Technical Datasheet

Type I Amber Glass

Type I Amber borosilicate glass
Manufacturing site: Vemula (India)
US DMF n°9527 / **Health Canada DMF** n°2007-046
Document Reference: F-008 V3

Glass is defined by ECHA (European Chemical agency) as an UCVB substance «Unknown or variable composition, complex reaction products or biological materials».
CAS 65997-17-3 EC 266-046-0
Compliant with European Pharmacopoeia §3.2.1 and United States Pharmacopoeia <660> in force.

Glass Matrix Composition:

- SiO_2 63 – 67%
- B_2O_3 10 – 12%
- RO (CaO + BaO) 1.5 – 5%
- R_2O_3 (Al_2O_3) 5 – 7%
- R_2O (Na_2O + K_2O) 7 – 12%
- TiO_2 2 – 3%
- Fe_2O_3 0.6 – 1.2%

Background Impurities:

- ZrO_2 <0.1%
- Heavy metals < 100 ppm (European Regulation 94/62/EC)

Physical properties:

- Coefficient of expansion: 55 to 65x10^{-7} $°K^{-1}$
- Density: 2.3 to 2.6 g/cm^3

Typical extraction profile:
Data below is provided for reference only and does not constitute a specification.
Listed soluates were extracted using the protocol described in European Pharmacopeia §3.2.1, test A. Pre-rinsed 100ml vials, extracted with high-purity water after 1 hour autoclave cycle at 121°C. Elemental analysis conducted using ICP-OES spectroscopy.
Data specific to SGD Pharma batch n° SVV035291121A1. SGD Pharma R&D Report n°1833 (April 12th, 2022).

Concentration	Si	Na	K	Ca	Mg	Al	Fe	B	Ba	Ti	Zn
(mg/L)	0.10	0.22	0.03	0.01	0.00	0.03	0.00	0.04	0.02	0.00	<0.002*

* values correspond to the quantification limit for that element

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