

SCHOTT
glass made of ideas

SCHOTT Ampoules

Dedicated to Superior
Fill + Finish



SCHOTT is a leading international technology group in the areas of specialty glass and glass-ceramics. With more than 130 years of outstanding development, materials and technology expertise we offer a broad portfolio of high-quality products and intelligent solutions that contribute to our customers' success.

SCHOTT Pharmaceutical Systems is one of the world's leading suppliers of primary packaging and specialized analytical lab services for the pharmaceutical industry. We provide our customers quality solutions while meeting their highest demands with our expertise and broad product portfolio; including ampoules, cartridges, vials and syringes made of glass and COC polymer. Our state-of-the-art production facilities and our products comply with the highest international quality standards for pharmaceutical needs.



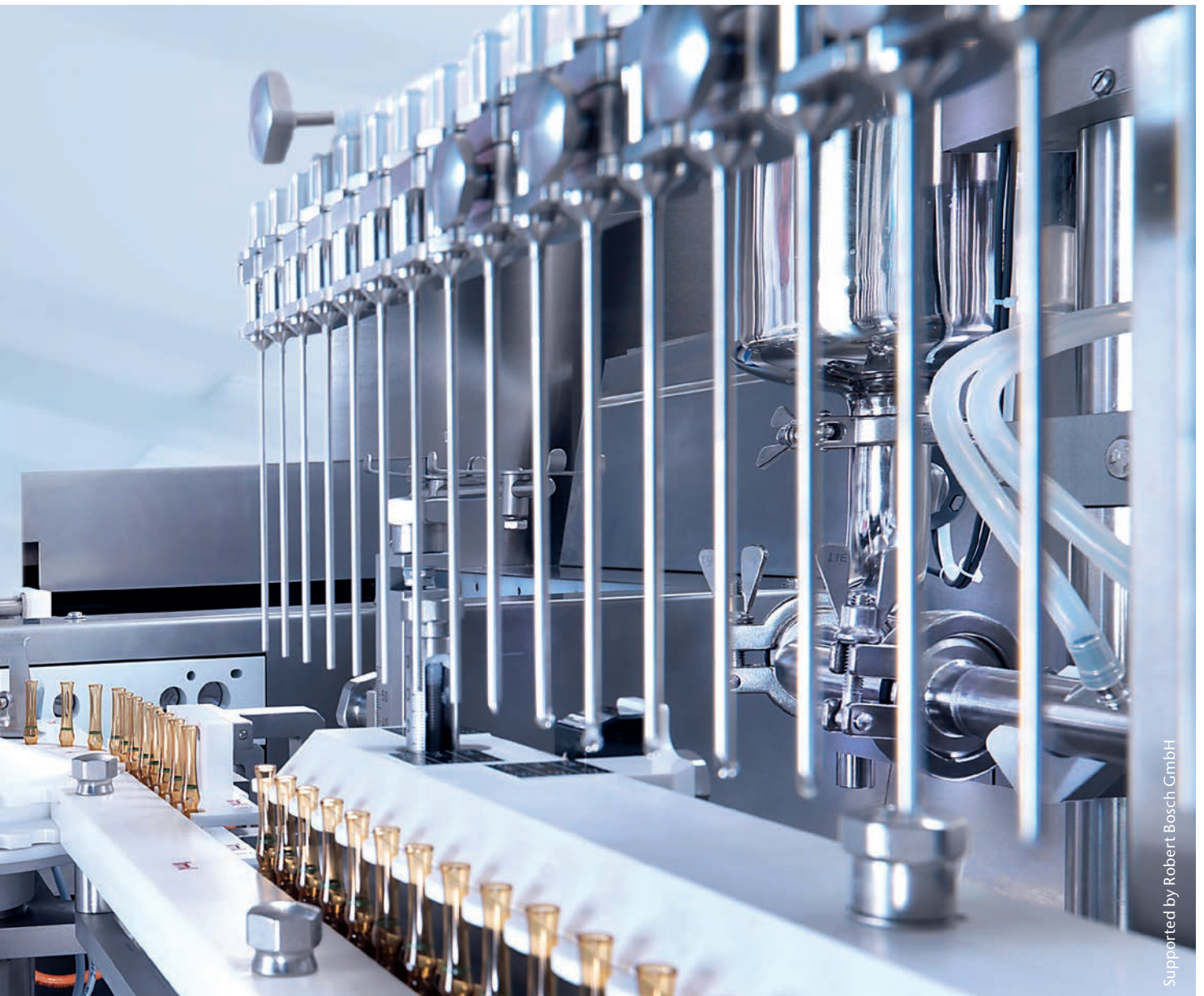
SCHOTT Ampoules – Dedicated to Superior Fill + Finish Performance

Our mission at SCHOTT is to convert decades of pharmaceutical research and investment into sustainable success. Working closely together with you, our team of forward-thinking professionals – spanning from R&D to sales – is dedicated to developing, producing and delivering ampoules that enable an excellent fill + finish



performance based on superior product quality and backed up by highly regarded technical support.

So, tell us – What's your next milestone?



