



**PharSQ<sup>®</sup>**

Touch the future



Better 



Safer 



Global 



PharSQ<sup>®</sup> for you

PharSQ<sup>®</sup> Base

PharSQ<sup>®</sup> Spheres

PharSQ<sup>®</sup> Active

Contact  
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PharSQ® for you

# Quality Safety Innovation



We make pharmaceuticals better and safer – this is what we are striving for. PharSQ® is more than just a product offer to you.

## Integrated: Safety

All our **PharSQ®** products are physically and chemically stable excipients. We are reliably fulfilling highest regulation requirements like ICHQ3D elemental impurity level limit values for oral use.

We have extended this approach even to those **PharSQ®** products, which are not listed in any monograph of the leading pharmacopoeias and are ready to offer further contributions to your risk assessment. A deep level of testing expertise is available in-house: Our accredited lab (DIN EN ISO/IEC 17025) has qualified state-of-the-art equipment using validated test-methods. All major production lines are certified by EXCiPACT (cGMP and cGDP) with Budenheim achieving this standard in 2014 already, the starting year of this new independent and international standard.

You are striving for the highest safety level: Take a look into our **PharSQ® Active** offer and enter the world of ICHQ7.

## Integrated: Quality

We have a long history in offering excipients and active pharmaceuticals to our customers, which goes back to the 50's of the last century. We know what we are doing and therefore our customers remain loyal to us. "Made in Germany" means, that we are following solid and controlled manufacturing processes in our Budenheim site. Secured and stable supply bases for raw materials and optimized processes are key to maintain this high quality standard. Thanks to our international network and our market access strategy our products are globally available in the same quality.

## Integrated: Innovation

Our mission is based on innovation: From new product solutions to formulation and application support. Technical competence is the basis for a close co-operation: Partnership with our customers is our goal. Our technical experts support our partners on a global basis in finding customized solutions. Latest example for a really new product solution is **PharSQ® Spheres CM**: A unique calcium-phosphate based pellet solution for controlled release applications opening up new opportunities to our partners.

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PharSQ® Base

# Biopharmaceuticals

Process aids Nutrients

## Starting materials



## Our branded offer for biopharmaceutical processes

In order to achieve the highest quality for your biopharmaceutical product you need to start with a solid base. Budenheim's portfolio is tailored specifically to your biopharmaceutical process, helping you to reach your quality goals. With **PharSQ® Base** we offer a wide range of products, offering you flexibility to address your needs in the fermentation process and supporting you in creating reliable products.

The **PharSQ® Base** portfolio offers a variety of options covering different dissolution rates, pH-value buffering, nutrient levels and physical properties. In this way we can support the optimization of your upstream and downstream processes.

## High quality for safer products

To increase product safety we follow the requirements from the pharmaceutical regulatory environment, which are now fully reflected in our specifications. Chemical quality parameters, including ICHQ3D elemental impurity limit values for oral use, will also be shown for those products, which are not

listed in a pharmacopoeia. That way we make a major contribution to your risk assessment now and in the future.

Therefore we are your partner of choice in biopharmaceuticals: Challenge us whenever you need reliable product solutions within the synthesis process.

Brand name	Chemical name	Compliance to
PharSQ® Base MP	Monopotassium phosphate	Ph. Eur., NF
PharSQ® Base DP	Dipotassium phosphate	Ph. Eur.
PharSQ® Base TP	Tripotassium phosphate	ICHQ3D
PharSQ® Base MS	Monosodium phosphate	USP, Ph. Eur.
PharSQ® Base DS	Disodium phosphate	USP, Ph. Eur.
PharSQ® Base TS	Trisodium phosphate	NF

Available in various hydration stages and particle sizes.

PharSQ® for you

PharSQ® Base

PharSQ® Spheres

PharSQ® Active

Contact us

# PharSQ® Spheres CM

Better  
Controlled release  
Pellets  
Unique



## Our newest solution for multiparticulates

With **PharSQ® Spheres CM** we offer unique calcium-phosphate based starter pellets for controlled release applications opening up new opportunities to our partners.

