Shandong Pharmaceutical Glass Co., Ltd.
Yaobo Rd.1#, Yiyuan County, Zibo, Shandong, China.

SPG

Certificate of Analysis

Article Name:	**Tubular Glass Vial**	Delivery Quantity:	1721250 pcs
Made of:	**Low borosilicate glass**	Batch No.:	20221231
Drawing No.(Spec.):	10MLCIS	Production Date:	20221231
Color/Glass type:	Clear Color, HCB Class	Exp Date:	20271231
Sampling Basis:	GB2828.1-2012	Cell to be expanded:	As required
Sample Quantity:	500	Test Basis:	YBB00302002-2015

Description as per Invoice: EBL22085

	Test Item	Test Standard	IL	AQL	Test Result	Judgment
Appearance	Bubble Line	Bubble lines with width larger than 0.1mm not allowed	I	0.65	0	Qualified
	Stone(cord)	≤0.5mm			2	Qualified
	Crack	No crack			0	Qualified
	Black Spot	No black spots that can not be washed away			0	Qualified
Dimension	Total Height	55+0.50/-0.50mm	I	1.0	54.77~55.33mm	Qualified
	OD of Body	22.6+0.25/-0.25mm		0.65	22.48~22.75mm	Qualified
	OD of Lip	19.8+0.25/-0.25mm		1.0	19.71~19.94mm	Qualified
	ID of Lip	12.9+0.25/-0.25mm		1.0	12.76~13.04mm	Qualified
	Length of Neck	3.60±0.30mm		1.0	3.36~3.77mm	Qualified
	OD of Neck	≤16.00mm		1.0	<16.00	Qualified
	Finish Height[to down corner]	4.00±0.20mm		1.0	3.86~4.03mm	Qualified
	Body Length	≥42.5mm		1.0	>42.5mm	Qualified
	Thickness of body	1.05±0.05mm	S-1	2.5	1.02~1.08mm	Qualified
	Thickness of bottom	≥0.8mm	S-3	1.0	>0.8mm	Qualified
	Bottom push up, t	≤1.0mm	S-3	2.5	<1.0	Qualified
	Vertical axie deviation, a	≤1.0mm	S-3	2.5	<1.0mm	Qualified
Physical and Chemical Property	COE of expansion ($\times10^{-6}K^{-1}$(20-300℃)		(6.2~7.5)		6.93-7.01	Qualified
	B_2O_3		≥5%		6.86%	Qualified
	Hydrolytic Resistance of Powered Glass at 121℃		Class 1		0.088ml/g, Class 1	Qualified
	Hydrolytic Resistance of Powered Glass at 98℃		N.A.		--	--
	Hydrolytic Resistance of Internal Surface		HC1/HCB Class		0.95ml, Class HCB	Qualified
	Acid Resistance		N.A.		--	--
	Alkali Resistance		N.A.		--	--
	Internal Stress	≤40nm	S-1	1.5	0 nm	Qualified
	Release of As, Sb, Pb, Cd	As≤0.1mg/L	—	—	<0.10mg/L	Qualified
		Sb≤0.7mg/L	—	—	<0.05mg/L	Qualified
		Pb≤1.0mg/L	—	—	<0.030mg/L	Qualified
		Cd≤0.25mg/L	—	—	<0.010mg/L	Qualified

Conclusion	According to YBB00302002-2015, this batch of products is qualified, and meets the requirements specified in the chapter of the lastest version of USP<660> and EP 3.2.1.

Inspector: Liu Yuan

SHANDONG PHARMACEUTICAL GLASS CO.,LTD

Approved by: Liu Jian

Digitally signed by Dumbravă Natalia
Date: 2023.11.09 16:38:18 EET
Reason: MoldSign Signature
Location: Moldova