Risk Management Report

1 Foreword

This report aims to describe the risk control measures taken for the medical antipyretic patches produced by our company. This report identifies all potential hazards and the potential causes of each hazard, evaluates the severity and likelihood of each hazard, takes necessary measures for unacceptable risks, and evaluates the remaining risk level after taking relevant measures.

By taking appropriate measures to reduce the acceptable level of potential hazards and control the total amount of various hazards at an acceptable level.

2 Propose

The purpose of risk control is to determine all risks that may be caused by the following factors: the company should also develop necessary measures to control the risk level within an acceptable range for medical antipyretic patches that have been put into production. Through risk control, the company can take relevant measures to continuously improve product quality and meet customer regulations or potential requirements.

3 Application

This risk analysis is applied to the production of medical antipyretic patches through the company.

4 Document reference

4.1 Standards

GB/T 191-2008 Packaging, Storage and Transportation Pictorial Symbols
GB/T 2828.1-2012 Sampling Procedures for Inspection by Attribute Part 1: Sampling Plans for Batch wise Inspection Retrieved by Acceptance Quality Limit (AQL)
GB/T 2829-2002 Sampling Procedures and Tables for Periodic Inspection by Attribute (Applicable to Testing Process Stability)
GB/T 9969-2008 General Principles of Industrial Product User Manual
GB/T 16886.1-2011 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in Risk Management Processes
GB/T 16886.5-2003 Biological Evaluation of Medical Devices Part 5: In vitro Cytotoxicity Test
GB/T 16886.10-2005 Biological Evaluation of Medical Devices Part 10: Stimulus and Delayed Type Hypersensitivity Test
YY/T 0313-1998 Packaging, Marking, Transportation, and Storage of Medical Polymer Products
YY/T 0466.1-2009 Medical devices - Symbols for medical device labeling, labeling, and providing information - Part 1: General requirements
Pharmacopoeia of the People's Republic of China (2020 edition)
Regulations on the Management of Medical Device Instructions and Labels by the State Food and Drug Administration
Measures for the Administration of Medical Device Registration

5 Risk control for the purpose

5.1 Intentional use

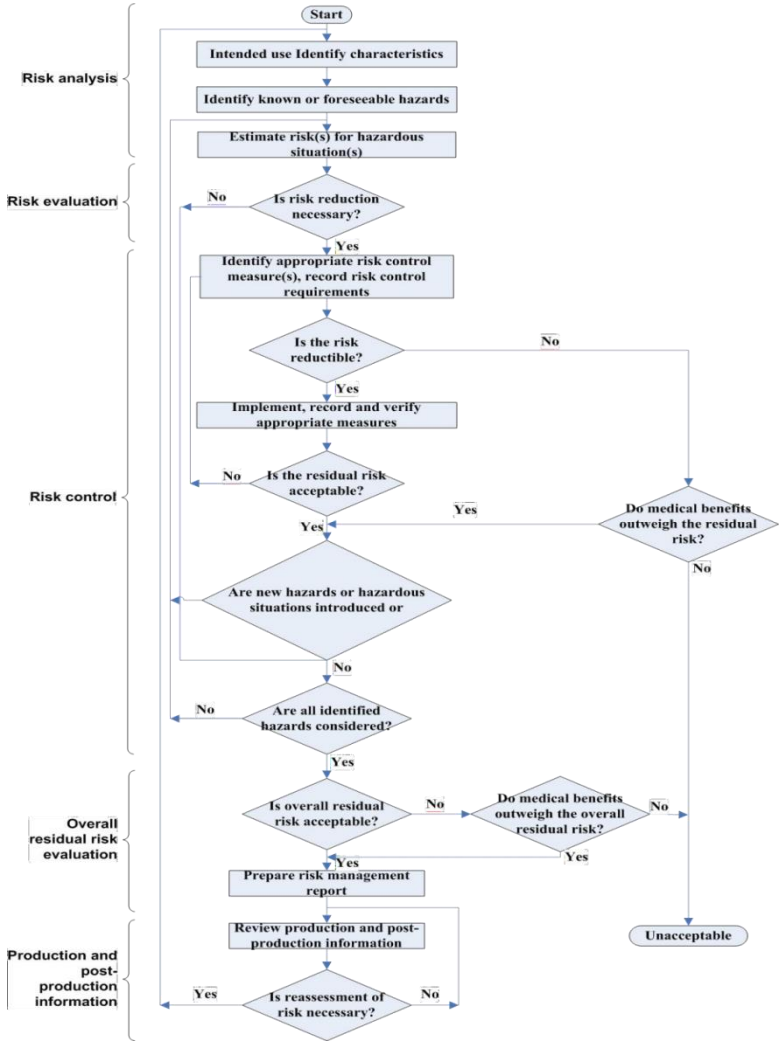
The medical antipyretic paste product consists of a backing layer, a gel layer and an anti sticking layer. The backing layer is non-woven fabric, the gel layer is made of polyacrylate sodium, glycerin and other auxiliary materials, and the anti sticking layer is polypropylene film. A large amount of purified water is loaded into the polymer gel through the polymer hydrogel with sodium polyacrylate as the base material, and the heat generated when the human body has a fever is taken away through the heat absorption of water evaporation, so as to achieve the effect of cooling and antipyretic, with a physical cooling effect. This product is used for physical antipyretic and cold compress therapy, only for intact skin on the body surface.

