

Title (en)  
MODULAR SYSTEM AND METHOD FOR CONTINUOUSLY PRODUCING AND/OR PREPARING A PRODUCT IN A DISINFECTED MANNER

Title (de)  
MODULARE ANLAGE UND VERFAHREN ZUR KONTINUIERLICHEN, KEIMREDUZIERTEN PRODUKTION UND/ODER AUFBEREITUNG  
EINES PRODUKTES

Title (fr)  
INSTALLATION MODULAIRE ET PROCÉDÉ DE PRODUCTION ET/OU PRÉPARATION D'UN PRODUIT EN CONTINU AVEC UN NOMBRE  
RÉDUIT DE GERMES

Publication  
**EP 3292195 A1 20180314 (DE)**

Application  
**EP 16722580 A 20160429**

Priority  
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• EP 2016059700 W 20160429

Abstract (en)  
[origin: CA2984981A1] The invention relates to a method for continuously producing and/or preparing a biopharmaceutical biological macromolecular product from a heterogeneous cell culture/fluid mixture in a disinfected manner, having the following steps: (a) providing a particle-free fluid from a heterogeneous cell culture/fluid mixture, said fluid containing the product, in the form of a product flow, (b) carrying out at least one filtering process, whereby a filtrate is obtained, (c) carrying out at least two chromatography steps for cleaning the product, (d) carrying out at least one virus-removing process, and (e) carrying out at least one ultrafiltration process and/or at least one diafiltration process on the product flow from step (b), (c), and/or (d), said method being characterized in that the at least two chromatography steps from step (c) include a cleaning process using at least two respective chromatography columns and/or membrane adsorbers and in that the method is carried out in a closed and modular manner. The invention further relates to a corresponding modular system for carrying out the method.

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EP 3292195 A1 20180314; HK 1254902 A1 20190802; IL 255383 A0 20171231; IL 255383 B 20210930; JP 2018518161 A 20180712;  
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