

NEG Pharmaceutical Glass Tubing **BS & BS-A** - Quality Driven Process -

November 27rd, 2017

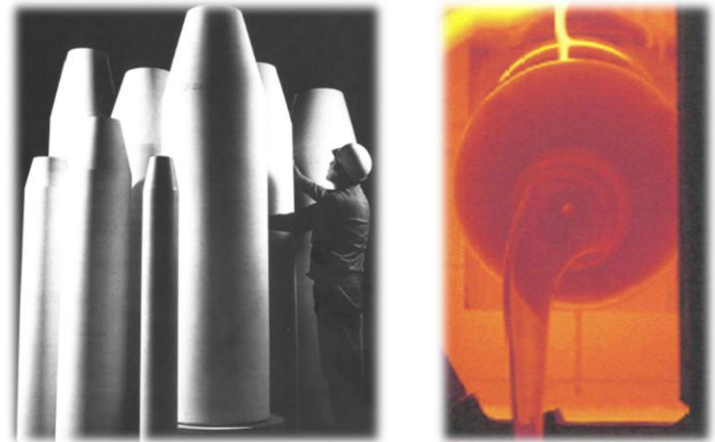
Kenichi HIROHASHI
Consumer Glass Division
Nippon Electric Glass

1. NEG Company Introduction

2. NEG Pharmaceutical Glass Tubing

2-1. Glass Composition & Properties

2-2. Production Process & Quality Control



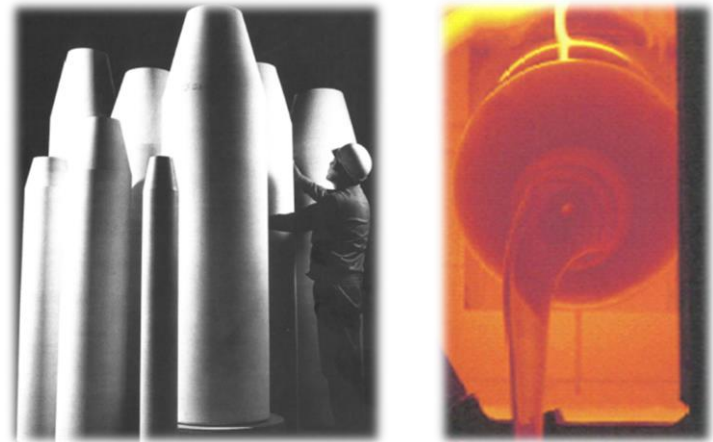
NEG supports Japan Pharma Market more than 60 years

