Information Letter

Pharmaceutical Glass Tubing

SCHOTT
glass made of ideas

Issue 02 | October 2010

Mr. Mohan Joshi
President
SCHOTT Glass India Pvt. Ltd.

Editorial

Dear Readers,

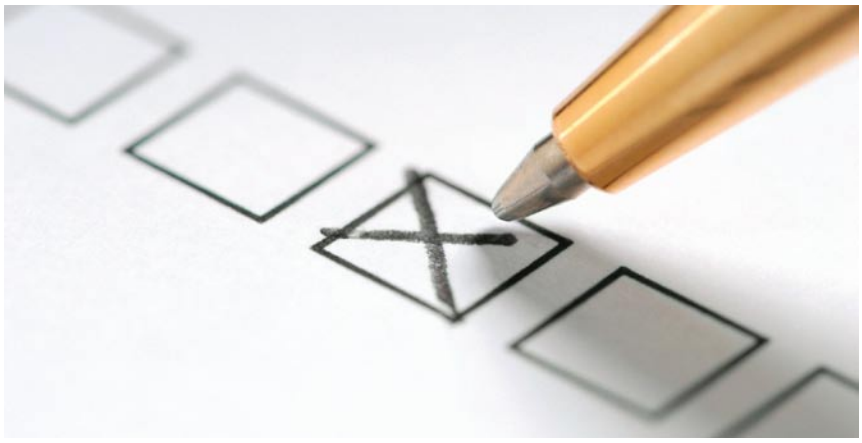
Thank you for your valued response to our “customer survey”, your feedback is of immense value to us and will help improve our quality and processes.

We strongly believe that with exceptional growth in the Pharmaceutical Industry in India your company will greatly benefit.

We have enjoyed working with you over the past years and are convinced that we will continue to be your partners for many decades to come.

Sincerely,
Mohan Joshi
President
SCHOTT Glass India Pvt. Ltd.

SCHOTT
glass made of ideas



Worth knowing

SCHOTT Customer Survey

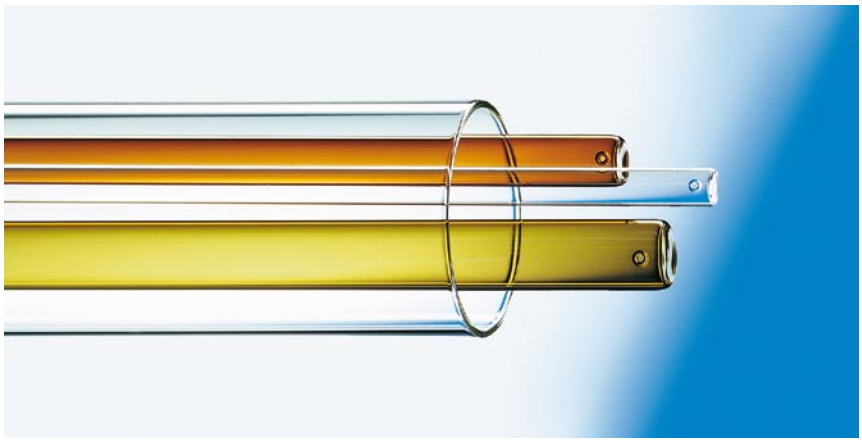
Once again, the majority of our customers have emphasised not only our technical competence in sales, but also product quality in general – also in comparison with the competition. We wish to maintain these strengths and expand them.

At the same time, the survey identified improvement potentials in delivery service and also in complaints management. But from your point of view, we can also improve in the field of cosmetic and geometrical product properties.

There were also a large number of comments and concrete suggestions on the fields inquired about, which help us to be able to react to your customer requirements even better.

We are using your feedback as an incentive for continuing work on various topics and hope to also be a reliable and competent partner for you in the future.

SCHOTT
glass made of ideas



Worth knowing

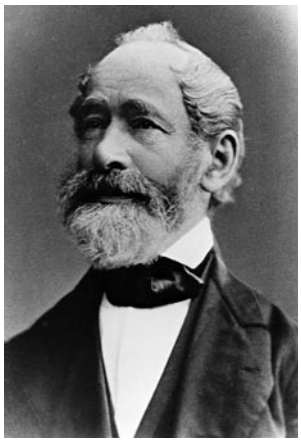
Quality Seal

In the meantime our quality seal has been launched and we should like to thank all customers involved for their contributions. The quality seal supports our converters in communication to their customers in the pharmaceutical industry in a clear easy way, which means: “We use premium quality tubing right from the very beginning – we use glass tubing from SCHOTT to produce our high quality containers.”

