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Date : 20/12/2017
Direction/Service : Quality Assurance VWR Chemicals
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Topic: ICH Q3D Elemental impurities

Article number: VWRC20181.*

Article name: BORIC ACID CRYSTALLIZED PH.EUR

Dear valued customer,

The development of a strategy to limit elemental impurities in drug products is consistent with risk management processes identified in ICH Q9. Guideline ICH Q3D describes the process to assess and control elemental impurities. Supplier information regarding production flow or the presence of potential elemental impurity levels can be used as part of the information to complete the assessment.

As VWR is a supplier, we hereby declare that BORIC ACID CRYSTALLIZED PH.EUR has been tested on the actual level of elemental impurities in reference to “ICH guideline Q3D on elemental impurities for Class 1 plus 2A elements by validated ICP-MS or ICP-OES technology.

This information allows manufacturers and users to perform their own risk assesment and to determine a control strategy and if applicable limits of content.

The concerned elemental impurities of class 1 and class 2A are determined with a high level of assurance after analysis of representative samples of BORIC ACID CRYSTALLIZED PH.EUR and the typical levels are listed in the table below:

	Class 1				Class 2A		
Element	**Cd**	**Pb**	**As**	**Hg**	**Co**	**V**	**Ni**
Typical values (ppm) (1)	≤1	≤2	≤2	≤2	≤1	≤1	≤4

(1) VWR will not release any batch which does not fullfill this specification

In case of any remarks or questions, please do not hesitate to contact us.
With kind regards,

Quality Assurance VWR Chemicals

Anja Vanhalle