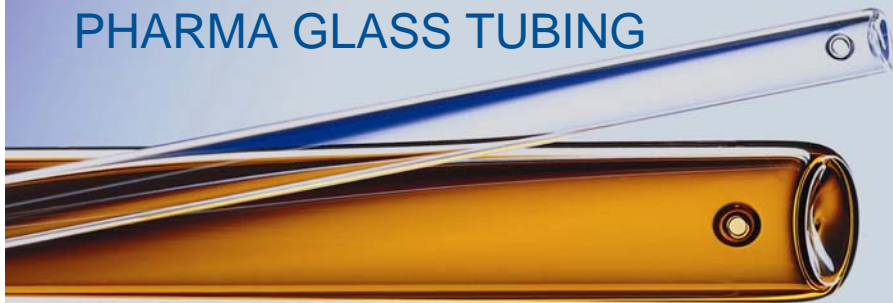


# Information Letter

## PHARMA GLASS TUBING



**SCHOTT**  
glass made of ideas

Issue 01 | February 2010



**Mr. Mohan Joshi**

President  
SCHOTT Glass India Pvt. Ltd.

### Worth to know

### History of Glass (part 1)

### FIOLAX® Traceability

### Interesting Links

## Editorial

Dear Readers,

Congratulations! You're holding the first Indian edition of the Pharmaceutical Tubing Information Letter. To support you in your future work even better, we wish to offer you a colorful variety of topics around the theme of glass tubing for pharmaceutical packaging materials for your reading pleasure.

I am confident that the Information Letter will allow us to offer you helpful information and suggestions. I hope you enjoy reading it and look forward to lots of feedback on this first edition.

Sincerely,

Mohan Joshi  
President  
SCHOTT Glass India Pvt. Ltd.



Worth to know

History of Glass (part 1)

FIOLAX® Traceability

Interesting Links

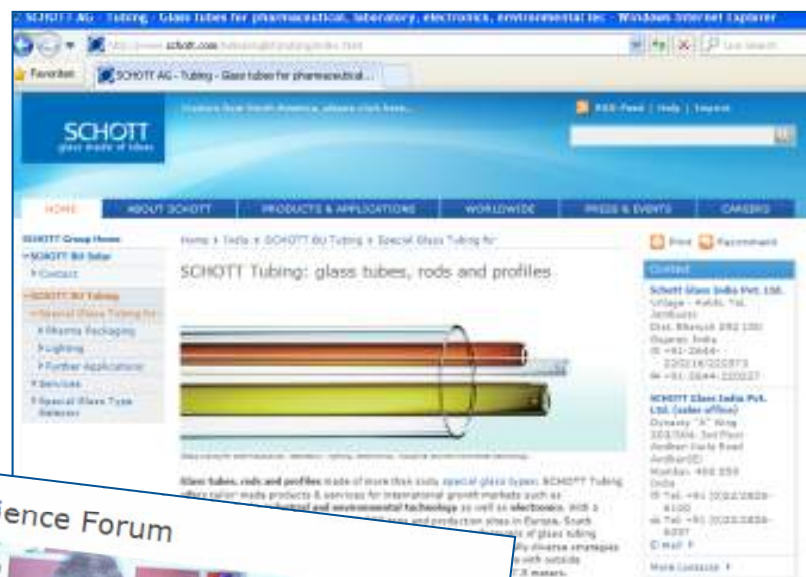
## Worth to know

SCHOTT Tubing has been producing glass tubing for pharmaceutical primary packaging in Jambusar, Gujarat, India since 1998. The addition to the geographic production portfolio for the international premium glass FIOLAX® in 2007, not only initiated delivery to customers outside of India. Instead, the decision to produce FIOLAX® in India showed that it was by the same token of paramount importance to the Indian Market for SCHOTT Tubing in Asia and offered customers new opportunities in the global pharmaceutical market.

For getting more information about our products and services, please feel free to call us (+91-2644-220216 or -222573) or have a closer look at our Indian website:

[www.schott.com/india/tubing](http://www.schott.com/india/tubing)

Here you will also find some detailed information about our recent newsletters and additional information to glass tubing in general.