1. NEG Company Introduction

2. NEG Pharmaceutical Glass Tubing

2-1. Glass Composition & Properties

2-2. Production Process & Quality Control



NEG supports Japan Pharma Market more than 60 years



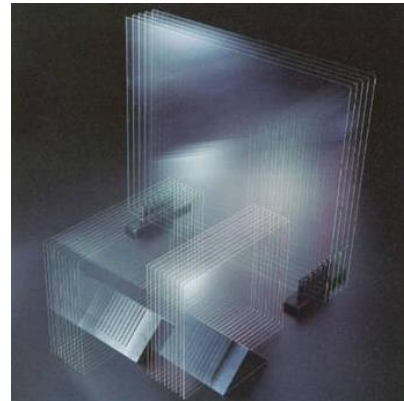
NEG Company Introduction

Various Glass Products

Glass Tubing for Pharmaceutical Containers



Glass for Flat Panel Displays



Glass Fiber



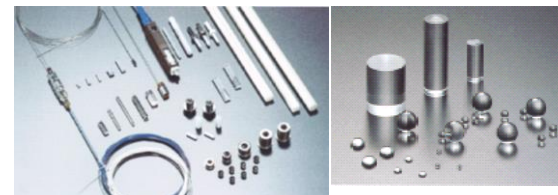
Heat-Resistant Glass-Ceramic



Glass for Building Materials



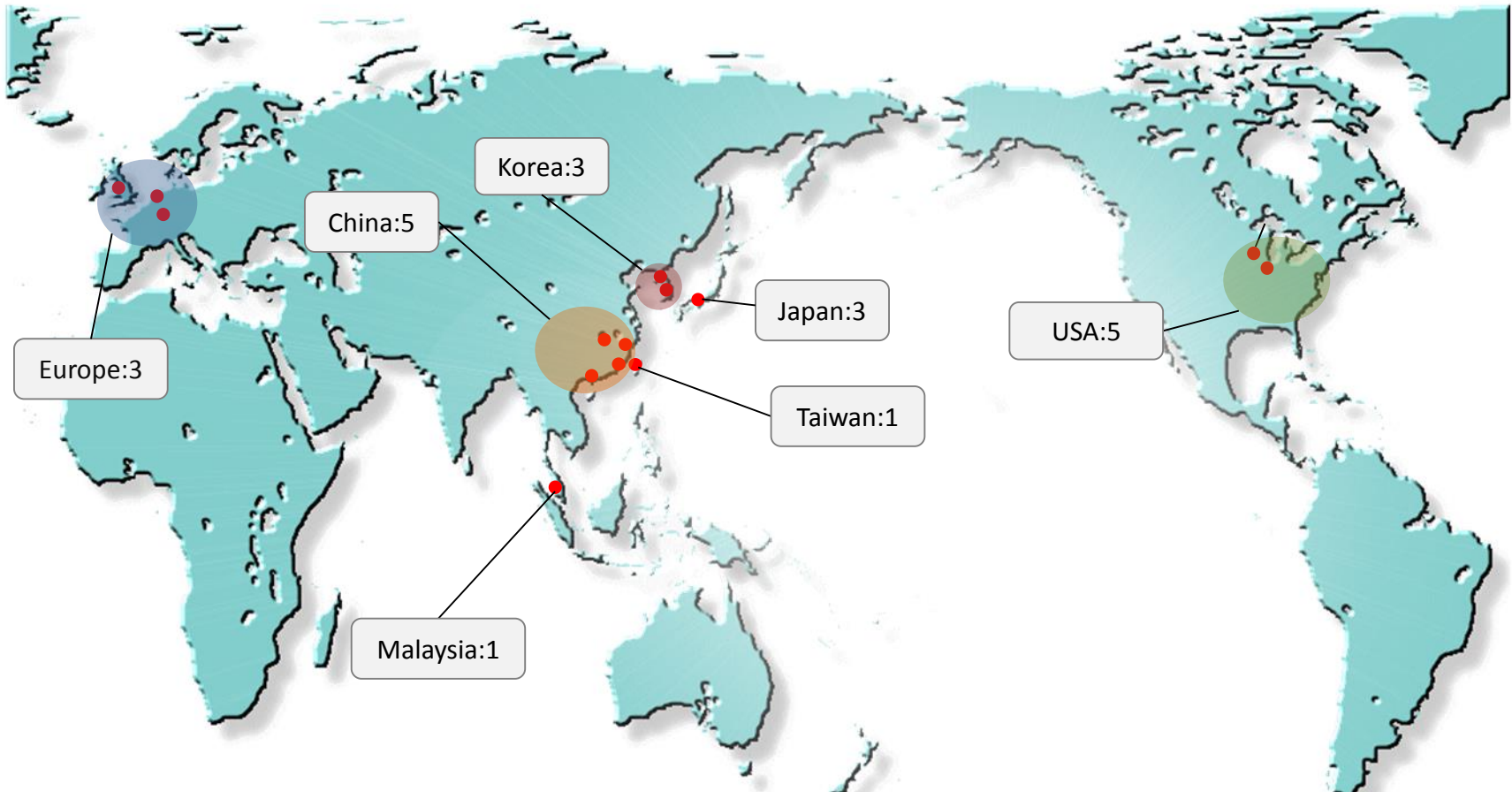
Glass for Optical & Electronic Devices



- 1949 Founded
- 1954 Started Pharmaceutical Tubing Production
- 1956 Started Danner Process
- 2001 Started relationship with Stevanato Group
- 2011 Started Pharmaceutical Tubing in Malaysia
- 2014 Japan plant renovation

NEG Company Introduction

Global Location



NEG concentrates to produce Glass Tubing for Pharmaceuticals and distributes to converters in the world

NEG Company Introduction

Production Sites for Pharmaceutical Glass Tubings



- Products : Tubing Glass, Heat-Resistant Glass, Radio-Shielding Glass, Thermos Glass,
- Glass Tubing for Pharmaceutical Containers :
Furnace : 2, Line : 4
- Capacity : 17,000 tons / year



