
Contents

Preface	v
Contributors	xi
1 Biopharmaceutical Proteins: <i>Opportunities and Challenges</i> John R. Birch and Yemi Onakunle	1
2 Expression of Antibody Fragments by Periplasmic Secretion in <i>Escherichia coli</i> Andrew G. Popplewell, Mukesh Sehdev, Mariangela Spitali, and A. Neil C. Weir	17
3 Secretory Production of Therapeutic Proteins in <i>Escherichia coli</i> Sang Yup Lee, Jong Hyun Choi, and Sang Jun Lee	31
4 Expression of Recombinant LTB Protein in <i>Marine Vibrio</i> VSP60 Wang Yili and Si Lusheng	43
5 Heterologous Gene Expression in Yeast Lee J. Byrne, Kenneth J. O'Callaghan, and Mick F. Tuite	51
6 Pharmaceutical Proteins from Methylotrophic Yeasts Eric C. de Bruin, Erwin H. Duitman, Arjo L. de Boer, Marten Veenhuis, Ineke G. A. Bos, and C. Erik Hack	65
7 Expression of Human Papillomavirus Type 16 L1 in Baculovirus Expression Systems: <i>A Case Study</i> Zheng Jin, Si Lusheng, and Wang Yili	77
8 Large-Scale Transient Expression of Therapeutic Proteins in Mammalian Cells Sabine Geisse, Martin Jordan, and Florian M. Wurm	87
9 Site-Specific Integration for High-Level Protein Production in Mammalian Cells Bhaskar Thyagarajan and Michele P. Calos	99
10 Production of Recombinant Therapeutic Proteins by Mammalian Cells in Suspension Culture Lily Chu, Ilse Blumentals, and Gargi Maheshwari	107
11 Transgene Control Engineering in Mammalian Cells Beat P. Kramer and Martin Fussenegger	123
12 Fusion to Albumin as a Means to Slow the Clearance of Small Therapeutic Proteins Using the <i>Pichia pastoris</i> Expression System: <i>A Case Study</i> William P. Sheffield, Teresa R. McCurdy, and Varsha Bhakta	145

13	High Throughput Recovery of Therapeutic Proteins from the Inclusion Bodies of <i>Escherichia coli</i> : An Overview Amulya K. Panda	155
14	Isolation, Solubilization, Refolding, and Chromatographic Purification of Recombinant Human Growth Hormone from Inclusion Bodies of <i>Escherichia coli</i> cells: A Case Study Surinder M. Singh, A. N. S. Eshwari, Lalit C. Garg, and Amulya K. Panda	163
15	Large-Scale Preparation of Factor VIIa from Human Plasma: A Case Study Teruhisa Nakashima and Kazuhiko Tomokiyo	177
16	Purification of Clinical-Grade Monoclonal Antibodies by Chromatographic Methods Alberto L. Horenstein, Ilaria Durelli, and Fabio Malavasi	191
17	Virus Elimination and Validation Nicola Boschetti and Anna Johnston	209
18	Virus Removal by Nanofiltration Marina Korneyeva and Scott Rosenthal	221
19	Determining Residual Host Cell Antigen Levels in Purified Recombinant Proteins by Slot Blot and Scanning Laser Densitometry Aaron P. Miles, Daming Zhu, and Allan Saul	233
20	Principles of Biopharmaceutical Protein Formulation: An Overview Scott P. Sellers and Yuh-Fun Maa	243
21	Solid-State Protein Formulation: <i>Methodologies, Stability, and Excipient Effects</i> Yuh-Fun Maa and Scott P. Sellers	265
22	Stabilization of Therapeutic Proteins by Chemical and Physical Methods Ken-ichi Izutsu	287
23	Extraction and Characterization of Vaccine Antigens from Water-In-Oil Adjuvant Formulations Aaron P. Miles and Allan Saul	293
24	Probing Reversible Self-Association of Therapeutic Proteins by Sedimentation Velocity in the Analytical Ultracentrifuge Bernardo Perez-Ramirez and John J. Steckert	301
25	Biological Characterization of Pegylated Interferons: A Case Study Lei Xie, Constance Cullen, Sheri Bradshaw, Marc DeLorenzo, and Michael J. Grace	319

26	Characterization of Interferon α 2B Pegylated Via Carboxyalkylation: A Case Study David C. Wylie, Marcio Voloch, Seju Lee, Yan-Hui Liu, Collette Cutler, Brittany Larkin, and Susan Cannon-Carlson	337
27	Quantifying Recombinant Proteins and Their Degradation Products Using SDS-PAGE and Scanning Laser Densitometry Aaron P. Miles and Allan Saul	349
28	Extraction and Denaturing Gel Electrophoretic Methodology for the Analysis of Yeast Proteins Kenneth J. O'Callaghan, Lee J. Byrne, and Mick F. Tuite	357
29	Characterization of Therapeutic Proteins by Membrane and In-Gel Tryptic Digestion C. Mark Smales, Rosalyn J. Marchant, and Michèle F. Underhill	375
30	Oligosaccharide Release and MALDI-TOF MS Analysis of N-Linked Carbohydrate Structures from Glycoproteins Rodney G. Keck, John B. Briggs, and Andrew J. S. Jones	381
31	Capillary Electrophoresis of Carbohydrates Derivatized with Fluorophoric Compounds Stacey Ma, Wendy Lau, Rodney G. Keck, John B. Briggs, Andrew J. S. Jones, Kathy Moorhouse, and Wassim Nashabeh	397
32	High-Throughput LC/MS Methodology for $\alpha(1\rightarrow3)$ Gal Determination of Recombinant Monoclonal Antibodies: A Case Study Lihua Huang and Charles E. Mitchell	411
33	Carbohydrate Structural Characterization of Fas Ligand Inhibitory Protein Lihua Huang, Charles E. Mitchell, Lei Yu, P. Clayton Gough, and Alice Riggin	421
34	Top-Down Characterization of Protein Pharmaceuticals by Liquid Chromatography/Mass Spectrometry: <i>Application to Recombinant Factor IX Comparability—A Case Study</i> Jason C. Rouse, Joseph E. McClellan, Himakshi K. Patel, Michael A. Jankowski, and Thomas J. Porter	435
35	Sample Preparation Procedures for High-Resolution Nuclear Magnetic Resonance Studies of Aqueous and Stabilized Solutions of Therapeutic Peptides Mark J. Howard	461
	Index	471



<http://www.springer.com/978-1-58829-390-9>

Therapeutic Proteins

Methods and Protocols

Smales, C.M.; James, D.C. (Eds.)

2005, XIV, 482 p., Hardcover

ISBN: 978-1-58829-390-9

A product of Humana Press