FIOLAX® Academy

In August 2010 the first FIOLAX® Academy was held in India. The Academy is a specialized training with several modules which can be chosen tailor-made according to the individual requirements. The benefits for the participants are that they learn more about glass as a basic material and about the effects it has on the converting process.

In India the focus was placed on glass basics, drug container interaction, more information about glass defects and a comparison of Type I glasses. We received a very positive feedback from the participants who were grateful that SCHOTT share their knowledge with the customers. We will repeat the FIOLAX® Academy in accordance with the customers needs.



Carl Zeiss (1816–1888)
Together with Otto Schott and Ernst Abbe, Carl Zeiss founded the "Glastechnische Laboratorium Schott und Genossen" in Jena 1884.

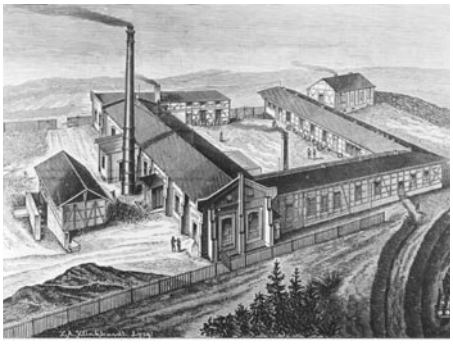
A history of glass (part 2)

The technical production of special glasses started in 1884 with the first melt in the newly founded factory "Glastechnisches Laboratorium Schott&Gen." in Jena, Germany. The partners of this factory were Otto Schott, Ernst Abbe and Carl and Roderich Zeiss.

Two years after its foundation, the first glass catalogue showed 19 completely new special glass types with new properties in addition to the other standard glasses. This allowed the production of precise lenses for microscopes and astronomical telescopes. The famous "Glas 16" for thermometers without thermal after effects which lead to a shift in the zero point was also developed at this time. Since then, precise temperature measurements up to 500 °C have been possible. This glass is still in use as a Standard glass today.

The different Borosilicate glasses with high resistance to thermo-shock and low chemical leaching have optimum properties for use in laboratories and pharmacy. The famous FIOLAX® was developed in 1908 and the brand name registered in 1911. The characteristic line on the outer surface of FIOLAX® glass tubing was in the first years a black line for FIOLAX® clear and a white line for FIOLAX® amber. Later the colour of that line was blue for both glass types.

With the introduction of optical vision systems nowadays for the control of filled ampoules and vials, this line became more and more problematic and was no longer required by the customers. With the development of special glasses, the different techniques for glass melting and processing also changed very quickly.



Glass technical laboratory 1884

Some important highlights for containers and container production were:

1903 Michael Owens, Patent for the automatic bottle machine
1917 Edward Danner, Patent for an automatic tube drawing process
1925 Invention of the IS-Machine
1925 AMBEG, first automatic Ampoule machine (U1)
1930 Leopoldo Sanchez Vello, Patent for an automatic tube drawing process

SCHOTT
glass made of ideas

A history of glass (part 2)

Besides glass and glass technology, Abbe and Schott showed great social engagement. In 1889 Ernst Abbe set up the Carl Zeiss Foundation. He therefore made the Zeiss Factory and his shareholding in the Schott factory a foundation enterprise in 1891 and Schott gave contractual assurance that his shares would also be transferred into this foundation. Schott transferred his shares to the foundation during his lifetime in 1919.

The goal of the foundation was to safeguard the long term existence of the two companies and to provide their employees with a high degree of personal, social and economic rights. These rights were published in the statute of the foundation and are one of the outstanding documents of the German social history.

In 1888 an old age pension scheme was introduced which was far more generous than the one introduced by the government one year later.

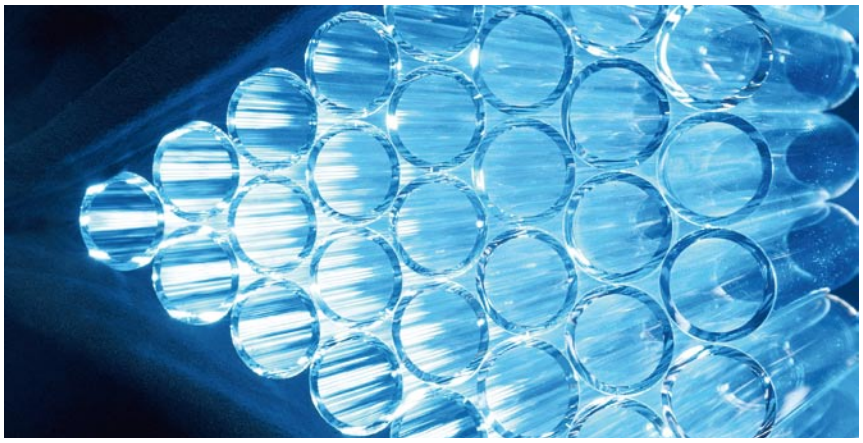
In 1889 Ernst Abbe founded the “Carl Zeiss Foundation” and in 1896 handed the famous “Statute” onto the employees. The Foundation is the sole owner of the factories SCHOTT and Zeiss and responsible for
– guaranteeing the future of both companies
– sponsorship of science and technology
– congenial atmosphere in both companies

