



Transparency and comprehensive documentation with Emprove® CCM

Emprove® Dossiers for Cellvento® CHO cell culture media products in Biomanufacturing Upstream Processes

Raw materials and process aids used during drug substance manufacture have come under increased regulatory focus. Recent best-practice industry publications^{1,2} broadened the scope of raw materials to be included in drug product risk assessments from excipients to the entire drug product production process, including Upstream Processing.

Cell culture media are of utmost importance to biopharmaceutical processes as they support cellular productivity and critical quality attributes of the final drug products. Therefore a high level of information for the media is needed to support the entire process risk evaluation.

With our new category Emprove® CCM we address the specific needs when selecting and qualifying products of our Cellvento® CHO cell culture media platform.

The platform consists of specially designed catalog media supporting the needs of process intensification in fed-batch and perfusion applications. The product formulations are chemically defined and of non-animal origin.

In line with the existing Emprove® product categories, detailed information is available in three different types of dossiers, supporting you throughout the different stages of your operations: material qualification, risk assessment, and process optimization.

Three Levels of Information for Material Qualification, Risk Assessment and Process Optimization

Material Qualification Dossier

- General information
 - Specification
- Manufacture
 - Address, Manufacturing Flowchart, ISO Cert, GMP Statement
 - Homogeneity Statement
- Characterization Statements
 - TSE/BSE, Virus Safety, GMO, Components of Interest
- Control of CCM
 - CoAs, Label, Batch Numbering
 - Packaging Material
 - Stability

Information to start a material qualification

Quality Management Dossier

- Supply Chain Information
- Product Quality Self Assessment
- Site Quality Self Assessment
- Supplier Management
- Stability data

Answers questions during risk assessment

Operational Excellence Dossier

- Trace Element Information
- Origin of Raw Materials
- Analytical procedures

Supports process optimization

Target Emprove® dossier for Cellvento® media

Product	Catalog Number
Cellvento® 4CHO-X COMP Expansion	103840
Cellvento® 4Feed COMP	103796
Cellvento® 4CHO	103795
Cellvento® CHO-200	101885
Cellvento® Feed-200	101883
Cellvento® CHO-220	102577
Cellvento® Feed-220	102578
Cellvento® CHO-210	102485
Cellvento® Feed-210	102488



Find out more on [merckmillipore.com/emprove](https://www.merckmillipore.com/emprove)

1. BioPhorum "Raw material risk assessments – A holistic approach to raw materials risk assessments through industry collaboration", Sept 2019.
2. European Biopharmaceutical Enterprises, "Management and control of raw materials used in the manufacture of biological medicinal products and ATMPs", Dec 2018.



For additional information, please visit
www.merckmillipore.com

To place an order or receive technical assistance, please visit
[merckmillipore.com/contactPS](https://www.merckmillipore.com/contactPS)

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

Merck, the Vibrant M, Cellvento, Emprove and SAFC are trademarks of Merck KGaA, Darmstadt, Germany and/or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.
© 2020 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved.

Gain 24/7 online access to all your dossiers with our Emprove® Suite at:

EMDMillipore.com/emprovesuite

SAFC®

Pharma & Biopharma Raw Material Solutions