- Products : Tubing Glass, Fiber Glass,
- Glass Tubing for Pharmaceutical Containers :
Furnace : 2, Line : 6
- Capacity : 23,000 tons / year



Product range

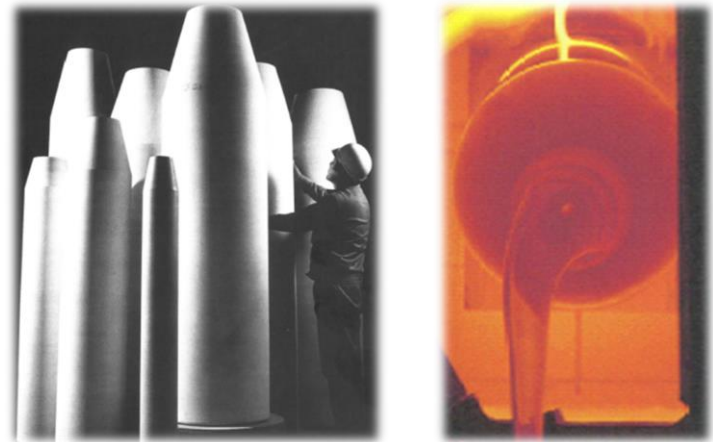
- Products: Glass Tubing for syringes, cartridges, vials and ampoules for pharmaceutical containers
- Glass types: Type I Borosilicate (Exp. coef. = 52-55, Clear and Amber)
- Product range: Diameter = 4 - 70 mm, Wall Thickness = 0.35 - 4.00 mm, Length = 1,200 - 2,100 mm

1. NEG Company Introduction

2. NEG Pharmaceutical Glass Tubing

2-1. Glass Composition & Properties

2-2. Production Process & Quality Control



NEG supports Japan Pharma Market more than 60 years



NEG Pharmaceutical Glass Tubing

Glass Composition & Properties

NEG Pharmaceutical Glass Tubing

- Type I neutral borosilicate glass tubing according to EP, USP, JP
- 1 Clear type : **BS**, 2 Amber types : **BS-A (Dark / Light)**
- High chemical resistance
- Environmentally friendly glass



NEG Pharmaceutical Glass Tubing

= Chemical Composition =

	BS	BS-A	
		Dark	Light
SiO ₂	72	72	71
Al ₂ O ₃	7	5	5
B ₂ O ₃	11	10	10
Na ₂ O	6	6	6
K ₂ O	2	2	2
CaO	1	-	1
BaO	1	1	1
TiO ₂	-	3	3
Fe ₂ O ₃	-	1.0	0.8

Chemical Composition

- Neutral Borosilicate Glass
- Chemical Stability / Thermal Stability

Typical Properties

- $\alpha=52-55$ Lower Converting Temperature
- Type I categorized (EP/USP/JP)

= Typical Properties =

	BS	BS-A	
		Dark	Light
CTE ($\times 10^{-7}/K$)	53	52	55
Density ρ (g/cm ³)	2.35	2.36	2.39
Annealing point Ta [C]	570	555	560
Softening point Ts [C]	785	775	765
Working point [C]	1175	1160	1130
Hydrolytic resistance acc. to EP (grain test)	Type I	Type I	Type I

BS-A Dark – Just developed this year

- same color as competitors
- similar thermal properties to others
- enough B₂O₃ wt% (YBB)