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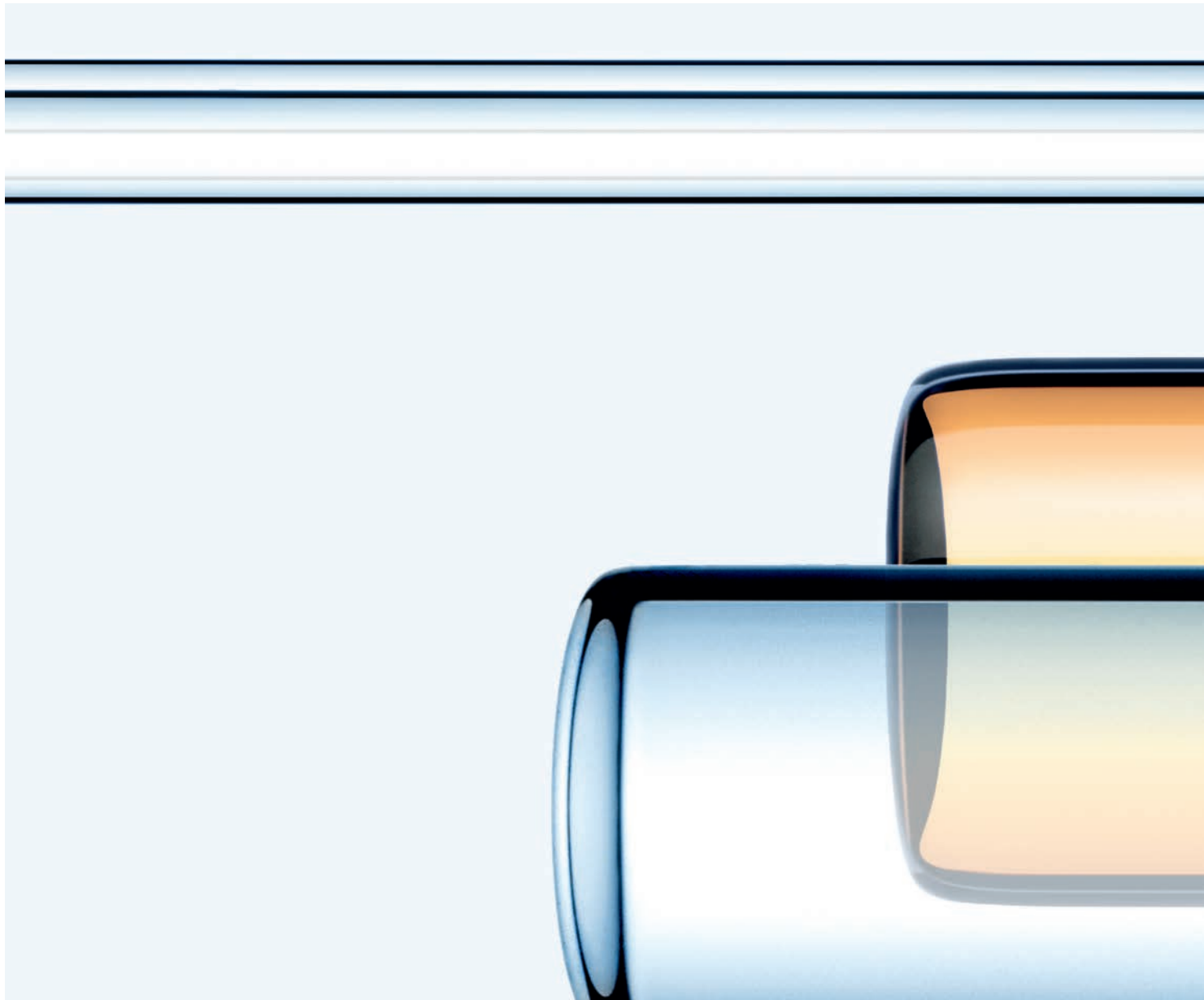


