

3M™ Harvest RC

Single-stage chromatographic purification for recombinant protein therapeutic manufacturing



3M™ Harvest RC is a single-stage single-use chromatographic clarification solution. It is the next generation in harvest and clarification technology and is designed as an efficient option for harvesting and clarification of modern Chinese hamster ovary (CHO) derived cell cultures.

Clarification using 3M™ Harvest RC provides many benefits from process compression, high product recovery, consistent clarified fluid quality to process economics.

3M Harvest RC provides many benefits to improve process economics.

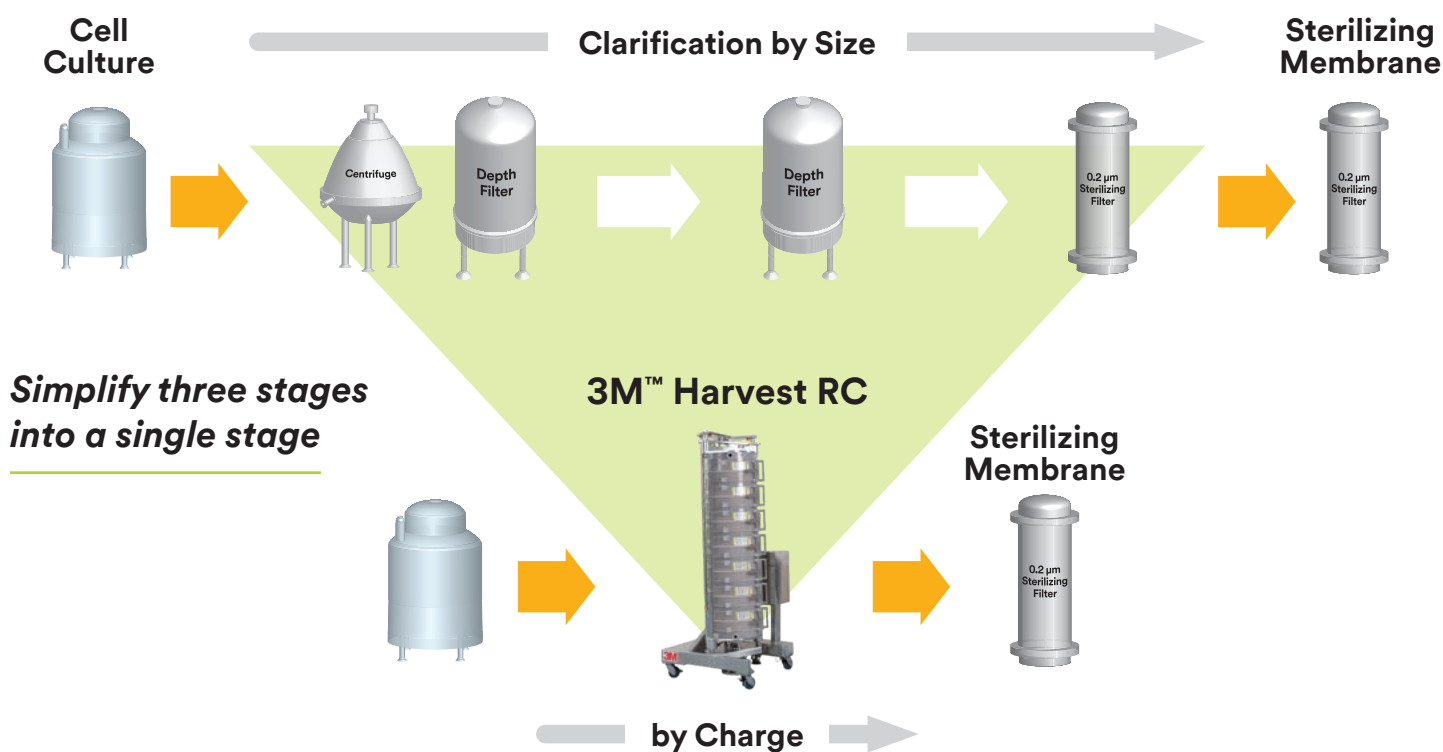
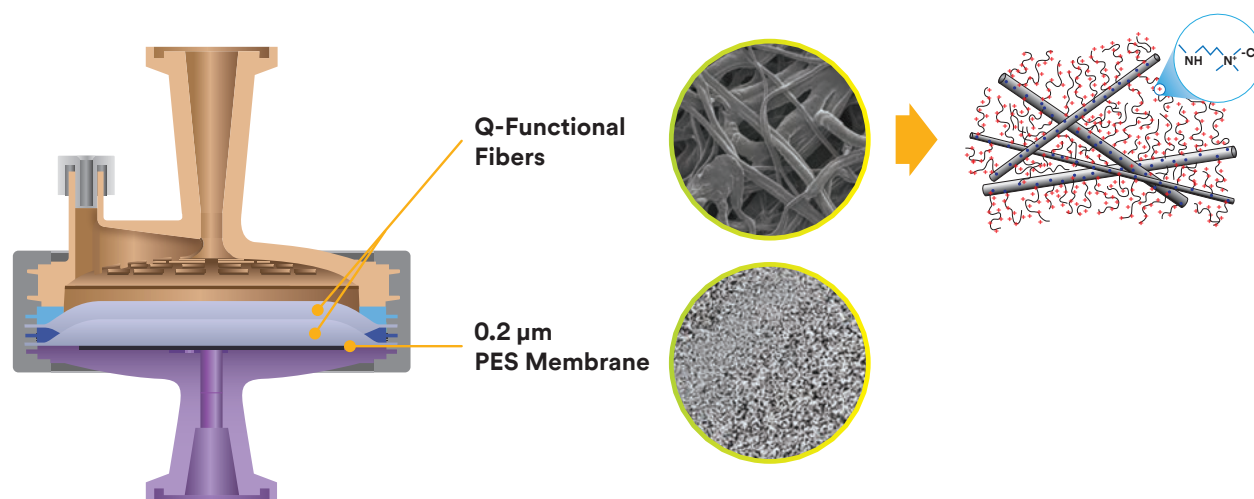
- ▶ Simplification of high cell density cell culture fluid clarification unit operations
- ▶ Optimized for PCV high density CHO cell culture (5-8% PCV)
- ▶ Replacement of primary, secondary, and guard membrane clarification stages
- ▶ Typical product recovery of 95+% (capsules)
- ▶ Synthetic chromatographic harvest media with chemically defined extractables
- ▶ Predictable scaling from discovery to manufacturing
- ▶ Lower total cost of manufacturing compared to centrifugation and depth filtration
- ▶ Lower consumption of buffer and water compared to depth filtration
- ▶ Capsules fit into laboratory to manufacturing scale workflows.

