,0 weight-%	Disintegrant
5. Water	2,0 weight-%	Granulation liquid
6. Silica absorbant	1,5 weight-%	Moisture absorbant
7. Magnesium stearate	0,5 weight-%	Lubricant

Mixing and granulation conditions

- Premix components 1 and 2 for 1 min.
- Spray water in fine droplets on that mixture
- Mix and form granules for about 3 min.
- Add **silica absorbant**, mix 3 min.
- Add Crospovidone, mix 2 min.
- Add magnesium stearate, mix 30 s.

} Granulation

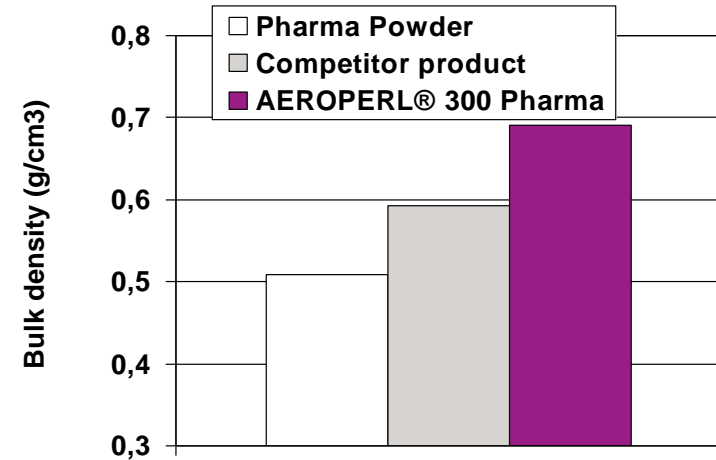
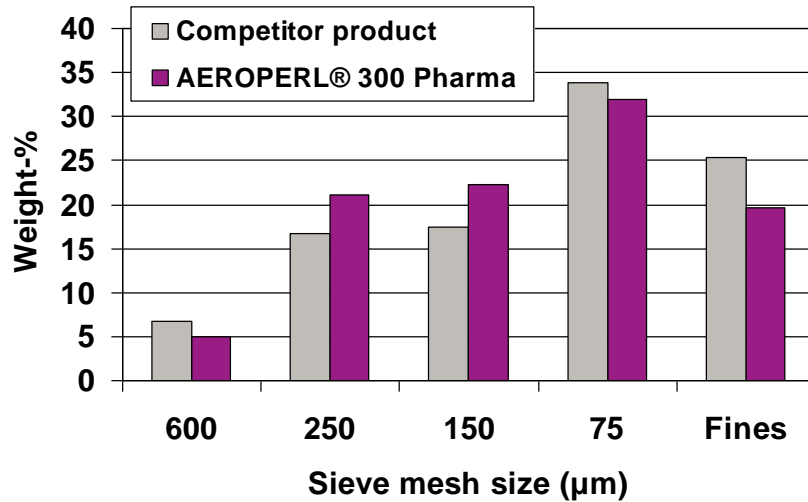
} Moisture distribution

} Finalize mixing

I. Ullah et al., Pharmaceut. Technol. 2009(12) 42

AEROPERL® 300 Pharma Performance in MADG formulations

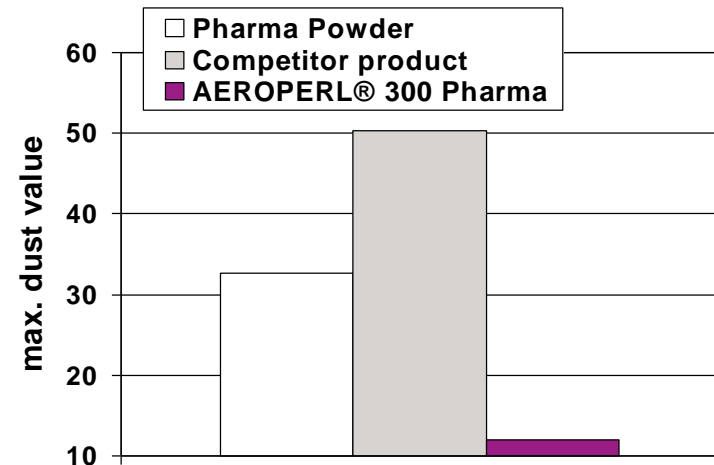
Sieve analysis



Bulk density

AEROPERL® 300 Pharma leads to

- a more uniform granule size distribution
- more compact granules
- by far less dusty granulate



Dust generation

AEROPERL® 300 Pharma:

Physico-chemical data and registration status



Properties and test methods	Unit	Value
Specific surface area (BET)	m ² /g	approx. 300
Average particle size	µm	approx. 30
Tamped density* acc. to DIN EN ISO 787/11, Aug. 1983	g/l	approx. 280
Loss on drying (moisture)* Tested according to USP/NF and Ph. Eur.	wt.%	≤ 2.5
Loss on ignition Tested according to USP/NF	wt.%	≤ 2.0
Loss on ignition Tested according to Ph. Eur.	wt.%	≤ 5.0
pH Tested according to USP/NF and Ph. Eur.		3.5 - 5.5
SiO ₂ - content Tested according to USP/NF and Ph. Eur.	wt.%	99.0 - 100.5
Chloride Tested according to Ph. Eur.	ppm	< 250
Heavy metals Tested according to Ph. Eur.	ppm	< 25
* ex plant The data represents typical values (no product specification)		

Registration status

CAS-No.	112 945-52-5 (ex 7631-86-9)
REACH (Europe)	registered
TSCA (USA)	registered
DSL (Canada)	registered
AICS (Australia)	registered
NZIoC (New Zealand)	registered
ENCS (Japan)	registered
IECS (China)	registered
KECI (Korea)	registered
PICCS (Philippines)	registered

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