FIOLAX® – Superior Tubing Quality for Outstanding Container Performance

FIOLAX® – The first choice for pharmaceutical packaging

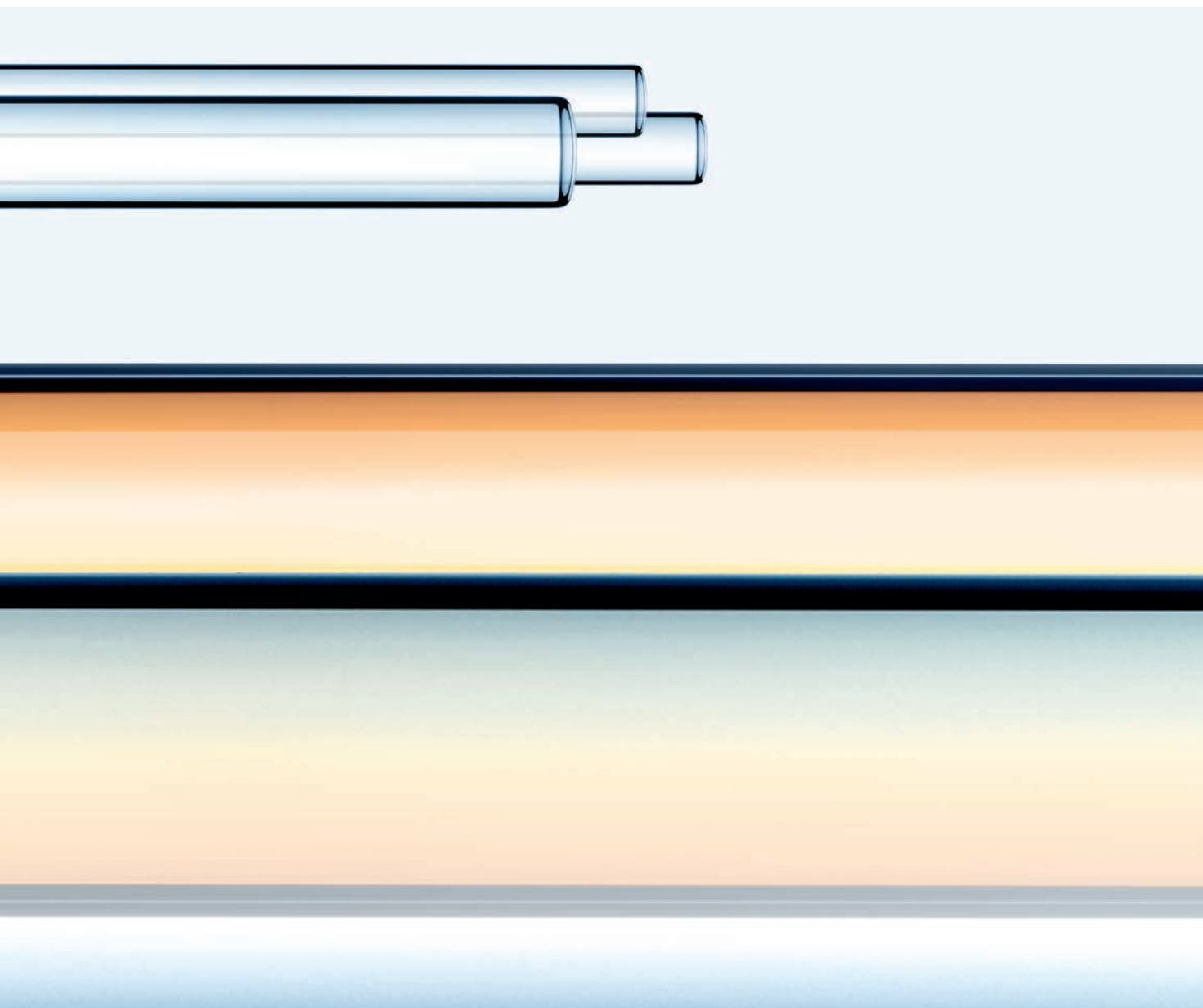
Glass has numerous advantages over other primary packaging materials available on the market. Otto Schott, founder of the present-day SCHOTT AG, was far ahead of his time when he introduced FIOLEX® tubing in 1911 for pharmaceutical packaging. Since then, FIOLEX® has been synonymous with premium quality glass of the first hydrolytic class.

This unique product is renowned for its outstanding chemical resistance, neutrality and impermeability, not to mention its exceptional strength. Containers from FIOLEX® are geared to storing and delivering a wide range of injectable, as well as sensitive biotech drugs. Today, FIOLEX® is still a key base component for top-of-the-range pharmaceutical packaging containers such as SCHOTT Ampoules.



SCHOTT FIOLAX® and SCHOTT Ampoules – the perfect match for outstanding process capability and drug stability

- Tight geometric tolerances exceeding the required DIN ISO 9187-1 norm
- Reduced glass particles, airlines, inclusions and scratches for improved camera inspection
- Outstanding chemical resistance, neutrality and impermeability



SCHOTT Ampoules – Dedicated to Superior Fill + Finish Performance

With the ever increasing focus on therapy costs in the healthcare sector, fast and easy processing of primary packaging containers is regarded as one of the key contributors for a total cost of ownership optimization. The outstanding dimensional quality of SCHOTT Ampoules enables superior fill + finish performance.

Excellent fill + finish

- Fast and reliable filling and closing of the ampoules due to an excellent 100% controlled dimensional quality
- Avoidance of rejects after fill + finish as a result of excellent camera inspected cosmetic quality
- Technical support for ampoule processing e.g. burner setting upon request

Outstanding stability during shelf life

- Different to other container formats, ampoules consist of glass only and therefore provide an excellent E&L profile, superior barrier properties and are 100% tamper-proof
- Reduced alkalinity for enhanced drug stability upon request

Easy handling at point of use

- Several color rings can be placed on the stem or body for identification purposes
- Different break systems available such as One Point Cut (OPC), Scoring (SCO), Color Break Ring (CBR), or Double Ring Break (DRB) for the double tip ampoules
- Convenient ampoules opening due to narrow break force tolerances



