

Declaration of Compliance with European Pharmacopoeia 8.0, paragraph 3.1.15 “Polyethylene Terephthalate for Containers for Preparations not for Parenteral Use”

Polisan Hellas hereby declares that **PoliPET** range of products which is Polyethylene Terephthalate copolymer, produced in Greece, by Polisan Hellas S.A, complies with European Pharmacopoeia 8.0, paragraph 3.1.15 as far as concern chemical composition.

Moreover, chemical analyses performed on containers made with Polyethylene Terephthalate identified by the brand name **PoliPET** are in agreement with the standards established by European Pharmacopoeia 8.0, paragraph 3.1.15, subject to compliance of the finished article with the requirements of the paragraph 3.1.15 pertaining to converter and end user obligation.

Especially for antimony (Sb): The limit for extractable antimony (Sb) from material is <1ppm – use of solution S4. Method for calculation of extractable antimony: atomic emission spectroscopy (ICP –AES: inductively coupled plasma-atomic emission spectroscopy). Analytical results obtained in samples using the above mentioned method and instrumentation (method 2.2.57, solution S4): <0.03ppm extractable antimony (Sb).

However, **Polisan Hellas S.A.** cannot assure that the final articles made with Polyethylene Terephthalate identified by the brand **PoliPET** will be in compliance, as regards chemical and physicochemical tests, with the standards established by European Pharmacopoeia 8, paragraph 3.1.15, since it is unaware of the subsequent processing treatment **PoliPET** will be subjected to before its final use.

For this reason, we would like to remind that all the tests must be performed by the producers or the end users on the finished article and in relation to its use.

This declaration covers 8th edition supplements up to: 8.6, January 2016

For queries or further information relating to this Compliance summary document please contact:

Mr. Kostas Papamargaritis (k.papamargaritis@polisanhellas.com),

Mr. Aristides Xinos (a.xinos@polisanhellas.com)