Furthermore there are fundamental rights for the employees such as:
– no restriction in personal rights and interests
– no discrimination because of religion, political views or descent.
– regulated dismissal protection

These fundamental goals of social and community responsibilities are still today the basic law for all employees of SCHOTT and Zeiss.

1896 – Ernst Abbe published the statute of the Carl Zeiss Foundation.

SCHOTT
glass made of ideas



Structure of glass

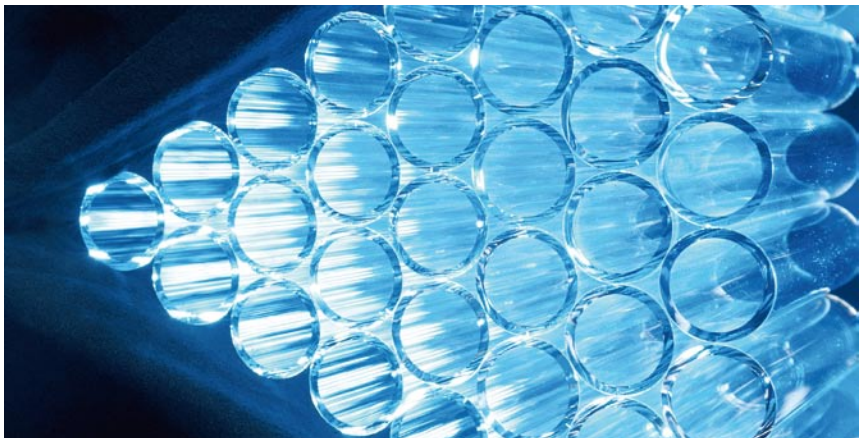
“Glass is not just a pure coincidence”. This was the motto of Dr. Otto Schott (1851 – 1935) founder of the SCHOTT company. Through his research, he was able to prove for the first time that the properties of glass can specifically be changed by certain chemical elements. These results are still valid today – over 125 years later.

In this manner, Schott e.g., reduced the thermal expansion of various glass types and also considerably improved the chemical resistance. The borosilicate glass types originating from this procedure were known all over the world for the production of ampoules, vials, syringes, thermometers or glasses resistant to thermo shock in laboratory and household. Even today, the glass types FIOLAX®, BORO-8330™ and DURAN® developed by Otto Schott are among the best known and proven glass types. In addition to silicon oxide and boron oxide in appreciable quantities, these borosilicate glass types also contain aluminium, alkali as well as earth alkali metal oxides. The physical and chemical properties of the glass are decisively influenced by these components.

Alkaline and earth alkali metal oxide create testing points in the SiO_2 framework of the glass, meaning that the structure is loosened and through this, the melting and processing temperatures are lowered. Such metal oxides are called “network modifiers”. It is necessary to add this since pure quartz glass has such a high melting temperature that it cannot be processed into ampoules and vials on machines at all. In any case, the alkali and earth alkali metal oxides in that network are very soluble in water meaning that it can be fairly easily released from the glass surface. This results in an inferior hydrolytic resistance in the so-called soda lime glass types – compared to the borosilicate glass types. This leads to a relatively high displacement in the pH value during the resistance examination which is not acceptable for injectable solutions and has to be controlled during the examinations stipulated in the Pharmacopoeia and Standards.

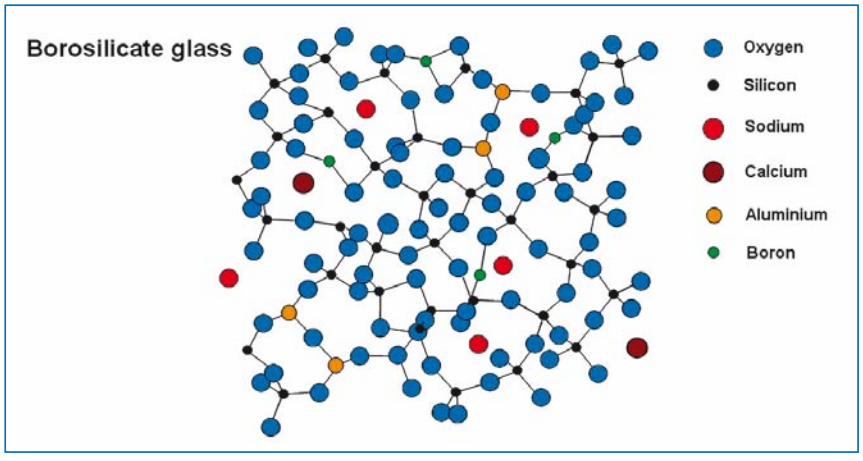
Boron Oxide forms bonding in the glass and is therefore called a “network former”.

