

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>7</b>
1.1	Background.....	7
1.2	Overview.....	10
1.3	Scope and Purpose .....	10
1.4	Benefits.....	11
1.5	Objectives .....	11
1.6	Key Concepts/Terms.....	11
<b>2</b>	<b>Pharmaceutical Water .....</b>	<b>13</b>
2.1	Introduction .....	13
2.2	Determining Sampling Locations .....	19
2.3	Developing Sampling Plans .....	24
2.4	Sample Valve Design.....	38
2.5	Sampling Techniques.....	40
2.6	Handling of Samples.....	44
2.7	Parametric (Real Time) Release.....	48
<b>3</b>	<b>Pharmaceutical Steam.....</b>	<b>51</b>
3.1	Introduction to Pharmaceutical Steam.....	51
3.2	Generation and Distribution of Pharmaceutical Steam.....	51
3.3	Sampling Locations.....	56
3.4	Sampling Plans (Frequency and Duration).....	63
3.5	Sample Valve Design.....	68
3.6	Pure Steam Sampling Techniques.....	68
3.7	Sample Handling.....	76
3.8	Other Factors Influencing Sampling Strategies .....	76
<b>4</b>	<b>Process Gases .....</b>	<b>81</b>
4.1	Introduction .....	81
4.2	Sampling Locations.....	83
4.3	Sampling Plan (Tests Performed, Frequency and Duration).....	88
4.4	Sample Valve Design.....	91
4.5	Gases Sampling Techniques for Compressed Air and Process.....	91
4.6	Sample Handling.....	94
4.7	System Monitoring .....	94
<b>5</b>	<b>Appendix 1 – Specification Summary for Various Non-Pharmacopeial Water Grades .....</b>	<b>95</b>
<b>6</b>	<b>Appendix 2 – Examples of Water System Sampling Point Locations .....</b>	<b>97</b>
<b>7</b>	<b>Appendix 3 – Factors Influencing Pure Steam Generator Performance .....</b>	<b>101</b>
7.1	Source Water .....	101
7.2	Steam Generator Mist Elimination Capability .....	102
7.3	Non-condensable Gas Removal Capability .....	103
7.4	Blow Down Adjustment .....	103
7.5	Potable Water Chloramine Use .....	103
7.6	Anti-scaling Steam Additives.....	103
7.7	Monitoring Locations and Frequency .....	104

<b>8 Appendix 4 – References .....</b>	<b>105</b>
<b>9 Appendix 5 – Glossary.....</b>	<b>107</b>
9.1    Acronyms and Abbreviations .....	107
9.2    Definitions .....	109