



ANALYSENZERTIFIKAT

Filopur AG
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Order No : 1409-00373
 Receipt : 10. September 2014
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Definition of task

Retention test of medicines on Filopur water filters. The water sample was worked up according to the SOP MS-041-006. The medicines were determined by LC-MS/MS.

Study design

With medicines spiked water was passed through the water filter. Two water samples were spiked with Diclofenac, Ibuprofen and Ethinylestradiol. The first sample with a concentration of 0.2 µg/kg and the second sample with 0.5 µg/kg.

Results

Samples	Concentration Medicine [µg/kg]	Concentration Filtrate [µg/kg]	Retention capacity [%]
Water sample 1 spiked with medicine*	0.2 µg/kg	not detectable**	99.9
Water sample 2 spiked with medicine*	0.5 µg/kg	not detectable**	99.9

*Diclofenac, Ibuprofen and Ethinylestradiol were tested

Maximum residue level [µg/kg]: 0.1

Matrix: drinking water

**Limit of Quantitation [µg/kg]: 0.05

Assessment basis: Verordnung des Eidgenössischen Departements des Innern (EDI) über Fremd- und Inhaltsstoffe in Lebensmitteln (FIV) (Stand 21. Oktober 2014) SR 817.021.23

Conclusions

The tested water filter has hold back all medicines at concentrations of 0.2 µg/kg and 0.5 µg/kg. There were no medicines detectable. The quantitation limit of the method was 0.05 µg/kg. The recovery rate of the methode was determined by spiking water samples. The average recoveries, measured at two concentration levels (0.2 µg/kg and 0.5 µg/kg) were in the range 80–95%

Belp, January 26, 2015



Legend: <: less than >: more than n.d.: not detectable, less than limit of detection LD: Limit of detection
 DM: Dry Matter cfu: colony forming units A value after "<" is the LD of the corresponding method.

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The scope of the accreditation is described in the official directory of accredited laboratories (www.sas.ch). The results in this report relate only to the items tested. For conformity to the Swiss GMP Guideline, a quality agreement for contract laboratory work is necessary for each product. The method is continuously monitored by the Interlabor Quality Management Program. Further parameters and the uncertainty of the method are available upon request. Examinations marked with an asterisk (*) are not covered by the scope of the accreditation. This report may be forwarded only complete and unaltered

BE1409-00373-98241585_6