11.0 Appendix 1

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| --- | --- | --- |
| ***Company:*** | **Drug Shortage Risk Register**  *(Template as part of TR-68 (Revised), ©2024 PDA, Inc.)* | ***Date:*** |

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| **ID** | **Product and Strength** | **Potential Drug Shortage Hazard** | **Hazardous Situations** | **Countries/ Regions Could be Affected** | **Affected Internal Area** | **Initial Risk Level** | **Risk Indicators** | **Planned Risk Control Actions** | **Rick Level After Risk Control** | **Person(s) Responsible** | **Status** | **Date Due** |
| *Unique reference number* | *Identify product and strength* | *Risk description in a newspaper headline style; reference as applicable* | *Root cause or risk assessment title* | *Identify countries/ regions that could be affected* | *All sites/locations, affiliates, and functional areas affected by a shortage* | *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* | *Potential leading and lagging indicators for this drug shortage risk* | *Planned mitigation actions, (CAPA number, if applicable)* | *Risk Level after mitigation or whether residual risk is high or medium* | *Who is responsible for coordination of the mitigation action(s)* | *“Planned,” “In process,” “Delayed,” or “Completed”* | *Current deadline forcompleting*  *recommended actions [dd.mm.yy]* |
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