Refining & Chemicals

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CERTIFICATE N° 37899

Feluy, April 12, 2018

POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe (Lavera site)

STATEMENT OF COMPLIANCE FOR PHARMACOPOEIA APPLICATIONS:

1. STATEMENT OF COMPLIANCE EUROPEAN PHARMACOPOEIA:

We hereby certify that the additives (i.e antioxidants, lubricants and/or antibloc agents) of **POLYPROPYLENE Aceso ® PPM H250** are included in the positive list of:

- European pharmacopoeia - 9th Edition (2018) – 9.3

§ 3.1.3 Polyolefines

§ 3.1.6 Polypropylenes for containers and closures for parenteral preparations and for ophthalmic preparations.

This Product was tested on batch Nr 17P2690- 2017 for physicochemical tests described in § 3.1.6 (9.3) Polypropylenes for containers and closures for parenteral preparations and for ophthalmic preparations.
The investigated samples fulfilled the physicochemical tests requirements prescribed in § 3.1.6 (9.3).

Moreover we remind you that the compatibility of the medicinal product with the plastic material depends on the physical state of the active substance and the pharmaceutical dosage form and route of application of the medicinal product. Consequently the packaging has to be controlled following the specific end-use conditions as described in guideline on plastic immediate packaging materials issued by EMEA and specific adequate Regulations dedicated for medical and/or pharmaceutical applications.

It pertains as usual to the manufacturer of the finished articles according to the rules of the profession and the usual practice, to verify the compatibility of the Product with the products or preparations to be packed.

2. STATEMENT OF COMPLIANCE WITH PHARMACOPOEIA IN THE USA:

The **POLYPROPYLENE Aceso ® PPM H250** (batch 16P1989 – 2016) was submitted in December 2017 to a study ref. nr 16-B6437 entitled: '*Tests according to United States Pharmacopoeia – according to United States Pharmacopoeia 39NF34– general chapters:* ***< 661.1>*** *Polypropylene sections ' Identification, Physicochemical Tests* , Extractable Metals and Plastic Additives' .Specifically were tested : the Absorbance, Acidity, Alkalinity, TOC, extractable metals (as Al, As, Cd, Pb, Co, Ni, V, Cr, Ti, Hg & Zn), Plastic Additives and Identification . Under the conditions of this test, the tested material passes.

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Moreover an *In Vitro* cytotoxicity test on the **POLYPROPYLENE Aceso ® PPM H250** (batch 16P1989 – 2016) was conducted to evaluate the potential for cytoxicity. This study (ref. nr 17-B0095 -N1 – dated on January 12, 2017) entitled '*qualitative MEM-elution: Dye Exclusion*' according to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices –Part 5: Tests for *In vitro* Cytotoxicity "and "USP 39 NF 34, 2016 : **< 87>** Biological reactivity test, *in vitro*" Under the conditions of this test , the extract of the test item is considered non-cytotoxic.

3. STATEMENT OF TRANSMISSIBLE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE):

We hereby confirm that we did receive an indication from our suppliers of additives used in the above-mentioned Product mentioning the absence of any substances which are of animal origin. Based on the above, we are confident that the above-mentioned Product is free of SRM (Specified Risk Materials).

4. NOTE:

The use of the here above mentioned Product for any medical or pharmaceutical applications is under the entire responsibility of your company. Results and conclusion apply only to test articles tested and are provided solely for information. Any extrapolation of these data to other articles is the customer's responsibility.
For obtaining more information regarding the Pharmacopoeia, please contact directly our ATC (Phone : +32.64.51.43.07, Fax : +32.64.51.46.50, e-mail: Fabienne.radermacher@total.com) or our vendor.

DISCLAIMER:

Our certificate is only valid for as far as above mentioned Product was bought from Total or its distributor and does not cover:

- Any modification of the above-mentioned Product by any addition of any other product or ingredient to it;
- Any prejudicial modification of the above-mentioned Product resulting from a processing of it;
- An inadequate use and/or storage of the above-mentioned Product and/or of the finished articles.

Under no circumstances are any products sold by Total Refining & Chemicals suitable for human or animal in the following applications: (i) medical implants material or implantable devices intended for human or animal body (ii) devices intended to be used in contact with internal body fluids (iii) Devices intended to be used in contact with internal body tissues.

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This disclaimer exclude the following typical applications used for medical devices and/or Pharmaceutical & diagnostic packaging as:

- Disposable non-prefilled syringes
- Needle hubs
- Catheter connections
- Laboratory disposable
- Diagnostic products

Information contained in this publication is true and accurate at the time of publication and to the best of our knowledge. The nominal values stated herein are obtained using laboratory test specimens. Before using one of the products mentioned herein, customers and other users should take all care in determining the suitability of such product for the intended use.
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The present certificate is valid for a period of eighteen months starting from the date first above written. Upon the expiration of this certificate, we can issue a new one at your request. In case of change during this period a new certificate will be issued automatically; kindly forward it to any recipient of the present certificate.

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