Break System OPC

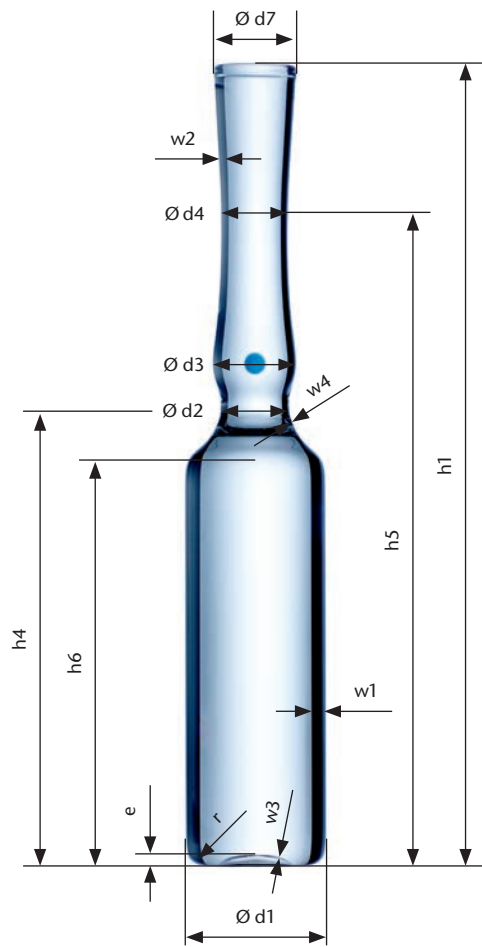


Break System CBR



Break System SCO

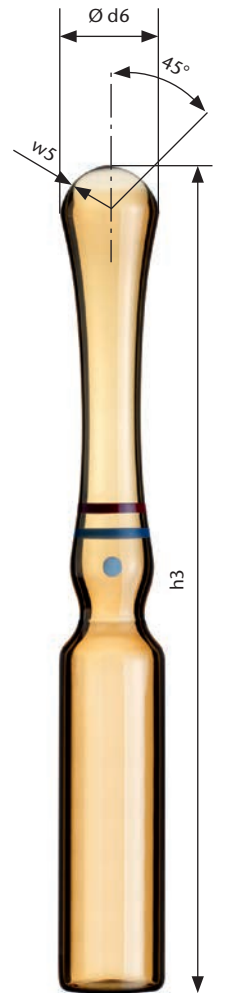
Nominal Volume ml	Tubing OD d1 mm		d2 mm		d3 mm		d4 mm		d5 mm		d6 mm		d7 mm		h1 mm		h2 mm	
		Tol		Tol		Tol		Tol		Tol		Tol		Tol		Tol		Tol
1	10,75		6,5		8,5		6		9		10		8		60		67	
2	10,75	± 0,15	6,5	± 0,5	8,5	± 0,5	6	± 0,35	9	± 0,8	10	± 1,0	8	± 1,0	72	± 1,0	79	± 1,0
3	12,75		6,5		8,5		6		10,7		10,5		8		75		82	
5	14,75		7		9		7		12,2		12		9		83		90	
10	17,75	± 0,20	7,5		9,5		7,1		13	± 1,0	13,5		9,5		102		109	
20	22,5		8,5		12	± 1,0	7,8	± 0,5	14		13,5		11		113	± 1,5	120	± 1,5
25	22,5	± 0,25	8,5		12		7,8		14		13,5		11		128		135	
30	22,5		8,5		12		7,8		14		13,5		11		143		150	



Form B



Form C



Form D

h3 mm			h4 mm			h5 mm			h6 mm		r mm		e mm		w1 mm		w2 mm		w3 mm		w4 mm		w5 mm	
	Tol			Tol		Tol	min.		Tol		Tol		Tol		Tol		Tol	min.		Tol		Tol		Tol
70	± 1,0	25,5	± 0,5	47	± 2,0	21	1	± 0,5	± 0,5	1	± 0,5	0,5	± 0,03	0,37	± 0,05	0,3	0,7	± 0,1	0,175	± 0,075				
83		37,5		57		33	1			1		0,5		0,37		0,3	0,7							
89		39,5		62		35	1,5			1		0,5		0,37		0,3	0,7							
95		46,5		68		41	1,5			1		0,55		0,40		0,4	0,7							
112		62	± 1,0	87		55	1,5			1,25	± 0,75	0,6	± 0,04	0,47		0,4	0,8	± 0,15						
126		76	± 1,3	100		65	2,0			1,5	± 1,0	0,7		0,50		0,5	1							
141		91		115		80	2,0			1,5		0,7		0,50		0,5	1	± 0,2	0,2	± 0,1				
156		106		130		95	2,0			1,5		0,7		0,50		0,5	1							

SCHOTT Ampoules – From Standardized to Customized Quality Options

A broad range of container geometries, quality levels and controlled surface chemistry enable us to tailor the primary packaging solution to your specific needs. All SCHOTT Ampoules are manufactured and packed in environmentally controlled areas certified by ISO 9001 and ISO 15378 and comply with PH.Eur., USP and JP international standards.

StandardLine – Standardized quality level according to ISO

The StandardLine includes:

- Production in cGMP environment
- Statistical in-process control
- Regulation system for ISO specific stem diameter
- 100 % inspection of key dimensional characteristics
- 100 % camera inspection of break systems (OPC, CBR, SCO)
- Quality level according to ISO for Type B, C and D

Drug Type	StandardLine
Injectables* 	<div data-bbox="528 1205 759 1496"> 1 SCHOTT Ampoules Form B 2 SCHOTT Ampoules Form C 3 SCHOTT Ampoules Form D 4 SCHOTT Ampoules Marzocchi </div> <div data-bbox="788 1189 1273 1581">  </div>
Non-Injectables (oral) 	<div data-bbox="549 1657 783 1753"> SCHOTT Ampoules Double tip (ILLAX® and FIOLAX®) </div> <div data-bbox="810 1641 906 2033">  </div>

