GERRESHEIMER

Primary Packaging Glass

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Confirmation

To whom it may concern

Glass Specification

March, 5th 2020

We herewith confirm that our amber and flint glass containers Type III and II comply with the current European Pharmacopoeia (EP), the United States Pharmacopoeia (USP) and the Japonica (JP).

Average composition of our amber and flint glass type III:

Flint Glass

SiO_2	71,60 ± 0,30%
AL_2O_3	1,70 ± 0,15%
Fe_2O_3	< 0,04%
CaO	10,10 ± 0,15%
MgO	3,10 ± 0,30%
Na_2O	12,00 ± 0,20%
K_2O	1,10 ± 0,20%
$Ti\ O_2$	0,03 ± 0,01%
SO_3	0,14 ± 0,05%

Amber Glass

SiO_2	71,50 ± 0,30%
AL_2O_3	2,30 ± 0,20%
Fe_2O_3	0,30 ± 0,05%
CaO	10,10 ± 0,15%
MgO	2,60 ± 0,15%
Na_2O	12,10 ± 0,20%
K_2O	0,75 ± 0,09%
$Ti\ O_2$	0,04 ± 0,02%
SO_3	0,04 ± 0,01%
Li2O	0,36 ± 0,04%

Remark - only for Glass-Type II:
The base glass is always Type III only the inner surface is changed to Type II by an chemical process: $(NH_4)_2SO_4$ ---> $2NH_3 + SO_3 + H_2O$
The **type II bottles** are to be used only once according to current, valid Ph.Eur. / USP/JP and have to be washed prior to filling.

Examinations regarding the contents of Heavy metals specifically Pb, Cd, Hg, and Cr^{+6} in our glass showed values below the limit of 100 ppm by weight. The content of arsenic is below the values of 0,1 ppm.

Therefore, and with the exception of marginal substances which do not affect human health, odour and taste and which cannot be avoided during manufacturing no other substances are released to food or its surface. This means, that we can confirm and reference to the paragraph 21 CFR 174-186.

It can be excluded that our glass contains substances like Latex, Gluten, Lactose, Bisphenol-A (BPA), Melamine or Phthalates.
We also confirm that products delivered by us, no raw materials, excipients and further materials of animal origin are used. Due to the fact that for the manufacture of these packaging material no materials are used, which might have a TSE / BSE risk, the bottles are not affected by the general text regarding vaccines, Ph.EUr.5.2.8,"Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products", and by the EMEA-guideline EMEA/410/01,"Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products".

Furthermore we can confirm, that our products will be produced according:
1. EMA "Guideline on the specification limits for residues of metal catalysts or metal reagents"(EMA/CHMP/SWP/4446/2000), Sept. 2008
2. Guideline for Elemental Impurities ICH Q3D, will be effective on January 1st 2018
3. General chapter of "Metal residues" in the European Pharmacopoeia (5.20)
4. USP general chapters <232> and <233> "Elemental impurities - limits" and "Elemental impurities- Procedure", will be effective on January 1st 2018

This confirmation base on our regular proceeds glass analyses. The specified Limits for elemental impurities are not passed.
Should you have any further questions, please do not hesitate to contact us.

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Yours sincerely

Ulrike Werner
Quality Management

Gerresheimer Essen GmbH