SCHOTT
glass made of ideas



Structure of glass

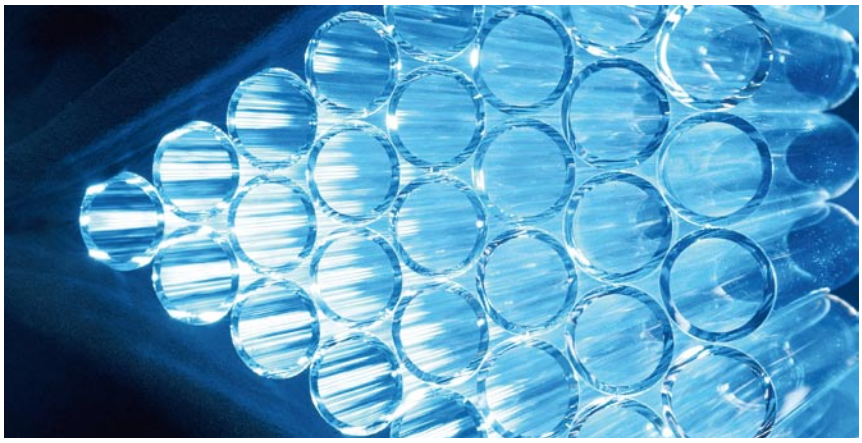
Aluminium Oxide can have varying effects depending on its quantity in the glass. Through these two glass components, the structure of the SiO_2 framework which has been loosened by the alkaline additives, is stabilized again and the resistance to water is improved. Through a combination of particular contents, a borosilicate glass type is produced which can be easily worked on machines and which has excellent hydrolytic resistance.



The influence of the glass components on physical properties such as density, viscosity and thermal expansion is also affected by the network formation or network separation functions in the SiO_2 network. In this manner, as network modifier, alkali and earth alkali metal oxides cause a lower softening point and working point. This means a lower viscosity of the melt. The mean coefficient of expansion is clearly increased and therefore the resistance to thermal shock is lowered.

Network formers such as boron oxide and aluminium oxide stabilise the SiO_2 framework which has been weakened by the alkali metal ions to such an extent that finally a glass with favourable processing properties and excellent hydrolytic resistance is formed.

SCHOTT
glass made of ideas



Structure of glass

Borosilicate Glass Type I for Primary Packaging/important Technical Data

	Borosilicate glass Expansion 3.3	Neutral glass Tubing Expansion 5	Neutral glass Tubing/Type 2 Expansion 7	Neutral glass moulded
Composition				
SiO_2	80 – 82	72 – 75	70 – 74	65 – 70
B_2O_3	12 – 13	9 – 11	5 – 8	9 – 11
Al_2O_3	2	5 – 7	4 – 6,5	3 – 7
Na_2O/K_2O	4	6 – 9	9 – 12	9 – 10
MgO/CaO/BaO	0	1 – 3	5 – 7	4 – 5
Physical Data				
Working Point	1260 °C	1145 – 1170 °C	1030 – 1100 °C	1050 – 1080°C
Transformation Point	525 °C	560 – 575 °C	550 – 580 °C	550 – 570 °C
Mean Coefficient of Thermal Expansion	3.3	4.9 – 5.5	6.3 – 7.5	6.0 – 6.5

The addition of so called polyvalent metal ions (Iron, Titanium, Manganese) colours the glass. The colour tone is dependent on the type and quantity resp. the relation of these polyvalent ions. In FIOLAX® amber a combination of ferric and titanium oxide causes the amber colouration, whereas the yellowish/pale brown colouring of some other amber glasses is caused by the system Ferric Oxide/Manganese Oxide. Contrary to glasses coloured by ferric and titanium oxide, these glasses do not fulfil the light protection criteria stipulated in the US and European Pharmacopoeia.

SCHOTT
glass made of ideas

Global market for pre-filled syringes is growing

Today, injectables are usually sold in ampoules made of glass and drawn up into a syringe for application. Pre-filled syringes simplify this sensitive process. In 2009, 2.5 billion systems were already in use all over the world.