## Worth to know

[History of Glass \(part 1\)](#)

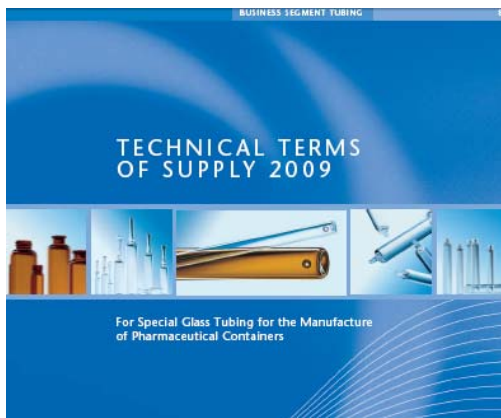
[FIOLAX® Traceability](#)

[Interesting Links](#)

## Worth to know

### New Quality Seal

With the current development of a special quality seal as evidence of the use of FIOLAX®, SCHOTT Tubing is providing its customers with a new important sales support. FIOLAX® converters can use the seal to prove that they have used high-quality glass tubes from SCHOTT in the manufacture of ampoules, syringes, and vials. This makes it easy for pharmacists in particular to be confident of the quality of their raw materials.



### Latest technical information

In autumn 2009 the new “Technical Terms of Supply for Glass Tubing for the Manufacture of Pharmaceutical Container” was launched. This terms of supply show our worldwide fixed quality levels due to several applications.

Beside a lot of geometrical aspects the cosmetic quality criteria were also improved.

### Customer survey

Due to the fact that the SCHOTT group wants to further improve its service quality, a global customer survey takes place in March 2010. We appreciate participation of many SCHOTT Tubing customers in this survey and we say “Thank you” in advance for your much valued feedback.

And also concerning this newsletter we are very happy to receive your short feedback to our Indian Sales Representative at SCHOTT Glass India Pvt. Ltd., Mr. Sundeep Prabhu: [sundeep.prabhu@schott.com](mailto:sundeep.prabhu@schott.com)



**Dr. Otto Schott**  
(1851 – 1935)

**Founder of the  
specialized glass industry**

**Worth to know**

**History of Glass (part 1)**

**FIOLAX® Traceability**

**Interesting Links**

## A history of glass (part 1)

The history of this excellent material is older than 7000 years. The first manmade glassy pieces in 5000 B.C were found on ceramic material in the area of Syria. People recognized very quickly the impermeability for gases and liquids as advantages of this material for the shelf life of their food and beverage. But it took another 3500 years until mankind could produce containers made of pure glass. The oldest findings are dated around 1400 B.C. from Egypt 18th. Dynasty, Thutmose III and are exposed in the museum of Munich and London. The origin where they were produced is not known, but they were used for precious content. The technique of the production of glass containers did not change until 100 B.C. when Syrian glassmakers invented the blowpipe. Since now it was possible to produce bigger containers with a higher production speed and a thin wall.



*18th. Dynasty,  
Thutmose III / 1400 b.C.  
Exposition from  
The British Museum*

During the Imperium of Rome glass was spread over the Roman Empire and its borders. Even in China Roman glass from the first century BC was found in a tomb near Guangzhou. Nevertheless the use of glass was limited as an expensive and high-status material.

About 1250 Venice, Italy became the centre of the glass production in Europe.

Its big competitors were production sites in France and in England

Making glass remained difficult and the formulation was kept as a secret. The basic recipe was known, but the special raw materials for making a good glass were given from glassmaker to glassmaker. The procedures and techniques for conversion became more and more perfect, but the physical and chemical properties of the glass remained the same.

In the 19th century there was a need for new glass types with different optical properties to make lenses for microscopes and telescopes with a bigger magnification. The known glasses showed a so called "secondary spectrum" and therefore they limited the magnification.

With his systematic investigation of ingredients for the glass composition in 1879 **Dr. Otto Schott** started the new era of Special Glasses.

## Worth to know

### History of Glass (part 1)

### FIOLAX® Traceability

### Interesting Links



Handdrawn glass tubes

## A history of glass (part 1)

In 1884, together with Dr. Ernst Abbe and Carl Zeiss, Otto Schott founded the *Glastechnische Laboratorium Schott & Genossen* in the city of Jena.

With the new glass types the construction of better microscopes and telescopes was possible. This resulted in big progress in medicine and astronomy.

During 1887 through 1893, Otto Schott developed the borosilicate glass which had excellent properties regarding high temperatures and resistance against thermoshock. With its high resistance against chemicals it was also optimal to be used in chemical laboratories.

Since 1908 there is also a production of glass tubing for the production of ampoules. Both glass tubes and ampoules were handmade. (see picture above)

In 1898 Schott requests a identification line on special glass tubes as a registered trademark. In March 1902 the registration is complete and the identification line on glass tubes becomes a well known brand mark for high quality special glass tubing. The advantages of FIOLAX® compared to the known other glass tubes for the production of ampoules are clear because the chemical reaction of FIOLAX® with the content is negligible and the stability of the drug allows a much longer storage of the content compared to former times.

