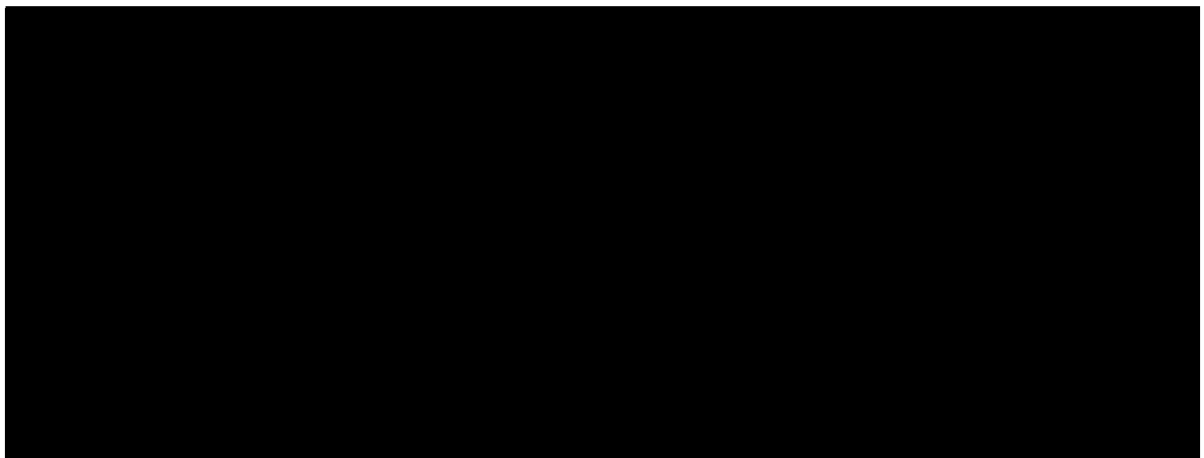


1. SPECIFICATIONS AND ROUTINE TESTS

1.1 Product Specifications and Tests for Release (at time of manufacture)

<u>PARAMETER</u>	<u>SPECIFICATIONS</u>	<u>TEST METHODS</u>
Description	A clear, colourless or almost colourless solution free from visible particulates.	Visual
Identification	[REDACTED]	[REDACTED]
Colour and Clarity of solution	[REDACTED]	[REDACTED]
Assay	[REDACTED]	[REDACTED]
Related Substances	[REDACTED]	[REDACTED]
pH	[REDACTED]	[REDACTED]
Removable Volume	Not less than nominal fill	B.P.
Sterility ⁽¹⁾	Complies with test	T.G.A.L.
Pyrogens ⁽¹⁾	Complies with test [REDACTED]	[REDACTED]



1. STABILITY TESTS ON THE ACTIVE INGREDIENT

Please refer to the information provided by the manufacturer of the active ingredient in Part IIC.

2. STABILITY TESTS ON THE FINISHED PRODUCT

**2.1 Quality Specification for the Proposed Shelf-Life
(Check Specification)**

<u>PARAMETER</u>	<u>SPECIFICATIONS</u>	<u>TEST METHODS</u>
Description	A clear, colourless or almost colourless solution free from visible particulates.	Visual
Identification	[REDACTED]	[REDACTED]
Colour and Clarity of solution	[REDACTED]	[REDACTED]
Assay	[REDACTED]	[REDACTED]
Related Substances	[REDACTED]	[REDACTED]
pH	[REDACTED]	[REDACTED]
Removable Volume	Not less than nominal fill	B.P.
Sterility ⁽¹⁾	Complies with test	T.G.A.L.
Pyrogens ⁽¹⁾	Complies with test [REDACTED]	[REDACTED]

[REDACTED]