About 50 agents and vaccines have already been packaged in syringes and submitted for admission. Their market value is estimated to be roughly 50 billion U.S. Dollars. The demand for innovative packaging solutions for injectables continues to increase. Experts project that the market for pre-filled syringes that currently accounts for sales of around 2 billion U.S. dollars will grow by about 12 percent each year.

Simple and safe

To date, two types of pre-filled syringes are available: One has a dual-chamber system that separates the freeze-dried active ingredient in the form of powder from a defined volume of dissolvent. These are then combined inside the syringe immediately before use and injected. In the other type, the active ingredient is already in a liquid state and can be applied directly.

Pre-filled syringes are easy to use and, at the same time, reduce the risk of injury and infections. This means they are especially well suited for use in hospitals. Each year, approximately 2 million needle injuries are recorded by healthcare professionals all over the world – and these are always associated with the risk of passing on infectious diseases.

Patients who inject the drugs themselves benefit from pre-filled ready-to-use systems. The dosage is extremely precise and bubbles and impurities can be ruled out. Because the solution no longer needs to be transferred from the storage container to the syringe, there is less risk of contamination.

SCHOTT
glass made of ideas

Global market for pre-filled syringes is growing

Biopharmaceuticals boost innovation

Biopharmaceutical agents are yet another reason for the widespread use of pre-filled syringes. These are usually proteins and peptides that are extremely sensitive to changes in the pH-value, salts, UV light and other influences. Biopharmaceuticals place the highest demands on their packaging.
These active ingredients are quite expensive and the volumes are often small. This requires packaging designs that feature an extremely fine dosing unit. While conventional ampoules are filled with as much as 25 percent more reserve volume than is actually needed, only around two percent more is needed for bottling pre-filled syringes. For manufacturers, this means there is enormous savings potential. Pre-filled syringes are more than a trend. In fact, they mark a dramatic change for pharmaceutical packaging and represent a chance for innovative packaging producers.

FIOLAX® – the ideal material for pre-filled syringes

SCHOTT FIOLAX® glass tubing is used around the world for the production of high-quality pharmaceutical packaging solutions. High cosmetic quality and extremely tight geometrical tolerances make FIOLAX® particularly suitable for the production of pre-filled syringes.
With its constant wall thickness and low inside diameter tolerances of up to +/– 0.05 mm, FIOLAX® glass tubing ensures optimum efficiency during the manufacturing process. The syringe can be formed precisely. This allows for exact filling quantities and an extremely low need for reserve volume. In addition, the stopper inside the injection body requires a low initiating force and slides very smoothly.

Sources:
Bosch Packazine 1-2007, www.boschpackaging.com
Pre-filled syringes 2010 – New ideas for the new decade
Pre-filled syringes 2008 – Innovation, Validation, Regulation
www.ondrugdelivery.com

SCHOTT
glass made of ideas

Interesting links

Can copycats only cope with biosimilars when they're big?

High development costs, complex manufacturing, and legal hurdles are preventing generic drugmakers from trying to copy pricey biotech medications. However, the market is attractive: sales of biological drugs are expected to grow two to three times faster than conventional drugs over the next five years with price discounts of only 20 to 30 percent – modest compared to an average mark-down of 90 percent at which generics sell.
http://uk.reuters.com

India's biotech industry is back on the growth track

The economic crisis seems to be over for India's Biotech industry. Revenues have been shooting up by more than half and will soon break the $5 billion mark. Clinical data management and discovery work are two key areas that India has developed expertise on. In order to expand its share R&D, the country is planning a new venture fund and new biotech schools.
www.fiercebiotech.com

SCHOTT
glass made of ideas

Interesting links

India discusses protective efforts for domestic drugmakers

The Indian government is anxiously watching Big Pharma expanding its influence in the market. The Department of Industrial Policy & Promotion has now suggested compulsory licenses for local companies to copy patented medicines. Even though this would result in royalty payments to the patent owner, it could prevent foreign companies from taking over completely.
www.fiercepharma.com

Does India have to learn from China

As a research by PriceWaterhouseCoopers shows, India might lose its competitive edge in the biopharmaceutical industry to China. PwC says India needs to act fast and implement its regulatory framework, legal protection, and infrastructure faster to support this young industry. After all: For every dollar India invests in innovation, China invests as much as ten times that amount.
http://blogs.ft.com

Please find all interesting links and every issue of this information letter at *www.schott.com/tubing/infoletter_in*

Imprint: Schott Glass India Pvt. Ltd., Village-Ankhi, Tal. Jambusar, 392 150 Gujarat, India.
Phone: +91-2644-220216.

SCHOTT
glass made of ideas