3M™ Harvest RC – Single step chromatographic clarification encapsulated solution

The innovative synthetic fibrous AEX chromatographic clarification media enables a single-stage clarification process of low to high-density CHO cell culture (> 40 million cells per mL) with high product recovery, and high fidelity of soluble and insoluble contaminant separation.

Downstream of the fibrous chromatographic clarification media is the 0.2 µm PES membrane which distributes the flow across the AEX media bed and enables protection of downstream sterilizing grade membrane filter. Also, 0.2 µm PES membrane enables simple process endpoint measurement using pressure reading.

Expanding fibrous media platform



Product Specifications



Product Name	BC4	BC25 Luer	BC25 Sanitary	BC340	BC1020	BC2300	BC16000
Model Name	EMP201HRC2FA	EMP301HRC2FA	EMP303HRC2FA	EMP513HRC2FA	EMP533HRC2FA	EMP710HRC2FA	EMP770HRC2FA
Global Part Number	70-0203-5331-7	70-0203-5332-5	70-0203-5333-3	70-0203-5335-8	70-0203-5336-6	70-0203-5337-4	70-0203-5339-0
Height x Diameter	5.9 cm x 4.3 cm (2.3 in x 1.7 cm)	5.3 cm x 7.7 cm (2.1 in x 3.0 in)	8.6 cm x 7.7 cm (3.4 in x 3.0 in)	10.4 cm x 24.1 cm (4.1 in x 9.5 in)	15.2 cm x 24.1 cm (6.0 in x 9.5 in)	5.7 cm x 45.2 cm (2.2 in x 17.8 in)	20.3 cm x 45.2 cm (8.0 in x 17.8 in)
Dry Weight	14.3 g	69.2 g	75.8 g	1.1 kg	1.6 kg	3.4 kg	9.8 kg
Media Surface Area	3.2 cm ²	25 cm ²	25 cm ²	340 cm ²	1020 cm ²	2300 cm ²	1.61 m ²
Cell Culture Volume Range (5-8% PCV) ¹	20 - 32 mL	150 - 250 mL	150 - 250 mL	2 - 3.4 L	6 - 10 L	14 - 23 L	100 - 160 L
Weight Wet Post Blow Down	17.2 g	81.2 g	88.1 g	1.2 kg	2.1 kg	4.4 kg	16.3 kg
Fill Volume ²	5.6 mL	27.6 mL	28.2 mL	0.66 L	1.7 L	3.3 L	16.3 L
Hold up Volume Post Blow Down ³	3.0 mL	12.0 mL	12.3 mL	0.16 L	0.47 L	1.1 L	6.5 L
Capsule Material	Polypropylene	Polypropylene, Glass Filled Polypropylene	Polypropylene, Glass Filled Polypropylene	Polysulfone, Polypropylene, Glass Filled Polypropylene, Thermoplastic Elastomer, Fluorocarbon	Polysulfone, Polypropylene, Glass Filled Polypropylene, Thermoplastic Elastomer, Fluorocarbon	Polycarbonate, Polypropylene, Glass Filled Polypropylene, Thermoplastic Elastomer, Silicone	Polycarbonate, Polypropylene, Glass Filled Polypropylene, Thermoplastic Elastomer, Silicone
Inlet / Outlet Connections	Luer-Lok	Luer-Lok	Sanitary	Sanitary	Sanitary	Sanitary	Sanitary
Maximum Inlet Pressure ⁴	3.4 bar	2.8 bar	2.8 bar	3.1 bar	3.1 bar	3.4 bar	3.4 bar
Maximum Differential Pressure	2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar
Maximum Temperature	40 °C (104 °F)	40 °C (104 °F)	40 °C (104 °F)	40 °C (104 °F)	40 °C (104 °F)	40 °C (104 °F)	40 °C (104 °F)
Required Preconditioning Flush Volume ⁵	8 mL	62.5 mL	62.5 mL	0.85 L	2.55 L	5.8 L	40.3 L
Recommended Use Flow Rate	0.53 mL/min	4.2 mL/min	4.2 mL/min	57 mL/min	170 mL/min	0.38 L/min	2.68 L/min
Storage Conditions	Controlled indoor temperatures: 0-30 °C (32-86 °F) in original sealed packaging						
Shelf Life	Up to 2 years from the date of manufacture @30 °C maximum storage temperature						