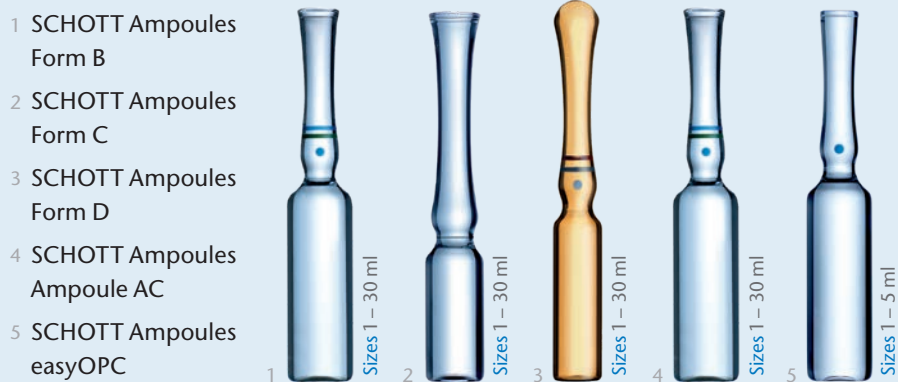
* Available in FIOLAX® clear and amber glass

TopLine – Customized product specifications and quality levels

The TopLine options includes:

- Production in cGMP environment
- Statistical in-process control
- Reduced stem diameter tolerance for superior processing
- 100 % camera inspection of break systems (OPC, CBR, SCO)
- Customized dimensional and cosmetic AQL levels
- 100% camera inspection of dimensional and cosmetic parameters
- Improved functionality, e.g. safe and easy opening ampoule, anti-counterfeiting ampoule

TopLine



SCHOTT TopLine Options for Safe and Easy Administration

SCHOTT Ampoule AC (Anti-Counterfeiting)

According to the World Health Organization, every tenth drug sold worldwide is counterfeit. Approximately 64 % of counterfeit drugs, which can apply to both branded and generic products, contain no or only low levels of the active ingredient. In general, counterfeits include products with either incorrect, insufficient or inactive ingredients, or are supplied with inaccurate or fake packaging/labeling.

SCHOTT Ampoules AC safeguard intellectual property and patient safety by enriching standard ink with light-emitting particles. Prints with enriched inks do not differ from the particle-free version if compared by the naked eye, but activation with a coupled reader or detector reveals the presence of the particles and proves the origin of production. Individualization is guaranteed by the customized combination of ampoule format, type, color rings and dots.

Properties:

- The presence of light-emitting particles proves the authenticity of the product

Benefits:

- Product to prevent counterfeiting
- Protects intellectual property
- Helps to ensure patient safety
- Particles are made of inorganic substance. Particle size: 5 – 20 µm

Sizes/Colours:

- Ampoules B, C and D forms made of clear or amber FIOLAX glass from 1 ml to 30 ml
- The anti-counterfeiting option is available for multiple color options



SCHOTT Ampoules easyOPC

Everyday, worldwide, millions of glass ampoules are used for injectable drugs. The opening of an ampoule is ultimately a controlled glass breakage and one of the main challenges for Health Care Professionals. Even when the majority of ampoules open correctly, some cases do not show consistency resulting in injuries or in rejection of unusable drugs. In fact, the main injury cause at hospitals is caused by challenges related to the opening of an ampoule*.

The new SCHOTT easyOPC ampoule offers an enhanced user experience thanks to an improved break force range. This leads to less market complaints, less injuries and less rejections. All in all, this new feature contributes to improvements along the whole supply chain.

Properties:

- The new feature does not change the appearance of the product
- New break force specification range supported by new quality specification

Benefits:

- Safe and easy opening for Health Care Professionals
- No changes in registration
- Less market complaints
- Less rejections of unusable drugs
- Overall improvement of total cost of ownership

Sizes/Colours:

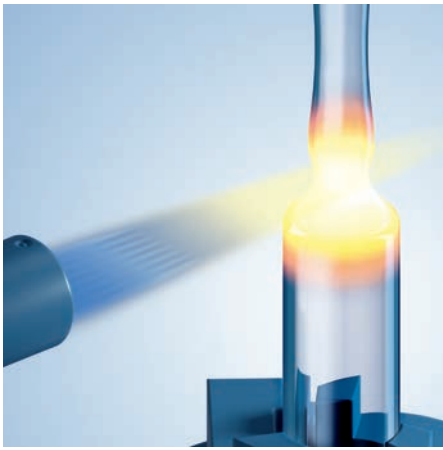
- ISO formats 1ml to 5ml using FIOLAX® Type I glass
- Form B, C and D
- Customization available on request



*Results based on poll performed by SCHOTT

Our Manufacturing Process – A Clear Commitment to High Quality

SCHOTT Ampoules are manufactured on state-of-the-art production lines with highly stable and validated processes. Permanent process optimization through Six Sigma principles and continuous training of employees help to maintain the highest cosmetic and dimensional quality levels for an improved filling and finishing process.