## Many advantages for our customer

**PharSQ® Spheres CM** are small beads onto which the drug manufacturer can load the desired active ingredient. The almost perfectly round pellets have a diameter of only 0.1 to 1 millimeter depending on the product grade. The use is versatile, from filling into hard capsules or sachets to compression into tablets.

The unique characteristic of **PharSQ® Spheres CM** supports the loading of active ingredient to the desired dosage, which increases the safety of the drug. Through a combination of differently coated spheres the controlled release of the active ingredient can be optimized: to the targeted place in the digestive tract over the right period of time. In this way, the effect of medicines can be precisely adjusted to the actual needs.

During production of **PharSQ® Spheres CM** no organic solvent is used. Consequently, there is no risk of presence of organic volatile residuals in the final product.

Due to their very low moisture content, **PharSQ® Spheres CM** can be safely used with moisture sensitive drug substances, which enhance their stability. Due to the comparatively high density of **PharSQ® Spheres CM** tablet or capsule size can be reduced – a substantial benefit particularly for people with difficulty swallowing.

Available in five different sizes to meet various customer needs.

Product grades	XS	S	M	L	XL
Product features PharSQ® Spheres CM	<b>Composition</b>				
	80% dibasic calcium phosphate anhydrous (NF/USP, Ph.Eur., JP)				
	20% microcrystalline cellulose (NF/USP, Ph.Eur., JP)				
	<b>Assay of dibasic calcium phosphate (%)</b>				
	75.0 – 85.0				
	<b>pH</b>				
	neutral				
	<b>Loss on Drying (105°C/3h)</b>				
< 1%					
<b>Bulk density (g/L)</b>					
> 1.000					
<b>Particle size (µm)</b>					
150–300	300–500	500–710	710–850	850–1000	
<b>Equivalent to U.S. Mesh</b>					
100–50	50–35	35–25	25–20	20–18	
<b>Common application</b>					
Tablet			Capsule, Sachet		

PharSQ® for you

PharSQ® Base

PharSQ® Spheres

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# PharSQ® Active

ICH Q7  
Safer  
Reliable  
EC GMP guide



## Active Pharmaceutical Ingredients for your formulations

Budenheim is committed to the pharmaceutical industry since the 1950's and known for its reliably high quality profile. Being one of the first companies adhering to the newly introduced EXCiPACT standard for pharmaceutical excipients in 2014 was a logical step for us and just an expression of this firm commitment.

Due to the high quality, our partners already started to use our products as so-called atypical API's many decades ago, providing a proven track record also in this application field. Now we have taken the next step in the quality ladder and introduced the **PharSQ® Active** line in our portfolio.

## PharSQ® Active DCF and Active DM

**PharSQ® Active DCF** offers a reliable source of Calcium and Phosphorous and **PharSQ® Active DM** a reliable source of Magnesium and Phosphorous for the human body. At the same time physical properties allow the use in standard dosage forms and standard granulation processes.

Our Actives are used in drugs for persons, which deserve special protection and therefore the highest quality of a proven and reliable product (e.g. pregnant women).

## PharSQ® Active DS

As part of saline enemas **PharSQ® Active DS** helps you to promote the osmotic activity. It is also used in related product applications like laxatives.

The following table provides an overview of our Active Pharmaceutical Ingredients offer.

Brand name	Chemical name	Pharmacopoeias	Quality
PharSQ® Active DCF	Dicalcium phosphate anhydrous	USP, Ph. Eur., JP	Approved compliance to EC GMP guide respectively ICH Q7 GMP guide
PharSQ® Active DM	Dimagnesium phosphate trihydrate	DAB (German Pharmacopoeia)	
PharSQ® Active DS	Disodium phosphate anhydrous	USP, Ph. Eur.	

Thus, if you require highest possible safety level for your formulations: Use our PharSQ® Active products in the future.

PharSQ® for you

PharSQ® Base

PharSQ® Spheres

PharSQ® Active

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Made in Germany ◀

For further information,  
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