QbDVision

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Risk Tables Report

Risk Table: FQA Risk Table

Date: Aug 29, 2018

Effective RMP:
Default 5x5 RMP V1.0

FQA Risk Table

As of *Aug 29, 2018 at 11:59 pm GMT*

FQA	Criticality	Criticality Justification	Process Risk	RPN	Recommended Actions	Control Strategy	Control Methods	TPP Links
FQA-32 - Appearance NOT APPROVED	1 (1%)	Color, shape and appearance are not directly linked to safety and efficacy. Therefore, they are not critical.	10 (1%)	100 (1%)		None	**CM-78 - NA** NOT APPROVED	*None*
FQA-40 - Assay NOT APPROVED	100 (100%)	Process variables may affect the assay of the drug product.	1000 (100%)	10000 (100%)		IPT and Release	**CM-79 - Unknown** NOT APPROVED	**TPP-88 - Dosage Forms and Strengths** NOT APPROVED **TPP-91 - Adverse Reactions** NOT APPROVED **TPP-95 - Overdosage** NOT APPROVED **TPP-98 - Nonclinical Toxicology** NOT APPROVED
FQA-52 - Container Closure System NOT APPROVED	100 (100%)	Packaging options have not been identified	1000 (100%)	10000 (100%)	Suitable packaging options will be investigated during development process	None	**CM-78 - NA** NOT APPROVED	**TPP-101 - How Supplied/Storage and Handling** NOT APPROVED
FQA-45 - Content Uniformity NOT APPROVED	100 (100%)	Variability in content uniformity will affect safety and efficacy.	1000 (100%)	10000 (100%)	Both formulation and process variables impact content uniformity, so this CQA will be evaluated throughout product and process development.	Release Test Only	**CM-79 - Unknown** NOT APPROVED	**TPP-88 - Dosage Forms and Strengths** NOT APPROVED **TPP-95 - Overdosage** NOT APPROVED
FQA-42 - Degradation Products NOT APPROVED	100 (100%)	Formulation and process variables can impact degradation products.	1000 (100%)	10000 (100%)	Degradation products will be assessed during product and process development.	IPT and Release	**CM-79 - Unknown** NOT APPROVED	**TPP-91 - Adverse Reactions** NOT APPROVED **TPP-98 - Nonclinical Toxicology** NOT APPROVED **TPP-101 - How Supplied/Storage and Handling** NOT APPROVED
FQA-47 - Dissolution NOT APPROVED	100 (100%)	Both formulation and process variables affect the dissolution profile.	1000 (100%)	10000 (100%)	This CQA will be investigated throughout formulation and process development.	Release Test Only	**CM-79 - Unknown** NOT APPROVED	**TPP-97 - Clinical Pharmacology** NOT APPROVED
FQA-37 - Friability NOT APPROVED	25 (25%)	A target of NMT 1.0% w/w of mean weight loss assures a low impact on patient safety and efficacy and minimizes customer complaints.	250 (25%)	2500 (25%)		Release Test Only	**CM-79 - Unknown** NOT APPROVED	**TPP-97 - Clinical Pharmacology** NOT APPROVED
FQA-38 - Identification NOT APPROVED	100 (100%)	Identification is critical for safety and efficacy.	1000 (100%)	10000 (100%)		IPT and Release	**CM-79 - Unknown** NOT APPROVED	**TPP-88 - Dosage Forms and Strengths** NOT APPROVED **TPP-91 - Adverse Reactions** NOT APPROVED
FQA-50 - Microbial Limits NOT APPROVED	10 (10%)	Non-compliance with microbial limits will impact patient safety. However, in this case, the risk of microbial growth is very low because roller compaction (dry granulation) is utilized for this product. Therefore, this CQA will not be discussed in detail during formulation and process development.	100 (10%)	1000 (10%)	None	Release Test Only	**CM-79 - Unknown** NOT APPROVED	**TPP-98 - Nonclinical Toxicology** NOT APPROVED
FQA-33 - Odor NOT APPROVED	1 (1%)	In general, a noticeable odor is not directly linked to safety and efficacy, but odor can affect patient acceptability.	10 (1%)	100 (1%)		None	**CM-78 - NA** NOT APPROVED	*None*
FQA-49 - Residual Solvents NOT APPROVED	5 (5%)	Residual solvents can impact safety. However, no solvent is used in the drug product manufacturing process and the drug product complies with USP <467> Option 1. Therefore, formulation and process variables are unlikely to impact this CQA.	50 (5%)	500 (5%)	None	Release Test Only	**CM-79 - Unknown** NOT APPROVED	**TPP-91 - Adverse Reactions** NOT APPROVED **TPP-98 - Nonclinical Toxicology** NOT APPROVED
FQA-35 - Score Configuration NOT APPROVED	1 (1%)	Score configuration is not critical for the acetriptan tablet.	10 (1%)	100 (1%)		None	**CM-78 - NA** NOT APPROVED	*None*
FQA-34 - Size NOT APPROVED	1 (1%)	See Target Justification	10 (1%)	100 (1%)		None	**CM-78 - NA** NOT APPROVED	*None*

FQA	Criticality	Criticality Justification	Process Risk	RPN	Recommended Actions	Control Strategy	Control Methods	TPP Links
FQA-43 - Water Content NOT APPROVED	25 (25%)	However, in this case, acetriptan is not sensitive to hydrolysis and moisture will not impact stability.	250 (25%)	2500 (25%)	None	Release Test Only	**CM-79 - Unknown** NOT APPROVED	**TPP-88 - Dosage Forms and Strengths** NOT APPROVED