



LICENSING AND ENFORCEMENT DIVISION

PRODUCT DEFECT RISK ASSESSMENT FORM

RISK ASSESSMENT FORM USING FAILURE MODE AND EFFECT ANALYSIS

Generic name of product:

Dosage form:

Strength:

Registration Number:

Pack size:

Batch Number:

Date of manufacture:

Expiry date:

Manufacturer:

Nature of defect/problem:

Date defect noted:

Date of report:

Sample available:

Risk Situation/ Problem statement:

Risk assessment initiator/ Team leader:

Risk assessment team:

Key:

Table 1: Risk rating

	Risk rating				
	1	2	3	4	5
Detectability	Failure easy to see before it happens	Intermediates			Failure difficult to see before it happens
Occurrence	Failure not likely to occur				Failure highly likely to occur
Severity	When failure occur minimum harm to product quality				High adverse effect to product quality when failure occurs

Table 2: Risk Priority Number (RPN) interpretation

RPN	Risk level	Risk decision
1-26	Low	Accept
27-64	Medium to High	Mitigate to RPN<27 and Accept
>64	High	Reject

FMEA Tool

	Risk situation	Failure Mode	Detectability (D)	Occurrence (O)	Severity (S)	RPN	Risk rating justification	Risk rating
	Overall mean risk							

Recommendations:

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1st Evaluator: **Signature:** _____ **Date:** _____

2nd Evaluator: **Signature:** _____ **Date:** _____