GERRESHEIMER

Primary Packaging Glass

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Confirmation

To whom it may concern

Glass Specification Gerresheimer Lohr GmbH

January, 07th 2019

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

Average composition of our amber glass and flint glass type III:

	Average values of the oxide concentration [mass% res. ppm]	
Elementary oxides	**Flint Glass**	**Amber Glass**
SiO_2	71,74	71,49
Al_2O_3	1,44	1,91
BaO	0,054	0,049
CaO	10,86	10,77
Cr_2O_3	0,0022	0,040
Fe_2O_3	0,052	0,355
K_2O	0,82	0,85
MgO	2,45	2,16
MnO	0,005	0,020
Na_2O	12,32	12,18
Li_2O	0,003	0,004
SO_3	0,166	0,042
As_2O_3	0,0006	0,0005
TiO_2	0,032	0,058
ZnO	0,004	0,005
ZrO_2	0,02	0,020
PbO	0,0094	0,0096
Co_3O_4	0,0003	0,0006
NiO	0,0002	0,0008
CuO	0,001	0,001
V_2O_5	0,001	0,002
Er_2O_3	< detection limit (DL)	< detection limit (DL)
Bi_2O_3	< detection limit (DL)	< detection limit (DL)
Ce_2O_3	0,002	0,004
MoO_3	< detection limit (DL)	< detection limit (DL)
SnO_2	0,003	0,004
CdO	< detection limit (DL)	< detection limit (DL)
HgO	< detection limit (DL)	< detection limit (DL)
CrO_3	< 1 ppm	< 1 ppm
Sb_2O_3	0,001	0,001
SrO	0,024	0,024

Examinations regarding the contents of **heavy metals**, especially Pb, Cd, Hg, and Cr +6, in our glass showed values below the limit of 100 ppm by weight.

Chrome IV content:	Flint glass:	< 1 ppm
	Amber glass:	< 1 ppm
Arsenic and Boron (analyzed according ICP-O ES DIN 51086-2**)**		
As_2O_3 weight%	Flint glass:	0,0006
	Amber glass:	0,0005
B_2O_3 weight%	Flint glass:	0,0000
	Amber glass:	0,0000
Chlorine content (X-ray fluorescence analyze according DIN 51001 (UV)**):**		
Cl^- (%)	Flint glass:	0,017
	Amber glass:	0,027

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, bisphenol-A (BPA), nitrosamine, furfural, 2-chloracetamid or lactose**.

TSE / BSE

We also confirm in 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. Guideline for **Elemental Impurities** ICH Q3D, Dec. 2014
2. EMA "Guideline on the specification limits for residues of metal catalysts or metal reagents"(EMA/CHMP/SWP/4446/2000), Sept. 2008
3. **RoHS** Directive 2002/95/EC
4. General chapter of "**Metal residues**" in the European Pharmacopoeia (5.20)
5. USP general chapters <232> and <233> "Elemental impurities - limits" and "Elemental impurities-Procedure".

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.

Yours sincerely

Gerresheimer Lohr GmbH

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