Today SCHOTT has more than 100 years experience with FIOLAX®. The SCHOTT Companies produce FIOLAX® with the same quality at five Locations on three continents with a production capacity of approx. 90.000 tons. All FIOLAX® manufacturing sites are ISO 9001 certified. With a regular Technology exchange routines and procedures SCHOTT ensures the same quality level for all manufacturing sites according to the SCHOTT Tubing technical terms of supply, better known as TLB. A very high level of equipment related standardization ensures both, very quick maintenance and repair routines and flexibility in production planning. This is the guarantee for worldwide availability and a safe supply of FIOLAX®



Advertisement of FIOLAX®  
H. Freund,  
The Production of Ampoules  
Berlin 1916

The History of Glass will be continued in the next Information Letter.



## Worth to know

## History of Glass (part 1)

## FIOLAX® Traceability

## Interesting Links

# FIOLAX® Traceability

The production sites of the SCHOTT Business Segment Tubing ensure data traceability of the tubing and important processes for a period of ten years from the tube's production date. The key information for traceability is on the pallet label and the bundle label. For complete information we need at least one of these important pieces of information.

To explain the traceability of FIOLAX® we will explain all information which is on the pallet label and on the bundle label.

## A. Pallet Label

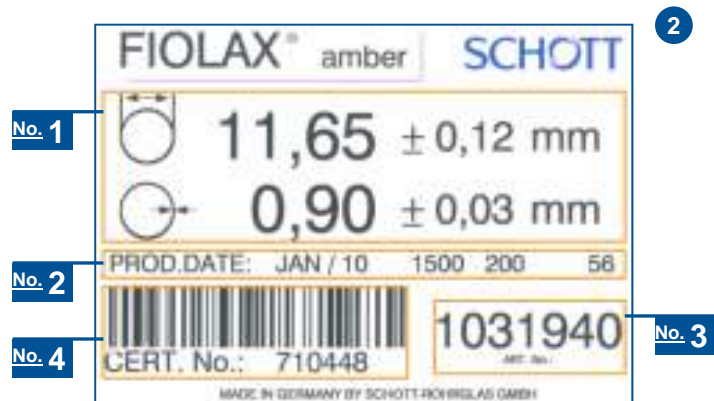
The pallet label is fixed to each single pallet of FIOLAX® (Picture 1). It is unique and divided into two parts. The first part of the pallet label, the left side, is glued onto the shrink foil of the pallet.

It contains the following information (Picture 2). Besides the glass type, here FIOLAX® amber, there is

- No. 1 OD and wall (or ID) and the tolerances in big letters so one can read them from a greater distance e. g. on a warehouse shelf.
- No. 2 The month and year of the production, the length of the tubes in mm, an internal execution code and the number of bundles on the pallet.
- No. 3 The SCHOTT article number which describes the glass tube
- No. 4 The key for traceability, the most important certificate number in letters and as an EAN Code. The **certificate number** is unique.



1



2

3



## Worth to know

## History of Glass (part 1)

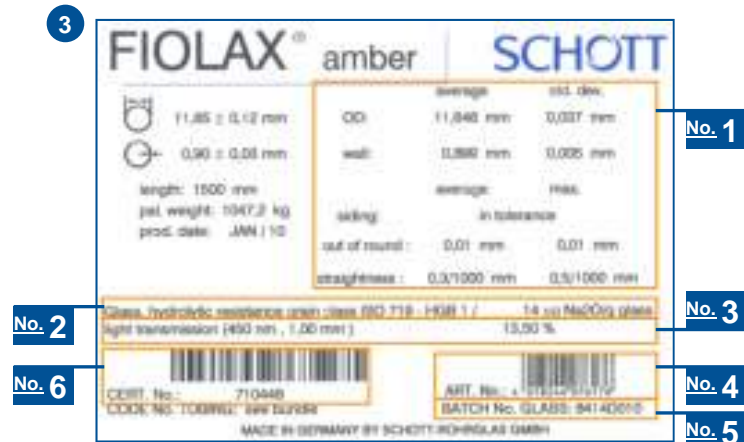
## FIOLAX® Traceability

## Interesting Links

# FIOLAX® Traceability

The second part of the pallet label can be easily removed from the pallet and used as a certificate as a substitution for an incoming control because this contains the results of the corresponding pallet (Picture 3). Besides the glass type, nominal tolerances and the month and year of the production on the left side. You can find:

- No. 1 The average and standard deviation of the measured values of the tubes on that pallet.
- No. 2 The measured result of the glass powder test which shows that the glass is Type I (limit of Type I is 31 µg Na<sub>2</sub>O/g glass).
- No. 3 Only for amber glass does it show the transmissivity of the tubes at a wavelength of 450 nm and a wall of 1,00 mm which is important for the light protection of light sensitive drugs.
- No. 4 The SCHOTT article number of the pallet which describes
- number of bundles on the pallet,
  - positioning of the bundles,
  - article number of the bundle,
  - packaging material of the pallet.
- No. 5 The Batch number which defines the glass batch as a material. This batch number is changed at the latest after one year, or after a tank repair, although there is no change in the glass composition or chemical and physical properties.
- No. 6 The most important **certificate number** in letters and as the EAN Code.



