

11.0 Appendix 1

Company:	Drug Shortage Risk Register <i>(Template as part of TR-68 (Revised), ©2024 PDA, Inc.)</i>	Date:
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ID	Product and Strength	Potential Drug Shortage Hazard	Hazardous Situations	Countries/Regions that Could be Affected	Affected Internal Area	Initial Risk Level	Risk Indicators	Planned Risk Control Actions	Risk Level After Risk Control	Person(s) Responsible	Status	Due Date
<i>Unique reference number</i>	<i>Identify product and strength</i>	<i>Risk description in a newspaper headline style; reference as applicable</i>	<i>Root cause or risk assessment title</i>	<i>Identify countries/regions that could be affected</i>	<i>All sites/locations, affiliates, and functional areas affected by a shortage</i>	<i>Risk Level or indication of the risk as high or medium. Note: Based on a consideration of current shortage prevention controls and their likely effectiveness</i>	<i>Potential leading and lagging indicators for this drug shortage risk</i>	<i>Planned mitigation actions, (CAPA number, if applicable)</i>	<i>Risk Level after mitigation or whether residual risk is high or medium</i>	<i>Who is responsible for coordination of the mitigation action(s)</i>	<i>“Planned,” “In process,” “Delayed,” or “Completed”</i>	<i>Current deadline for completing recommended actions [dd.mm.yy]</i>