

March 25, 2015

Two new materials of glass tubing for pharmaceutical containers developed ~“Glass improving hydrolytic resistance” and “Glass durable to delamination”~

Nippon Electric Glass Co., Ltd. (Head office: Otsu, Shiga, Japan; President: Masayuki Arioka)(NEG) has successfully developed new materials that “improve hydrolytic resistance” and “durable to delamination” for glass tubing for pharmaceutical containers* and is now providing samples.

* Glass tubing manufactured by NEG is converted as ampuls, vials, etc. by container manufacturers.

Glass material is mainly used for pharmaceutical containers, such as ampuls, vials, prefilled syringes, etc., from the viewpoint of its chemical resistance and physical strength. On the other hand, a wide array of new pharmaceutical drugs for advanced medical care has been developed day by day. In this background, NEG has undertaken the development of glass materials with high chemical resistance for use with new pharmaceutical drugs, in addition to existing pharmaceuticals, and this time NEG has successfully developed two new materials of glass tubing, one that “improves hydrolytic resistance” and the other that “durable to delamination,” both important technical issues. The details of the new materials are as follows.

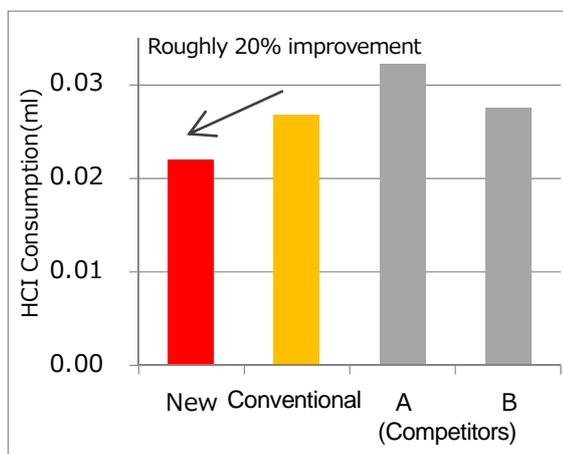
(1) Glass that improves hydrolytic resistance

Borosilicate glass currently used for pharmaceutical containers generally excels in chemical resistance with low alkaline elution (less eluted alkaline). However, minute amounts of the eluted alkaline component are unavoidable, and the risk of affecting the quality of pharmaceutical drugs during long-term storage has been pointed out. NEG has developed a glass material which substantially improves hydrolytic resistance.

(Characteristics)

- Improved hydrolytic resistance by 20% and achieved the top figure in the industry. (Test of hydrolytic resistance carried out according to glass grains test of European and U.S. pharmacopeia.)
- Does not contain halogen, e.g., fluorine and chlorine, or cause white ring by heat when processing containers.
- Does not contain environmentally hazardous materials, such as arsenic, as with our conventional products.
- Does not contain barium or cause precipitation of barium sulfate by chemicals containing sulfate ion.

(Comparison of hydrolytic resistance*)



*Performance compared by measuring the consumption volume of hydrochloric acid required to neutralize the alkaline component in a test solution.

(2) Glass durable to delamination

The phenomenon called “delamination,” in which glass lamellae peels off the interior walls of glass pharmaceutical containers and contaminates the chemical solution, has been reported. “Delamination” is said to be caused by alkali-borate vapor generated when heating glass tubing during the converting to containers. The vapor condenses and coagulates on the interior walls of the glass, and reacts with the chemical solution over time and eventually peels away. As with alkaline elution mentioned above, countermeasures to mitigate risk to the quality of pharmaceutical drugs during long-term storage are essential. This time we have developed a new material that substantially reduces the risk of delamination by inhibiting the vaporization of alkali-borate during converting.

(Characteristics)

- World’s first as a material able to be converted to container at the same level of temperature as conventional borosilicate glass, despite the fact that “aluminosilicate” glass hardly contains boric acid, which is a substance that generates alkali borate
- Does not contain halogen, e.g., fluorine and chlorine, or cause white turbidity by heating when processing containers.
- Does not contain environmentally hazardous materials, such as arsenic, as with our conventional products.
- Does not contain barium or cause precipitation of barium sulfate by chemicals containing sulfate ion.

NEG supplies more than 90% of glass tubing for pharmaceutical containers in Japan. Along with our conventional line-up, we are actively promoting these new materials for containers that can safely store, transport and be used with an increasingly diversified range of pharmaceutical drugs, and will continue to operate our business for these new materials for pharmaceutical drugs used in a variety of fields. We expect our international and domestic customers to positively evaluate the performance of these containers, and we aim to expand our sales to roughly two billion yen annually by 2020.

(Glass tubing for pharmaceutical container)



Contact

Consumer Glass Products Division, Sales
Nippon Electric Glass Co., Ltd.
(Tel: +81-77-537-1804(Direct))
(e-mail: cgtube@neg.co.jp)