

GASIL[®] Mesoporous Silicas

Elevating Pharmaceutical and Nutraceutical Excellence



Elevating Pharmaceutical and Nutraceutical Excellence with Gasil® Mesoporous Silica

INTRODUCTION

In the pharmaceuticals and nutraceuticals sector, the quest for superior solid formulations is unending. Achieving them is a complex challenge. Formulations are mixtures of powders of different granulometry and hygroscopicity and liquids with different viscosity and hydrophilicity. Synthetic and natural ingredients and excipients like polymers are also often sensitive to moisture. Those that are liquid will render formulations sticky and affect their processability and require accurate dosing that can only be delivered in a dry form. The use of flow aids is essential to ensure solid actives flow well for tablet compaction. Many APIs have low solubility and require amorphization to enhance their solubility and effectiveness in vivo.

Gasil® mesoporous silica gels provide solutions to many of the problems encountered in solid pharmaceutical and nutraceutical formulations. They are multi-functional excipients that:

- Improve moisture stability
- Serve as glidants at any relative humidity
- Improve tablet strength and friability at lower compression forces
- Enhance tablet coatings by providing antitacking properties through microroughness
- Increase the amorphous stability of APIs and polymer based solid dispersions
- Help optimising disintegration vs strength.

Manufacturing Process

Gasil® mesoporous silicas are manufactured from sodium silicate and sulfuric acid. Further steps in the process are used to improve purity, tailor the porosity and control the particle size distribution. This generates powders with unique combinations of physical properties and related benefits in the pharmaceutical and nutraceutical formulations.

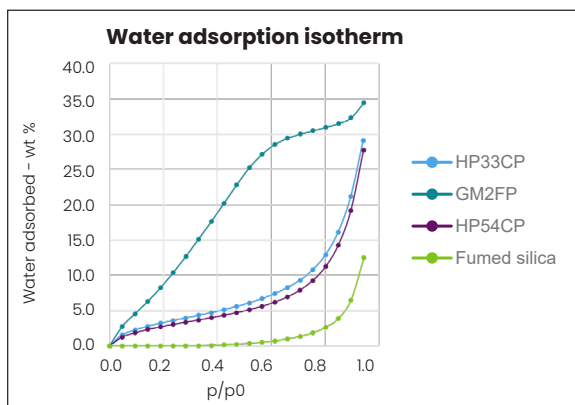
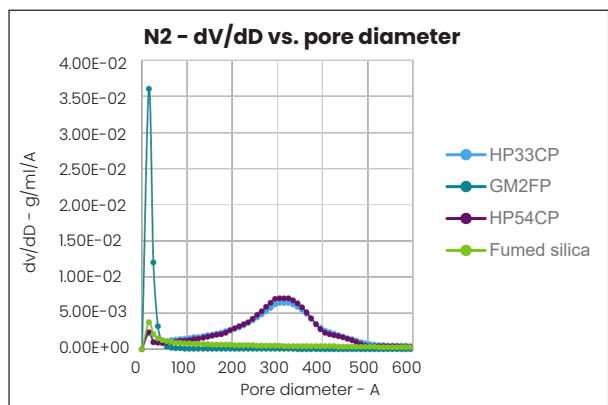
Gasil® Range of Excipients for Pharmaceutical and Nutraceutical Formulas

PQ manufactures mesoporous silicas for pharmaceutical applications. The table below shows their physical properties:

	TYPICAL VALUES				
PRODUCT	D(50) (microns)	Oil Absorption (ml/100g)	Pore Volume (ml/g)	Surface Area (m ² /g)	Average Pore Diameter (Angstrom)
Gasil® GM2FP	7.8	75	0.3	600	20
Gasil® HP33CP	3.3	270	1.7	300	225
Gasil® HP54CP	5.4	260	1.6	290	200

Physical Properties and Internal Porosity

Gasil® mesoporous silicas boast superior physical properties that contribute to the varied benefit of their use in formulations. High internal porosity, as measured by nitrogen adsorption, ensures a high moisture adsorption capacity and controlled API interactions. Gasil® silicas display high water adsorption capacity. Gasil® GM2FP shows high absorptive capacity at low relative humidities for API moisture protection and Gasil® HP33CP and Gasil® HP54CP have high absorptive capacity at higher relative humidity, which can be used effectively in moisture activated dry granulation (MAGD). Relatively low surface area products Gasil® HP54CP and Gasil® HP33CP aid tablet compaction properties, enhancing friability, hardness and disintegration.



Gasil® Mesoporous silicas excel within many pharmaceutical applications, which are detailed in the table below.

	APPLICATION	DESCRIPTION	GASIL® :	GM2FP	HP33CP	HP54CP
	Glidant	- Enhances flow properties for cohesive solid formulations - Maintains formulation uniformity - Avoids bursting and lamination and other physical formulation challenges when processing hygroscopic APIs and excipients - Improves tablet compaction			● ●	● ●
	Anti-caking	Scavenges moisture preventing the formation of cohesive agglomerates			●	● ●
	Chemical Moisture Protection	- High water binding capacity - Allows for the protection of moisture sensitive APIs from water induced chemical degradation during storage		● ●		
	Physical Moisture Protection	- High water adsorption capacity - Allows for the protection of moisture sensitive APIs, excipients and preparations from physical degradation caused by water during storage such as swelling and changes in hardness and dissolution rates		●	●	● ●
	Tablet Hardness	Boosts tablet hardness and friability at low compaction pressures			● ●	●
	Moisture Activated Dry Granulation	Enhances moisture activated dry granulation (MADG) – aiding tableting by direct compaction			● ●	
	Liquid Carrying	- High carrying capacity - allows ease of handling for difficult to handle/transport liquids - Enhanced flow properties with hydrophobic and hydrophilic liquids uniformly distributed within the mesoporous structure - Liquid's effectively stored and then released from the mesoporous structure under suitable conditions			●	● ●
	API Carrying	- Capable of amorphization of APIs by hot melt extrusion (HME) - Enhancing the solubility and bioavailability of APIs in vitro			● ●	●
	Tablet Coating	- Microroughness for antistick properties - Processability enhancement			● ●	● ●

● ● Recommended

● Suitable

TECHNICAL SERVICE

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Strategic Manufacturing Locations

PQ has manufacturing facilities in Europe, Asia and North America and is well placed for global distribution into the excipient market.



QUALITY & REGULATORY STANDARDS

ISO 9001
ISO 14001
EFfCI GMP
FSSC 22000
HACCP
HALAL
KOSHER
GMO FREE
ALLERGEN FREE

USP SILICON DIOXIDE
Ph.Eur SILICA COLLOIDAL
NATURALLY DERIVED (ISO 16128)
ANHYDROUS
SEDEX REGISTER
VEGAN SUITABLE
NON-ANIMAL TESTED
REACH REGISTERED