APPENDIX A3.2.1-11

PROCESS RISK ASSESSMENTS SUMMARY

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Table 1 is an executive summary of the main process-related risks having a potential impact on one or more Critical Quality Material Attribute(s) / Critical Quality Attribute(s). Those risks were identified during Process Development and Process Characterization and mitigated with the actions described in Table 1.

Table 1: Process Risk Assessment Executive Summary

Processing Step	Description of the Risk	Mitigation Plan in Place
(b) (4)		

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Processing Step	Description of the Risk	Mitigation Plan in Place
(b) (4)		

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Processing Step	Description of the Risk	Mitigation Plan in Place
(b) (4)		

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Processing Step	Description of the Risk	Mitigation Plan in Place
(b) (4)		

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Processing Step	Description of the Risk	Mitigation Plan in Place
(b) (4)		

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Approval

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