BS-A (Light) – Original

- easier visual inspection

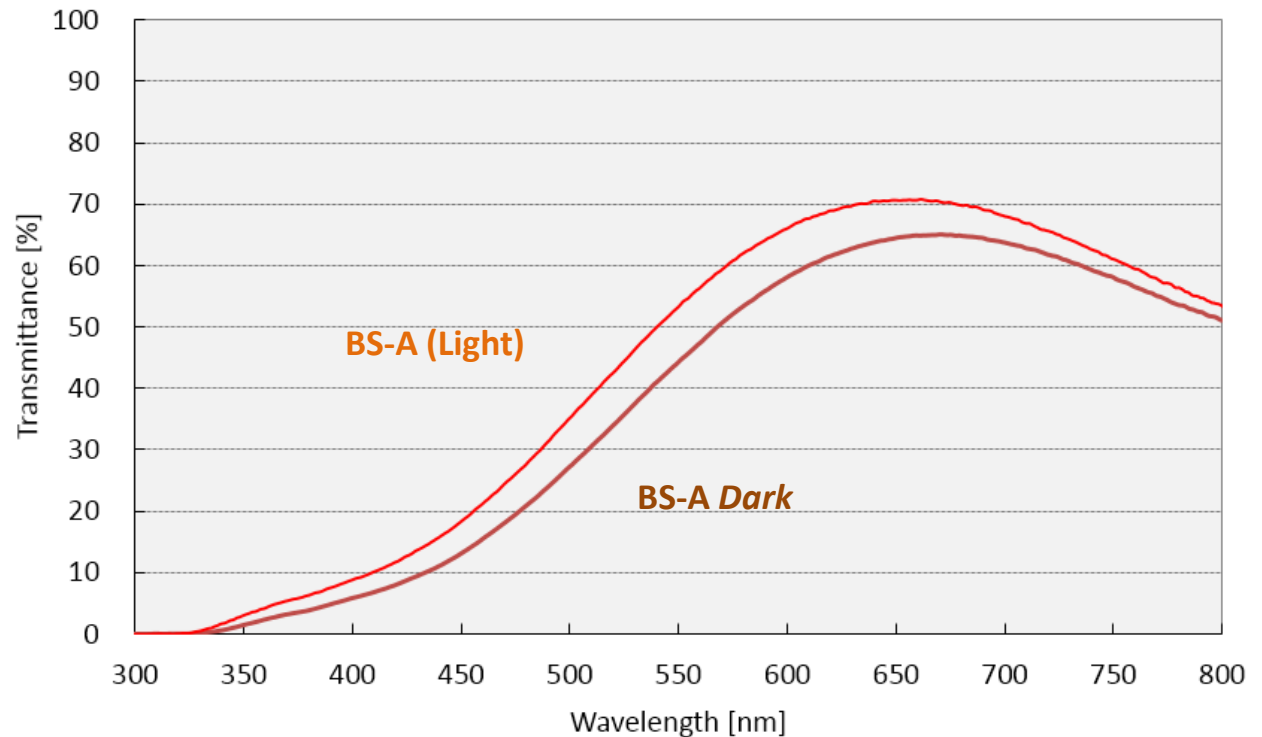
NEG Pharmaceutical Glass Tubing

Glass Composition & Properties

BS-A Dark was developed to correspond to global common color.



Color Comparison
(Wall Thickness 1mm)





NEG Pharmaceutical Glass Tubing

Glass Composition & Properties

Environmentally Friendly Glass

- NEG Glass Tubings are taken special care of hazardous elements.

= Hazardous elements in glass =

	BS	BS-A	
		Dark	Light
As			
Cd			
Pb		Free	
Hg		< 2 ppm	
Cr (VI)			

= Hazardous elements extracted =

	BS	BS-A	
		Dark	Light
As			
Cd		Not Detected	
Pb		< 0.01 ppm	
Hg			
Cr (VI)			



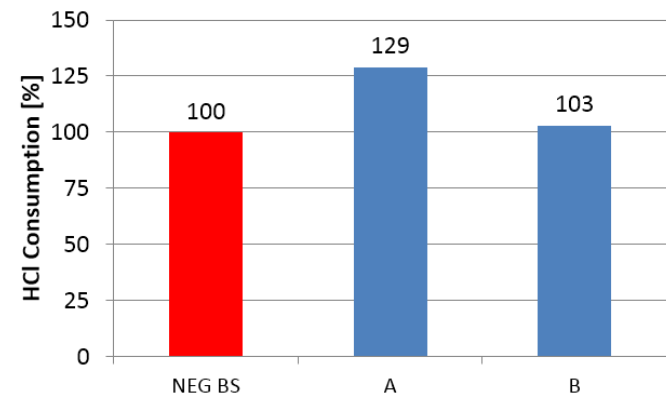
Tested acc. to EP surface test

Extractables & Leachables

All 24 elements proposed by ICH-Q3D can't be detected as extractables from both **BS** and **BS-A**.

High Performance of Hydrolytic resistance

- NEG Clear Glass (**BS**) has higher hydrolytic resistance than any other tubing suppliers.



