Polyethylene

Bormed™ LE6609-PH

We confirm that this product fulfils the requirements on materials used for the manufacturing of articles or components of articles intended for medical use as described in:

Council of Europe Material complies with the following European Pharmacopoeia monographs:

Monograph 3.1.3. Polyolefins

Monograph 3.1.4. Polyethylene without additives for containers for parenteral

preparations and for ophthalmic preparations

Tests are made according to the current Pharmacopoeia edition at the time of the

testing: 11th edition (2023), and supplement 11.2 (07/2023). (

Monograph 3.2.2. Plastic containers and closures for pharmaceutical use: This monograph relates specifically to the $\underline{\text{container}}$ and closure $\underline{\text{system}}$ and does not contain tests that are required for compliance assessment of the raw materials used for said container and closures. The composition of the product is in

compliance with this monograph.

The product follows the VDI 2017 Guideline on "Medical Grade Plastic" that Germany

covers the requirements for change management, quality management, supply

security and support for regulatory requirements.

USA Material has passed the following United States Pharmacopeia tests:

Biological reactivity tests - in vitro <87>: Cytotoxicity (Elution test)

Biological reactivity tests - in vivo <88>: Class VI - 70 °C

Physicochemical tests for plastics according to <661>, so far applicable to polymer pellets (with no reference to the specific surface area requirements), including heavy metals, buffering capacity and non-volatile residue test with

purified water extract.

Plastic materials of construction <661.1>: Identification, physicochemical and

extractable metals (as listed in the chapter) tests.

Tests are made according to the current Pharmacopeia edition at the time of the

testing (USP 36/37/39/42/2022/2023).

During the manufacturing process of this product, we neither use nor intentionally Elemental impurities

incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D(R2)

Guideline on Elemental Impurities (May 2022).

DMF number Material has been assigned the FDA Drug Master File number(s):

DMF 017927 (for material no. 24086 ex Porvoo) DMF 028752 (for material no. 27148 ex Schwechat)

Additional information If a customer wishes to take advantage of the pre-notice period in case of deletion

or modification of Bormed grades, such pre-notice period needs to be included in

Technical Delivery Specifications.

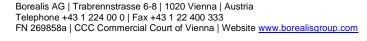
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