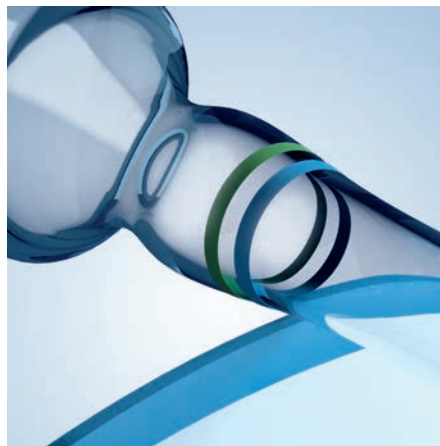
Forming



Dimensional Inspection



OPC Break System



Ring coding
1, 2 or 3 rings can be printed



Printing

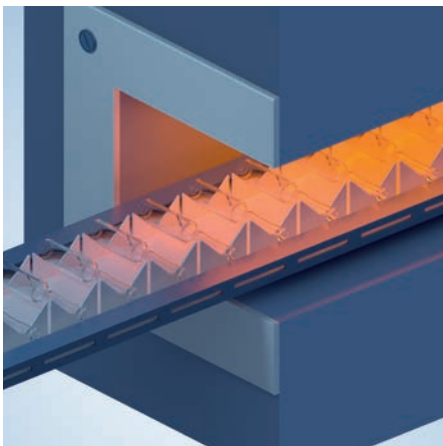
Application of Break Systems



CBR Break System



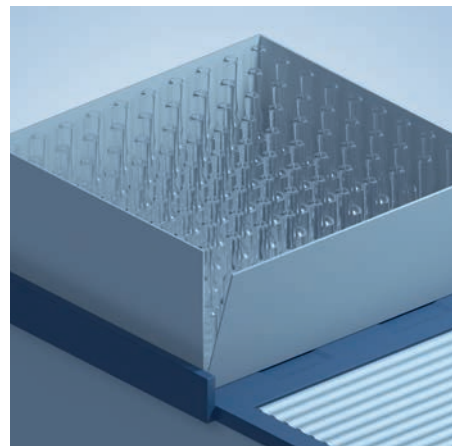
SCO Break System



Annealing



Cosmetic Inspection



Packaging

Compliance with International Norms: Quality that Exceeds Standard Expectations

As a fundamental basis for quality, SCHOTT Ampoules benefit from:

- Fully automated production lines
- Advanced camera systems for dimensional and cosmetic control
- Rigorous In-Process-Control (IPC) and self-inspection to ensure compliance with specified ampoules dimensions, cosmetic quality and functionality

Quality management system

- All SCHOTT Ampoules are manufactured according to ISO 9001 and ISO 15378
- The production process is continuously optimized using a program based on Six Sigma principles
- Reliable quality system and strict quality control



Regulatory compliance

- SCHOTT Ampoules comply with the international norms such as EP, USP and JP
- For its comprehensive ampoule portfolio, SCHOTT has filed individual DMFs with FDA and Health Canada
- SCHOTT adheres to relevant cGMP production regulations



SCHOTT – Your Partner throughout the Drug Life Cycle

Our dedicated cross-functional team offers sophisticated customer consulting services through every stage of the drug life cycle, delivering optimal, tailored solutions to meet your individual needs.

Drug development

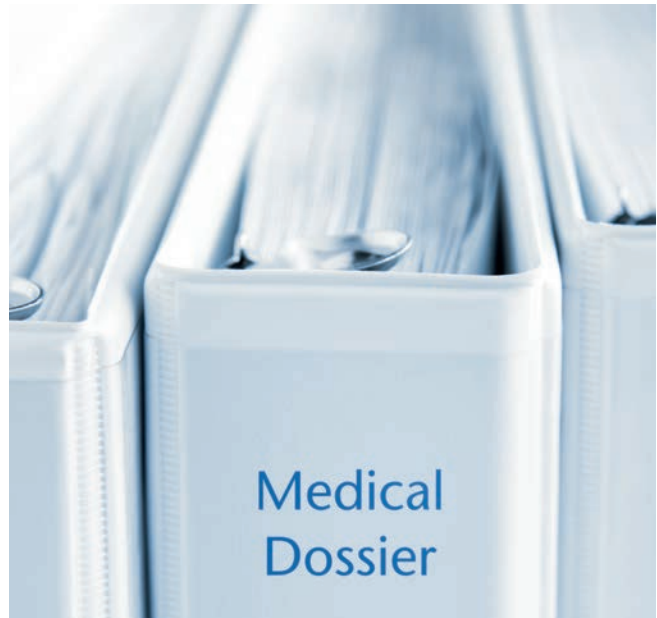


Extensive support for packaging selection:

- Customer value chain evaluation
- Technical product specifications (TPS)
- Samples from stock
- Project management

Your partnership with SCHOTT begins with an evaluation of your value chain in order to understand the drug and primary packaging requirements entailed. SCHOTT will provide you with all the relevant information on our ampoule systems, along with samples from stock and standard Technical Product Specification (TPS). Should you have any special design requirements, we will support you in defining ampoule specifications and in managing the development along the agreed milestones and timeline to save time at customers side.