The **certificate number** is a key information for traceability.

After removing the second part of the pallet label from the pallet, there is still the **certificate number** on part 1 as a link to the rest of the pallet.



## Worth to know

## History of Glass (part 1)

## FIOLAX® Traceability

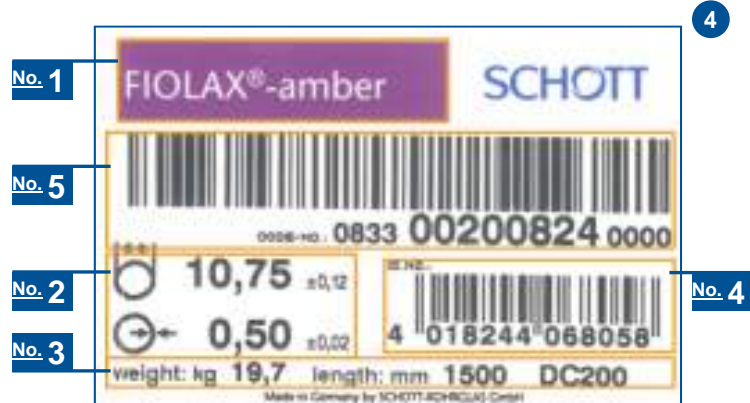
## Interesting Links

# FIOLAX® Traceability

## B. Bundle Label

The bundle label is fixed to each bundle and has the following information (Picture 4).

- No. 1 The glass type with the following colour codes:  
Mauve: FIOLAX® amber  
Pink: FIOLAX® clear
- No. 2 The nominal dimensions and tolerances of the tubes in the bundle.
- No. 3 The weight of the bundle, the length of the tubes in mm and a SCHOTT internal code for the tubing end execution.
- No. 4 The SCHOTT SAP article number for the bundle as code EAN 13.
- No. 5 The most important 16-digit control number in letters and as Code 128.



The **control number** is a second key information for traceability.

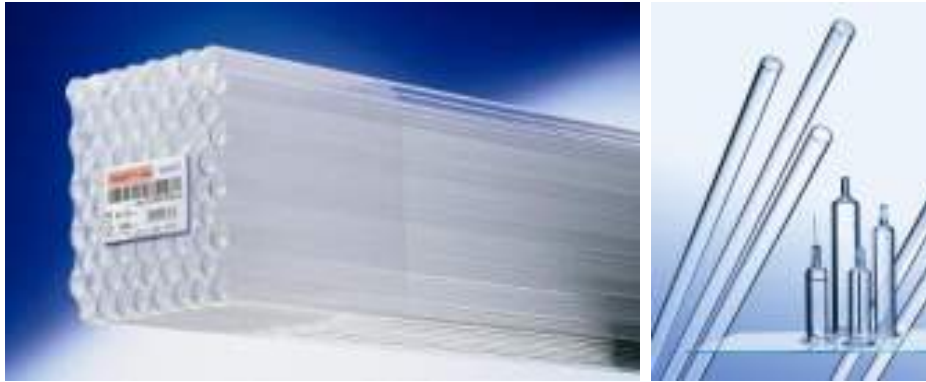
We have the following possibilities for information on traceability:

With the **glass batch number** (e.g. 8414D010) we can give the information about the

- glass type
- production year
- tank where the tubes were produced (all within the SCHOTT Business Segment Tubing)
- results of glass grain tests acc. to ISO 719, USP, Ph. Eur, JP, for this glass batch
- result of arsenic release acc. to Ph. Eur. (which is equal to USP) for containers made of this glass batch

With the **certificate number** of the Pallet Label we can find out the above and in addition:

- the drawing Line of the tank
- the glass type with nominal dimensions and tolerances
- the production month and day of the pallet
- the production time frame of the pallet within one day



## Worth to know

## History of Glass (part 1)

## FIOLAX® Traceability

## Interesting Links

# FIOLAX® Traceability

- The bundle numbers of the pallet.
- The position of the single bundles.
- The measured values of OD.
- The measured values of wall.
- The measured values of ovality.
- The measured values of weight of single tubes.
- The measured values of straightness.
- The mean values of the above measurements.
- The standard deviations/or maximum values of the above measurements.
- The result of ISO 719.
- If FIOLAX® amber is concerned, there is in addition the transmission at 450 nm with a wall of 1,00 mm which is important for the protection of light sensitive drugs.

