MICROBIAL QUALITY ASSURANCE IN PHARMACEUTICALS, COSMETICS AND TOILETRIES

Editors:

S. F. BLOOMFIELD, B.Pharm., Ph.D.
Chelsea Department of Pharmacy, King’s College London (KQC)

R. BAIRD, B.Pharm., Ph.D.
Pharmaceutical Microbiology Laboratory, St. Bartholomew’s Hospital, London

R. E. LEAK, B.Pharm., Ph.D.
Glaxo Group Research, Ware, and

R. LEECH, B.Sc.(Hons)
Unilever Research, Port Sunlight Laboratory, Merseyside

ELLIS HORWOOD LIMITED
Publishers • Chichester

Halsted Press: a division of
JOHN WILEY & SONS
New York • Chichester • Brisbane • Toronto
# Table of contents

1. **Control of microbial contamination in non-sterile pharmaceuticals, cosmetics and toiletries** ........................................ 9  
   S. F. Bloomfield, Chelsea Department of Pharmacy, King's College London, University of London, Manresa Road, London SW3 6LX

2. **Hazards associated with the microbial contamination of non-sterile pharmaceuticals, cosmetics and toiletries** ....................... 15  
   D. F. Spooner, formerly Boots Company Limited, Radcliffe-on-Trent, Nottinghamshire NG12 2GZ

3. **Microbiological control of raw materials** ........................................ 35  
   M. Russell, Roche Products Limited, Welwyn Garden City, Hertfordshire

4. **Control of microbial contamination during manufacture** ....................... 49  
   A. Clegg, Richardson-Vicks Europe, Research and Development Laboratories, Rusham Park, Whitehall Lane, Egham, Surrey TW20 9NW

5. **Microbiological contamination of manufactured products: official and unofficial limits** ........................................ 61  
   R. M. Baird, North East Thames Regional Health Authority, Pharmaceutical Microbiology Laboratory, St Bartholomew's Hospital, West Smithfield, London EC1

6. **Natural and physical preservative systems** ........................................ 77  
   R. Leech, Unilever Research, Quarry Road East, Bebington, Wirral, Merseyside L63 3JW

7. **The effect of container materials and multiple-phase formulation components on the activity of antimicrobial agents** ....................... 94  
   G. Dempsey, Chelsea Department of Pharmacy, King's College London, University of London, Manresa Road, London SW3 6LX
<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Pages</th>
<th>Authors/Institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Preservation of solid oral dosage forms</td>
<td>104</td>
<td>T. C. Blair, G. Buckton and S. F. Bloomfield, Chelsea Department of Pharmacy, King's College London, University of London, Manresa Road, London SW3 6LX</td>
</tr>
<tr>
<td>9</td>
<td>Preservative efficacy testing of non-sterile pharmaceuticals, cosmetics and toiletries and its limitations</td>
<td>119</td>
<td>A. L. Davison, Glaxo Pharmaceuticals Ltd, Greenford, Middlesex UB6 0HE</td>
</tr>
<tr>
<td>10</td>
<td>Challenge tests and their predictive ability</td>
<td>129</td>
<td>R. E. Leak, Glaxo Group Research, Ware, Hertfordshire SG12 0DJ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R. Leech, Unilever Research, Quarry Road East, Bebington, Wirral, Merseyside L63 3JW</td>
</tr>
<tr>
<td>11</td>
<td>Safety evaluation of preservatives</td>
<td>147</td>
<td>J. Hayden, BIOS (Consultancy and Contract Research) Ltd, Bagshot, Surrey</td>
</tr>
<tr>
<td>12</td>
<td>Development of preservative systems</td>
<td>156</td>
<td>S. P. Denver and R. O. King, Department of Pharmacy, University of Nottingham, University Park, Nottingham NG7 2RD</td>
</tr>
<tr>
<td>13</td>
<td>Microbial resistance to preservative systems</td>
<td>171</td>
<td>P. Gilbert, Department of Pharmacy, University of Manchester, Oxford Road, Manchester M13 9PL</td>
</tr>
<tr>
<td>14</td>
<td>New methodology for microbiological quality assurance</td>
<td>195</td>
<td>R. Leech, Unilever, Research, Quarry Road East, Bebington, Wirral, Merseyside L63 3JW</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Index</td>
</tr>
</tbody>
</table>