Produktdatenblatt-Technical Data Sheet

Art. No 41322..., -41323..., - 41324..., - 41325...

We herewith confirm that our amber and flint glass containers Type lll and ll 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 lll:

Flint Glass

SiO_2	71,60 ± 0,30%
AL_20_3	1,70 ± 0,15%
Fe_20_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_20_3	2,30 ± 0,20%
Fe_20_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 ll:

The base glass is always Type lll only the inner surface is changed to Type ll by a chemical process:
(NH4)2SO4 ---> 2NH3 + SO3 + H20

The **type ll bottles** are to be used only once according to current, valid Ph. Eur. / USP/JP and have to be washed prior to filling.

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Geschäftsführer: Karl-Heinz Hecht, Thomas Diepholtz | Einzelprokura: Tonja Müller

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, odor 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/O1,"Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products".

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