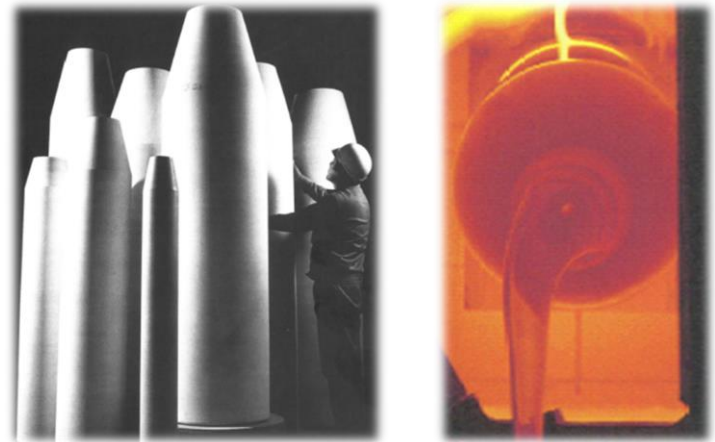
Tested acc. to EP/USP glass grains test

1. NEG Company Introduction

2. NEG Pharmaceutical Glass Tubing

2-1. Glass Composition & Properties

2-2. Production Process & Quality Control



NEG supports Japan Pharma Market more than 60 years

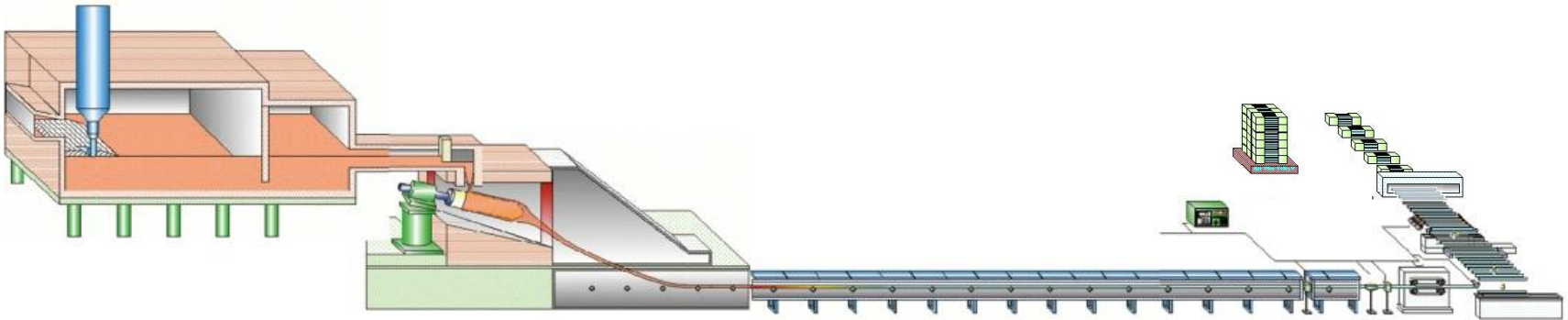
NEG Pharmaceutical Glass Tubing

Production Process

24hours Continuous Operation is well maintained for good quality.

