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TO WHOMSOEVER IT MAY CONCERN

An Extractable study was performed on type-III Amber Glass bottles/vials. Therefore, glass bottles/vials were washed and filled with purified water and autoclave for 60 minutes at 121 °c accordingly to the procedure specified in the USP<660> for surface glass test .The received extract solution was used for quantitative analysis of Elements Impurities as listed in ICHQ3D and USP <232,233>.

Result for wet chemical test -

Element	Limit of detection	Method	Actual content in sample (result)	Remarks
As	0.05 PPM	ICP	Not detected	OK
Cd	0.05 PPM	AAS	Not detected	OK
Hg	0.05 PPM	ICP	Not detected	OK
Pb	0.05 PPM	AAS	Not detected	OK
Co	0.05 PPM	AAS	Not detected	OK
Ni	0.05 PPM	AAS	Not detected	OK
V	0.05 PPM	AAS	Not detected	OK
Ag	0.05 PPM	AAS	Not detected	OK
Au	0.05 PPM	ICP	Not detected	OK
Pd	0.05 PPM	ICP	Not detected	OK
Pt	0.05 PPM	ICP	Not detected	OK
Ba	0.05 PPM	AAS	Not detected	OK
Cr	0.05 PPM	AAS	Not detected	OK
Cu	0.05 PPM	AAS	Not detected	OK
Li	0.05 PPM	ICP	Not detected	OK
Mo	0.05 PPM	AAS	Not detected	OK
Sb	0.05 PPM	AAS	Not detected	OK
Sn	0.05 PPM	AAS	Not detected	OK

Conclusion –It is well known that glass is an inorganic substance with the stable chemical properties. PGP confirms from the extract results of elemental impurities as listed in ICH Q3D and USP <232,233> that PGP type-III Amber glasses/vials are suitable for the pharmaceutical Products

For PGP Glass Pvt. Ltd.,Jambusar

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