6 Risk control group of members

NO.	Contact Person	Position	Department	Responsibility and risk Management
1	HuangQing	Project Leader	Manager Dept.	The project leader Who is fully responsible for the risk management process.
2	RongCheng	Member	Technology Dept.	Deputy project leader, responsible for the implementation of the risk management process.Estimate operator errors from the application point of view.
3	ZhuoZhuoFeng	Member	Produce Dept.	Determine possible manufacturing defects from a technical point of view.The probability of hardware failure is estimated from a technical point of view. Identify and evaluate the risks during the contract review phase.
4	LiuQiaoPing	Member	QA Dept.	Determine possible problems from the point of view of equipment operation.

7 Risk management process

Overview of the steps in the risk management process see the following flowchart:



8 Risk management for execution

8.1 Step 1: Resolve to address known and foreseeable hazards

The hazard will be marked with "H……" in risk control form.

Information resources: the following information can be regarded as potential hazard list

- Available risk analysis report on homologous product
- Investigations on developer of the product
- Determinations made by medical experts
- Analysis medical devices report from foreign authorities
- Site documents, complains and accident records gained from homologous products which

8.1.1 Estimation on severity level of each hazard

The severity level of each hazard must be estimated and semi-quantitative judged (in the form of serious level) by the medical expert.

Severity level	Code	Description
Negligible	S1	Minor injury or no injury
Minor	S2	Moderate injury
Serious	S3	One person was killed or seriously injured
Critical	S4	Many were killed or seriously injured

8.1.2 Judgment of potential causes of each hazard

Members of the group shall at first find the potential causes directly based on their professional knowledge.

The founded hazard causes must be recorded in "Cause" column of risk control report, and mark with "C…".

8.1.3 Estimation on probability of occurrence of each cause

Occurrence probability of each potential cause must be estimated. In addition, the relative information resources are:

- Using experience of equivalent products (e.g. service statistic data)
- Customers complain
- Investigation on service life of self-product
- Expert judgment

Such estimation carried out by relative personnel can be divided into following 5 categories:

8.2 Step2: Risk estimation (before taking control measures)

Two risk factors were concluded in first hazard/cause item: hazard severity level and occurrence probability, relative risk. Three “risk area” can be defined according to advise of **EN ISO14971:2019**

1. Not acceptable area: U

2.Wide acceptable area: A

3.Reasonable and depressed (ALARP) risk: ALARP

Level	Code	Probability of occurrence (per year)
Improbable	P1	$<10^{-6}$
Remote	P2	10^{-4}~10^{-6}
Occasional	P3	10^{-2}~10^{-4}
Probable	P4	10^{-1}~10^{-2}
Sometimes	P5	1~10^{-1}
Frequent	P6	>1

8.3 Step3：Risk evaluation

Probability of occurrence		Severity level			
		4	3	2	1
		Critical	Serious	Minor	Negligible
Frequent	6	**U**	**U**	**U**	**R**
Sometimes	5	**U**	**U**	**R**	**R**
Probable	4	**U**	**R**	**R**	**R**
Occasional	3	**R**	**R**	**R**	**A**
Remote	2	**R**	**R**	**A**	**A**
Improbable	1	**A**	**A**	**A**	**A**

U: Unacceptable risk
A: Insignificant risk
R: Reasonable and depressed (ALARP) risk

All risks estimated for each hazard/cause must be recorded in column of risk control form in the form of risk range (U, ALARP, A) categories, and noted separately whether control measures are available.

8.4 Step4: Taking risk control measures

If no control measures are available for estimated risks, it is unacceptable, then control measures must be taken for each hazard cause. If several control measures were designed at the same time, then the effect will be the result when all relative control measures are taken.
All the measures must be recorded in the column “relative measures” of risk control form and marked with “M….”.

8.5 Step5: Evaluation on residual risks

The severity level or occurrence probability will be decreased, or both stated after taking control measures. Sometimes it cannot be quantificationally determined that in which level a group of relative control measures can decrease the risk factors (severity level or occurrence rate).
The evaluation on residual risks is the summing-up of analysis of the group members based on their individual professional knowledge.
All changing of each category must be recorded in the column “residual risk” of risk control form.
The residual risk of each hazard/cause may base on the determined risk area (N/AC AC R) stipulated in the previous chapter.

8.6 Step 6: Risk/benefit analysis

U does not mean that the aim has been reached, it can be acceptable only when it is technically unpractical, or the expense raised the further risk decrease measures is larger than the benefit it will bring, and the benefit is larger than the risk. If U range is the result of risk decreasing, then an explanation must be made on why the further risk decreasing is unpractical.

8.7 Step 7 Result of risk control

As showing in the risk control form, the residual risks of each hazard/cause shall be reduced to acceptable or R range, total amount of residual individual risk shall also be regarded as acceptable.

8.8 Step 8 Production and post-production information

Collect and review information about the production and post-production stages of medical fever strips.

9 Conclusion on risk control

As shown in the risk analysis report, through the above analysis, a more detailed risk analysis and assessment of the harm that may be caused by medical fever patch is carried out, and it is believed that all risks are within the control range and acceptable range, and after long-term clinical use verification, the probability of occurrence is extremely low, the safety of the medical device has been fully stipulated, comprehensive analysis of the above, We believe that all risks are manageable and acceptable. When new documents and data are used, a new round of risk analysis is required, for example, risks may change over time, production processes and product structures may also change accordingly, new risks may emerge, or new risks may be identified for the first time.