

## ALPHA GLASS DROP BOTTLE (100ml)

### Material Specification Sheet

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

Average composition of our amber and flint glass type III:

Flint Glass

SiO <sub>2</sub>	71,5 ± 0,3 %
AL <sub>2</sub> O <sub>3</sub>	1,7 ± 0,15 %
Fe <sub>2</sub> O <sub>3</sub>	< 0,035 %
CaO	9,80 ± 0,2 %
MgO	3,10 ± 0,30 %
Na <sub>2</sub> O	12,30 ± 0,50 %
K <sub>2</sub> O	1,20 ± 0,2 %
Ti O <sub>2</sub>	0,02 ± 0,01 %
SO <sub>3</sub>	0,15 ± 0,04 %
B <sub>2</sub> O <sub>3</sub>	0,2 ± 0,05 %

Amber Glass

SiO <sub>2</sub>	71,3 ± 0,3 %
AL <sub>2</sub> O <sub>3</sub>	2,3 ± 0,2 %
Fe <sub>2</sub> O <sub>3</sub>	0,3 ± 0,05 %
CaO	9,90 ± 0,30 %
MgO	2,6 ± 0,15 %
Na <sub>2</sub> O	12,20 ± 0,20 %
K <sub>2</sub> O	0,54 ± 0,09 %
Ti O <sub>2</sub>	0,035 ± 0,02 %
SO <sub>3</sub>	0,04 ± 0,01 %
B <sub>2</sub> O <sub>3</sub>	0,28 ± 0,04 %
Li2O	0,36 ± 0,04 %

Remark: The base glass is always Type III only the inner surface is changed to Type II by an chemical process:  $(\text{NH}_4)_2\text{SO}_4 \rightarrow 2\text{NH}_3 + \text{SO}_3 + \text{H}_2\text{O}$

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

Examinations regarding the contents of Heavy metals specifically Pb, Cd, Hg, and Cr <sup>+6</sup> in our glass showed values below the limit of 100 ppm by weight. The content of arsenic is below the values of 5 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. It can be excluded that our glass contains substances like latex, gluten or lactose.

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".