Product Name	WP6	CT15
Model Name	EMP006HRC2FA	EMP015HRC2FA
Global Part Number	70-0203-5328-3	70-0203-5328-1
Height x Diameter	12.8 cm x 8.5 cm x 8.8 cm (5.0 in x 3.4 in x 3.5 in)	2.9 cm x 6.1 cm (1.2 in x 2.4 in)
Dry Weight	Plate (w/ Media): 100 g Collector Plate: 110 g	10 g
Cell Culture Volume Range (5-8% PCV) ¹	15 mL per well	15 mL
Fill Volume ²	15 mL per well	15 mL
Capsule Material	Polycarbonate	Polycarbonate
Maximum Temperature	40 °C (104 °F)	40 °C (104 °F)
Maximum Relative Centrifugal Force	750 x g	750 x g
Recommended Relative Centrifugal Force	400 x g	400 x g
Recommended Spin time	10 minutes	10 minutes
Storage Conditions	Controlled indoor temperatures: 0-30 °C (32-86 °F) in original sealed packaging	
Shelf Life	Up to 2 years from the date of manufacture @30 °C maximum storage temperature	

Footnotes:

1. Cell Culture Volume Range is the estimation for CHO cell culture fluid at 5 - 8% packed cell volume
2. Fill Volume is defined as the volume of liquid that is required to fill the capsule.
3. Post Blow-Down Hold-Up Volume is defined as the volume of the residual liquid after air/gas blow down
4. Do not use this product for continuous service with compressed gasses. The use of compressed gas is permissible for post-use integrity testing and blow down purposes.
5. A Preconditioning Flush is required for the product to be compliant with USP Biological Reactivity Tests, including USP <87> and <88> Class VI. Refer to Installation and Operation Instructions for complete instructions on how to perform the preconditioning flush.



Well Plate



Conical Tube

For more information about 3M™ Harvest RC, please contact your local 3M sales representative by calling 1300 FILTER (345837), or visiting 3M.com.au/biopharmaceutical or 3M.co.nz/biopharmaceutical



3M™ Encapsulated Production System holder in use

Intended Use: 3M™ Harvest RC products are intended for use in biopharmaceutical processing applications of aqueous based pharmaceuticals (drugs) and vaccines in accordance with the product instructions and specifications, and cGMP requirements (for BC340, BC1020, BC2300 and BC16000) or GLP requirements (for CT15, WP6, BC4 and BC25), where applicable.

Since there are many factors that can affect a product's use, the customer and user remain responsible for determining whether the 3M product is suitable and appropriate for the user's specific application, including user conducting an appropriate risk assessment and evaluating the 3M product in user's application.

Product Selection and Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, customer is solely responsible for evaluating the product and determining whether it is appropriate and suitable for customer's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug safety, conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate, select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

Restrictions on Use:

For CT15, WP6, BC4 and BC25: For laboratory use only. Not intended for use with materials that will be used on humans or animals.

For all sizes: 3M advises against the use of these 3M products in any application other than the stated intended use(s), since other applications have not been evaluated by 3M and may result in an unsafe or unintended condition. Do not use in any manner whereby the 3M product, or any leachable from the 3M product, may become part of or remains in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDD), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA) or in applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring food contact compliance.

Limitation of Liability: Except for the limited remedy stated above, and except to the extent prohibited by law, 3M will not be liable for any loss or damage arising from or related to the 3M product, whether direct, indirect, special, incidental, or consequential (including, but not limited to, lost profits or business opportunity), regardless of the legal or equitable theory asserted, including, but not limited to, warranty, contract, negligence, or strict liability.

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