The information from the pallet label are on a special program and stored on a separate server.

In addition we have information about the shipment:

- The month and day when the pallet was shipped to the customer.
- The truck/container and forwarder.
- The position of the pallet on the truck/container.

With the **16-digit code number** of the bundle label we can find out the above information, and in addition:

- Production time (accuracy to a minute) of the bundle.

With the information from the **certificate number** of the pallet label or the **16-digit code number** of the bundle label we have the possibility of finding out most detailed information about the complete production process beginning from the raw material.



Worth to know

History of Glass (part 1)

FIOLAX® Traceability

Interesting Links

## Interesting Links

### Outsourcing Trends for 2010

2009 was quite a challenging year for the whole industry and also for contract manufacturers and contract research organizations. Now 2010 gives a little hope. Here is an article about the top 10 outsourcing trends, which are listed by International Association of Outsourcing Professionals (IAOP).

[www.in-pharmatechnologist.com](http://www.in-pharmatechnologist.com)

### 2016: Vaccine market worth more than \$50 bn

*Experts in pharma industry predict an compound annual growth rate of 11.5% until 2016. Increased investments in Research & Development activities will underpin this trend, but the launch of novel vaccines needs financial support of R&D activities. Therefore the companies focuses on product differentiation to be sure that innovative vaccines become a success.*

[www.in-pharmatechnologist.com](http://www.in-pharmatechnologist.com)

### Partnerships between Drug and Packaging Manufacturers

*The search after improved manufacturing techniques and new container closure systems as well as improved drug delivery systems is forced by the rise in biopharmaceuticals. This fact is also forced by increased compliance requirements. All these challenges the drug and packaging manufacturers have to face. Therefore the packaging manufacturers build partnerships with pharmaceutical companies.*

[www.pharmpro.com](http://www.pharmpro.com)



## Worth to know

## History of Glass (part 1)

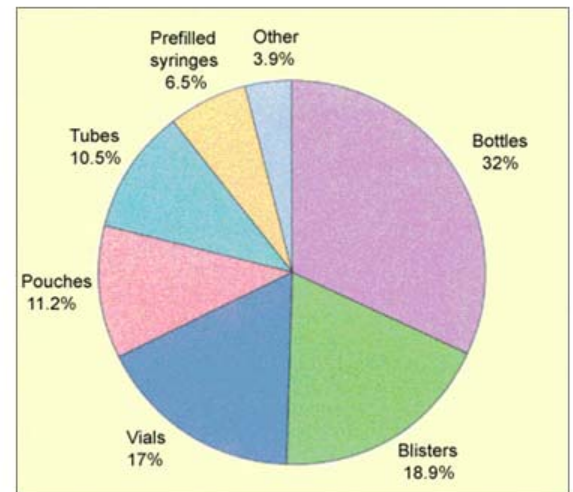
## FIOLAX® Traceability

## Interesting Links

# Interesting Links

## By 2020: Significantly improvements by medical device and pharmaceutical packaging

In the last decades medical products have developed very well, but also the medical packaging is in a permanent improvement process. One of the future items is a RFID tag with a unique code, which gives information about all relevant information related to drug and packaging or tactile code on the packaging with information about product name, dosage and expiration date. The world pharmaceutical packaging demand is projected to increase 6.3% per year by 2013 from \$ 45.9 up to \$ 62.3. This growth is rapidly driven by expanding pharmaceutical manufacturing capabilities on the one hand and also by government programs which forces an increasing quality and integrity of nationally produced medicines. Experts expect the fastest growth opportunities within sector of prefilled inhalers and prefilled syringes.



Global Pharmaceutical Products Distribution in 2008

**Source:** *Institute of Packaging Professionals (IOPP)*

[www.plastemart.com](http://www.plastemart.com)

## FDA approvals for 2009

Green light for 26 new therapies given by FDA in 2009. Seven of them were newly-approved biologics. The complete list can be found at [www.fiercebiotech.com](http://www.fiercebiotech.com)

Please find all interesting links and every issue of this information letter at [www.schott.com/tubing/infoletter\\_in](http://www.schott.com/tubing/infoletter_in)