1. Raw Materials & Mixing

Glass composition & properties control



2. Melting

Homogenization & Fining



3. Danner Forming

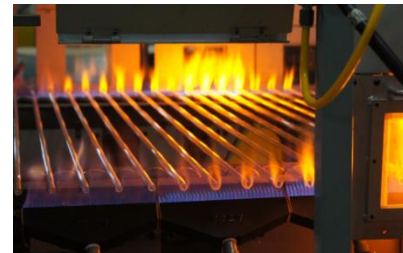
Dimension control

4. Glazing & Packing

Preventing breakage & contamination

5. Inspection

Quality control

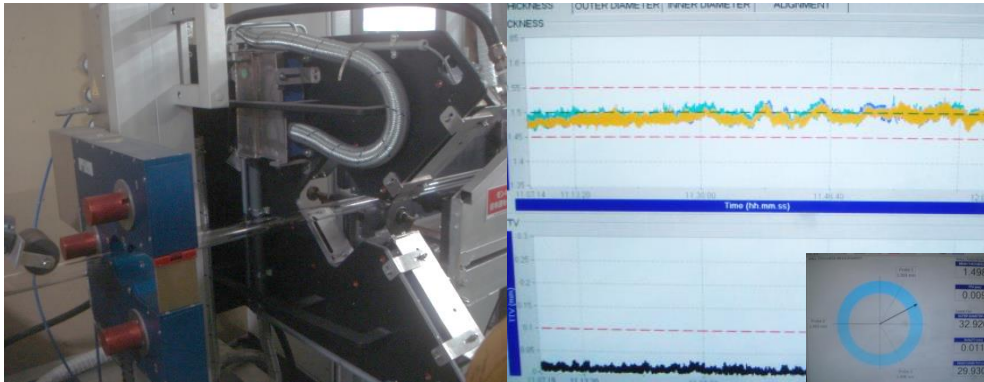


NEG Pharmaceutical Glass Tubing

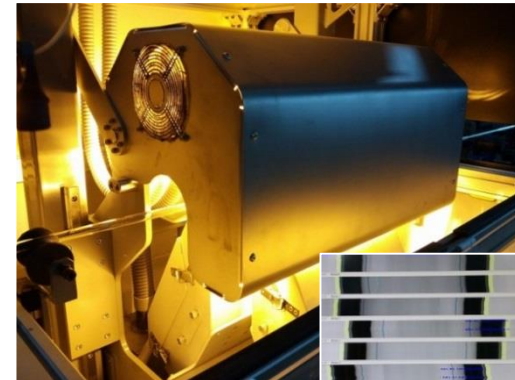
Quality Control

High Dimensional and Visual Control is carried out for stable quality

Automatic dimension measuring



Automatic visual inspection



Sampling inspection



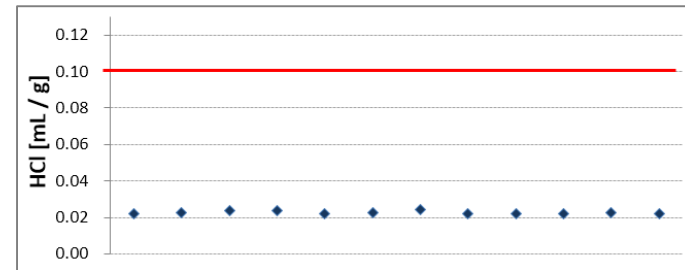
NEG Pharmaceutical Glass Tubing

Quality Control

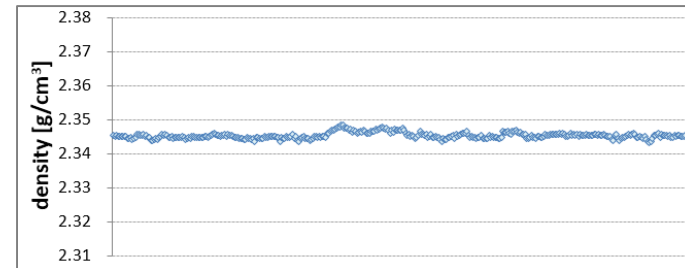
Both glass composition and its properties are strictly controlled

- Glass composition
- Physical properties
 - Coefficient of Thermal expansion
 - Density
 - Viscosity
- Chemical properties
 - Hydrolytic resistance
 - Acid & Alkali resistance
 - Extractables
- Optical properties
 - Transmittance

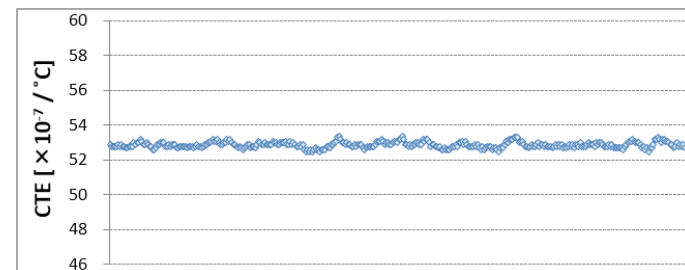
Hydrolytic resistance acc. to EP & USP



Density



Coefficient of Thermal Expansion



1 year data

NEG Pharmaceutical Glass Tubing

Summary

NEG is supplying high-quality glass tubing for pharmaceutical containers.

- Type I Neutral Borosilicate (EP / USP / JP)($\alpha=52-55$)
- **BS** (clear) / **BS-A Dark** **BS-A (Light)** (amber)
- Special care of hazardous elements
- Long experience as pharmaceutical glass tubing supplier
- Strictly process control and high quality control