

Re: Position paper on Chromium absence in Quali-G™ / Quali-V® capsules

Alcobendas, September 5th, 2018

To Whom It May Concern,

In light of recent concerns regarding possible Chromium contamination in gelatine capsules that are produced with raw materials for industrial use and/or originating in China, as well as the application of Chromium-coated moulds for their manufacture, Qualicaps Europe S.A.U. is pleased to certify the following information:

- Quali-G™ two-piece hard gelatine capsules are produced by Qualicaps Europe S.A.U. and Qualicaps Romania S.R.L. with pure bovine origin, pharma-grade gelatine from CEPs:
 - PB GELATINS: R1-CEP-2002-110-Rev. 00; R1-CEP-2000-045-Rev. 03.
 - ROUSSELOT SAS: R1-CEP-2000-027-Rev. 02; R1-CEP-2000-029-Rev. 05.
- Neither of these gelatine CEPs includes bovine bones sourced from China.
- Gelatine raw material batches used for Quali-G™ capsules are analysed and released as compliant with USP/EP/JP compendia, before incorporation into the production process.
- Quali-V® two-piece hard hypromellose capsules are produced by Qualicaps Europe S.A.U. using hypromellose raw material supplied from qualified non-Chinese manufacturers, analysed and released as compliant with USP/EP/JP compendia before incorporation into the production process.
- Quali-G™ and Quali-V® capsule production complies with the ICH Q3D Guideline for elemental impurities, including Chromium analysis in regular analytical monitoring.
- Qualicaps Europe S.A.U. and Qualicaps Romania S.R.L. employ stainless steel moulds (pin sets) exclusively, for both Quali-G™ and Quali-V® capsule manufacture. No chromium-coated moulds are in use by any Qualicaps site worldwide, and as such, there is no risk of contamination with Chromium from this source.

For any further information, do not hesitate to contact your Qualicaps representative.

Attentively,



Federico García Sagrado, PhD
Vice President of Quality & Regulatory, EMEA