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Published in

PDA Letter

Volume LIII, Issue 9, October 2017

Publication reprint

SCHOTT

glass made of ideas

People • Science • Regulation

PDA Letter

Volume LIII • Issue 9 www.pda.org/pdaletter October 2017

Extractables Profile of Aluminosilicate Glass Prior to Chemical Treatments

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As the complexity of modern drug products grows from a chemical and physical point of view, packaging and storing these products safely against environmental influences is ever more challenging. Therefore, possible drug/container interactions are an increasing focus in primary packaging development.

These interactions mainly depend on three factors: the chemical composition of the glass packaging material, the conversion process (i.e., the transformation of glass tubing into containers), including any additional surface treatments and, finally, the drug product itself. Regarding the first aspect, the composition of glass varies among different glass types as well as among different manufacturers. In consequence, the composition of a glass gives first indications for potential sources of extractables.

Glass, in general, consists of so-called network formers, such as silicon, boron and aluminium, as well as network modifiers like alkaline metals (e.g., sodium, potassium) and alkaline earth metals (e.g., calcium, magnesium). In this case study, the number of components, which are extracted from the inner surface of two different glass types, namely a borosilicate and an aluminosilicate glass (see **Table 1),** are compared.

This study used untreated glass tube sections of the different glass types in order to exclude the influence of the converting process. These tube sections were closed in a suitable manner, filled with ultrapure water and autoclaved for one hour at 121 °C according to ISO 4802-2 ***(1).*** Due to the harsh conditions, this method is suitable to quickly reveal the chemical stability of the inner surface of the glass. The analysis of the extracted elements was performed by means of inductively coupled plasma mass spectrometry and inductively coupled plasma-optical emission spectrometry, respectively. The exemplary results are given as their oxides and displayed in **Figure 1.**

This study shows that the total amount of extractables from the borosilicate glass is ~60% lower compared to the aluminosilicate glass type. Tests of the hydrolytic resistance as described in current regulations do not include all these elements, but rather focus mainly on the extraction of sodium oxide ***(2,3).*** As can be seen in **Figure 1**, sodium oxide exhibited the largest difference (0.5 mg/L vs. 2.2 mg/L, respectively) in extractables between these two glass types. Furthermore, the study also revealed that the major proportion of the extractables can be attributed to silicon (2.8 mg/L vs. 6.5 mg/L, respectively) as it represents the major component of both glass types. These exemplary results indicate a weaker glass attack and a higher stability toward water for the borosilicate glass type.

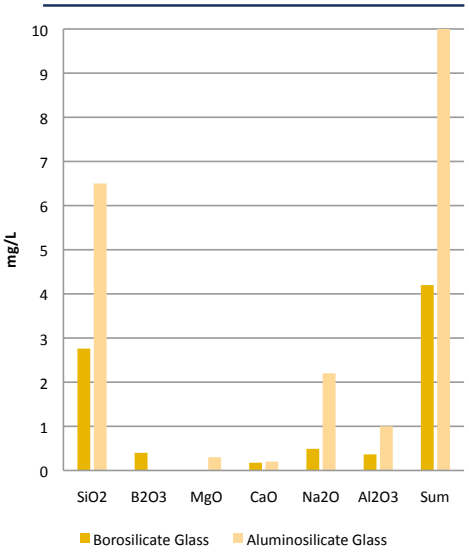

Figure 1 Extractables from Borosilicate and Aluminosilicate Glass Tubing after Autoclaving with Ultrapure Water (1 h, 121°C)

In conclusion, this case study demonstrates that the amount of extractables significantly differs between different glass types, not only in the level of network modifiers, such as sodium, but also network formers such as silicon.

Taking into account that the converting process tends to negatively, rather than positively, affect the extractables profile, there is a risk that without complex chemical treatment of the inner contact surface of an aluminosilicate glass container, certain standards expectations and requirements

	Network Formers			Network Modifiers			
	Si	Al	B	Na	K	Ca	Mg
Borosilicate Glass	✓	✓	✓	✓	–	✓	–
Aluminosilicate Glass	✓	✓	–	✓	✓	✓	✓

Table 1 Elements in the Composition of the Glass Types Tested

for today's parenteral primary packaging might not be achieved. Subsequently, a stringent incoming inspection would need to be implemented to unambiguously avoid intermixture with potentially untreated containers.

References

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