**﻿﻿INTRODUCTION**

This report is to summarize the results and outcome of the Risk Assessment for the new Mundipharma Plant, a Greenfield site at Plot 4, 10 Tuas South Avenue 14, Tuas Industrial Estate, Singapore.  The new production facility shall be used for the manufacturing and filling of Betadine® antiseptic liquid products.

**﻿﻿PURPOSE**

The purpose of the Risk Assessment is to identify potential failures and causes of the failures, associated with the facility and process design in order to prevent or reduce the occurrence of these causes thereby mitigating the risk to the patient.  The outcome of the assessment shall summarize the risks that require design action or further analysis , if any and also determine the appropriate level of qualitication and testing (Test Matrix) required for the system, in order to remediate the risks identified.

**SCOPE**

The scope of the assessment is confined to Direct Impact Systems which has been identified through the System Level Impact Assessment per PES-SOP-002.

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**METHOD**

The Risk Assessment was performed using Figaro per PES-SOP-003, which utilize the process Failure Modes Effects and Criticality Analysis (PFMECA) methodology to identify the possible failure modes and ranks their overall impact based on their individual *Severity (1-10),* *Probability (1-10)* and *Detectibility (1-10)* .

**DEFINITION**

Refer to the Standard Operating Procedure (SOP) for Risk Assessment and Test Matrix, PES-SOP-003 for the definition of acronyms e.g. CPP, RPN and risk score or rating.

**CONCLUSION**

A Risk Assessment for the new Mundipharma Plant – Greenfield Project have been performed and the results are documented in Appendix 1 to this document.  Furthermore, the generated Test Matrix documented in Appendix 2 have been identified for testing and qualification to mitigate the risks identified in the assessment.