Regulatory support

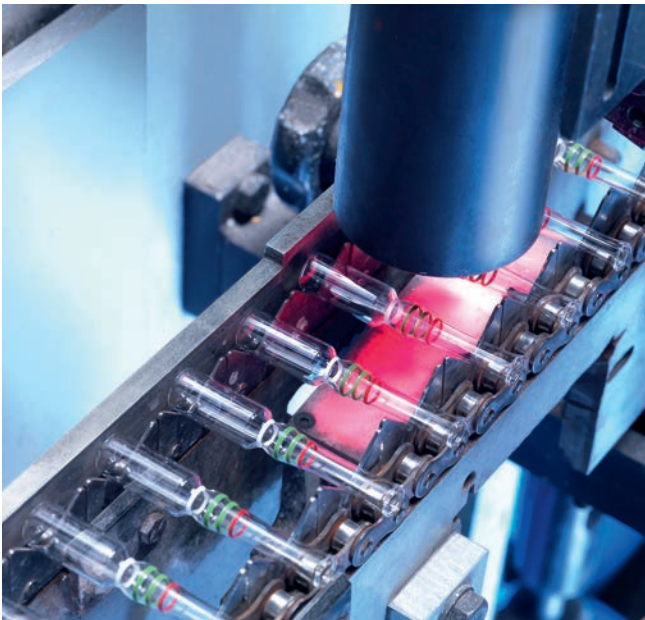


Regulatory filing facilitated by:

- Cooperative audits
- LOA for DMF
- Test method development and alignment

To support your registration activities, an established TPS and Letter Of Authorization (LOA) for the Drug Master File (DMF) will be provided. SCHOTT also offers product functionality tests and analytic support with regard to mechanical stability, material analytics and surface chemistry.

Commercial manufacturing



Enabling smooth operation and supply chain:

- Support fill & finish by technical experts
- Reliable supply from multiple production sites to shorten lead times
- Competent complaint management
- Improved machinability

In the commercial phase, we ensure products are delivered securely through flexible and efficient supply chain management, thereby minimizing total cost of ownership. Should any issues relating to quality or technical improvements occur, our expert problem-solving team at SCHOTT – drawing from Quality Management, Process Engineering, and R&D – is on hand to provide you with a fast, reliable root cause analysis and solution.

Life-cycle management



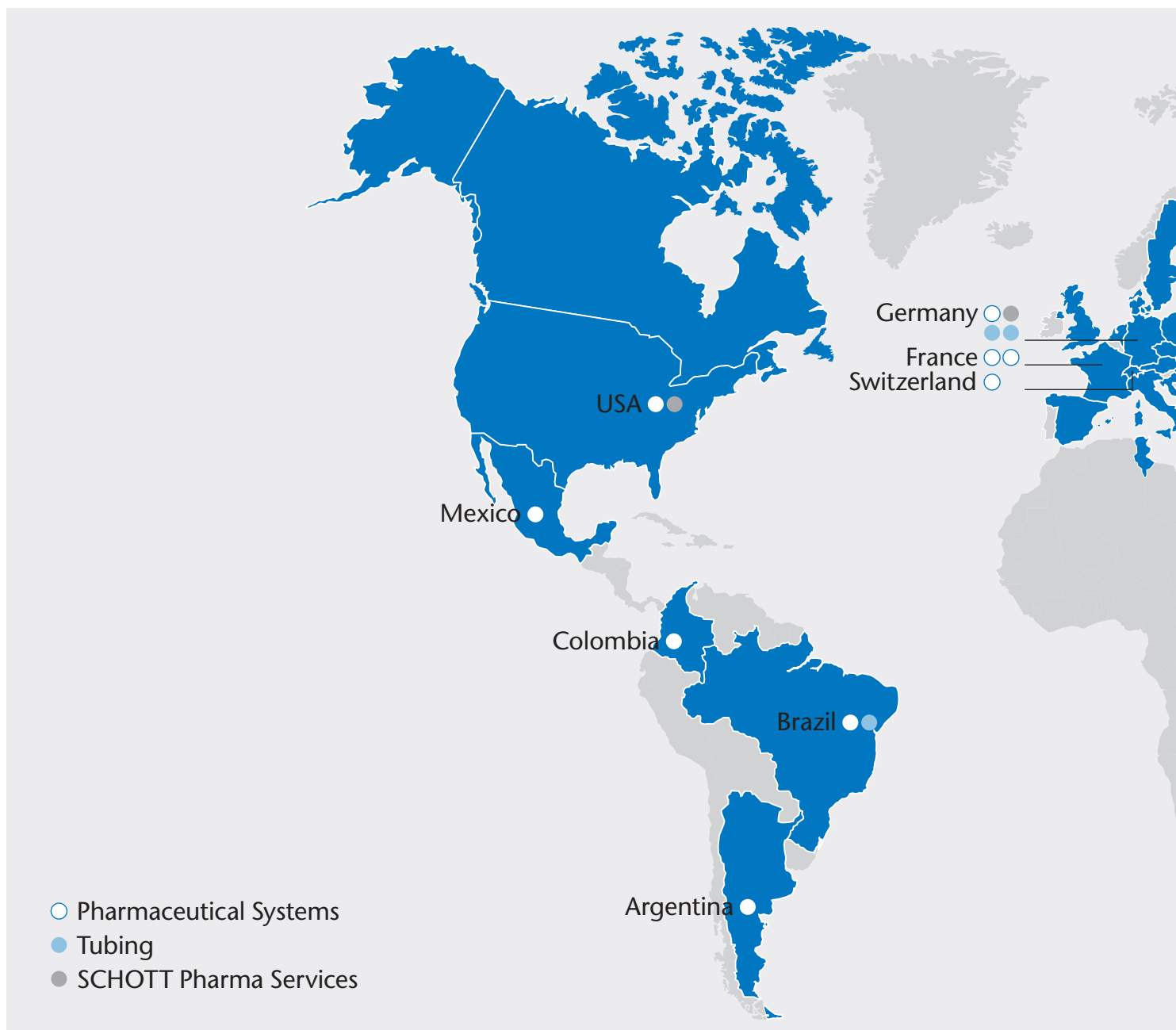
Added value through innovative solutions:

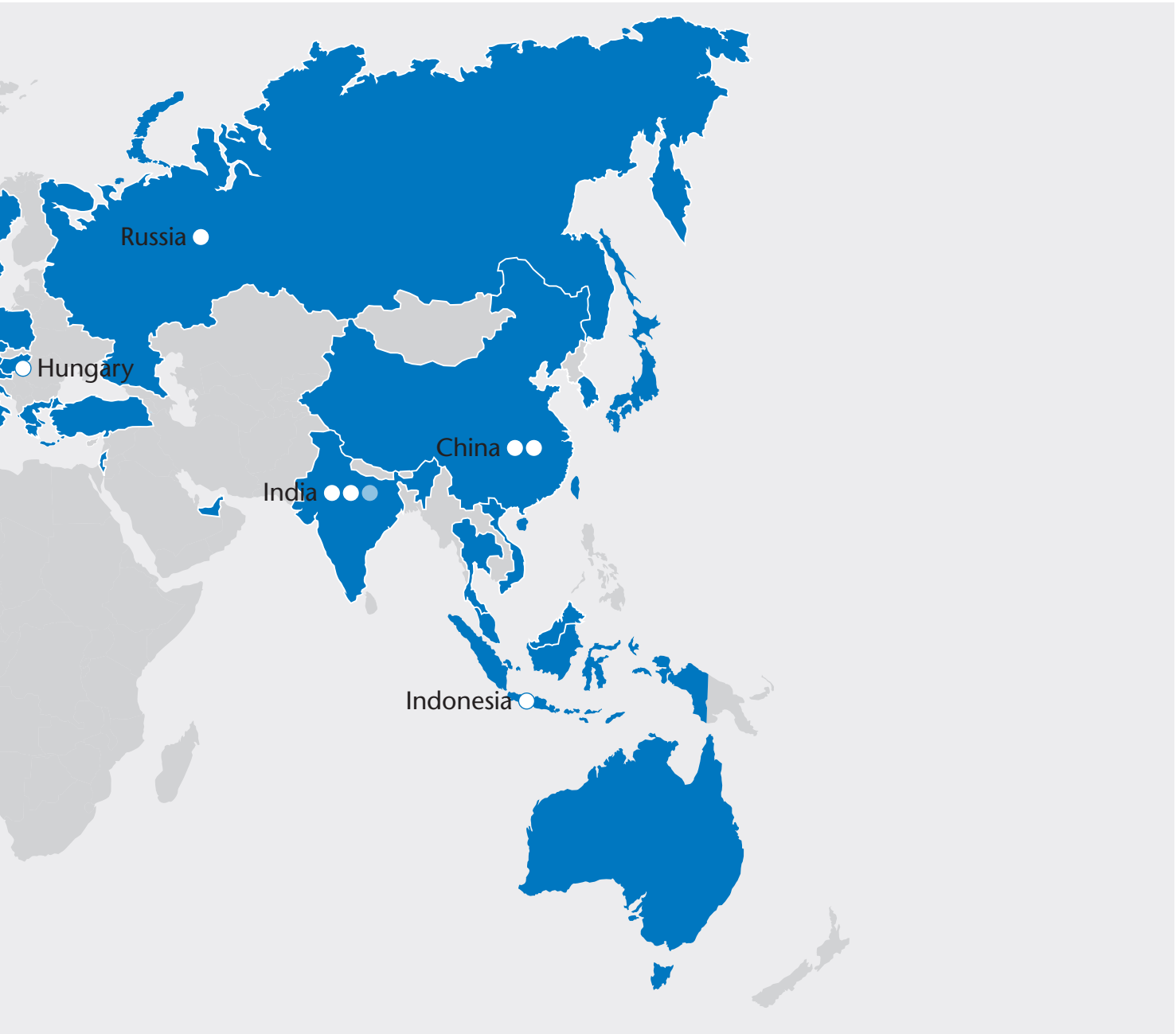
- Continuous technology development
- Constant product improvement
- Product innovation
- Support change management and technology transfer

Primary packaging is considered a differentiating factor in a competitive marketplace. Life-cycle management of existing products may involve a change in primary packaging. In such cases, a dedicated, cross-functional project team is appointed to evaluate feasibility, development costs and timeline.

SCHOTT – Global Player. Local Partner.

When you team up with SCHOTT, you are embracing a truly global partner. Our extensive production network of 16 packaging, 4 tubing production sites and 2 SCHOTT Pharma Service centers offer safe supply, technical support and local, on-site servicing.





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