ANNUAL PRODUCT QUALITY REVIEW

Name of Product	Chloramphenicol capsules 250mg
Shelf Life	36 months
Batch Size	1,000,000 Capsules
Manufacturing Location	Private Economy Garden , Xinyan Town , Yanzhou City, Shandong, China
Protocol No.	SDXK/PQR/C001/22/01

TABLE OF CONTENT

1.0 Product Details:

(a) Product Name: DERM CHLORAMPHENICOL CAPSULE

(b) Generic Name: Chloramphenicol capsules 250mg

(c) Dosage Form: Capsule

(d) Therapeutic Activity: Bactericidal antibiotic.

(e) Pharmacopoeia Grade: BP2022

(f) Label claim: Each capsule contains: Chloramphenicol 250mg.

(g) Pack type: 10 capsules per blister, 10 blisters per box.

(h) Storage: Store in a dark and dry place below 30 ℃.Protect from light.

(i) Shelf life: 36 Months

2.0 Objective

This document is to demonstrate that the production of Chloramphenicol capsules 250mg has taken place satisfactorily according to documented procedures and they are of consistent quality as per the approved specifications.

This document also demonstrate the quality system parameters like deviation, changes, market complaints, out of specification, stability, recall for the product throughout the year.

This document evaluates the compliance to the critical process parameter and critical quality parameters which may have direct or indirect impact on safety, identity, strength, purity or quality of the medicinal product under evaluation.

This review report also provides any suggestions and recommendations to improve quality or to make the process robust so as to achieve consistent quality product. Identify product or process improvements. Identify any adverse trends and the need to take corrective and/or preventive action.

3.0 Scope

This procedure is intended to describe the minimum requirements of WHO regarding evaluation of the batches and the batch records on an annual basis in order to assure the quality standard requirements of the product. This procedure covers the approved marketed products manufactured for commercial distribution,Which are manufactured from Jan 2022 to Dec 2022.

4.0 Responsibility

The Senior Site Quality Manager of the Company Site or External Manufacturing Unit that releases the Active Pharmaceutical Ingredient or Drug Product is responsible for ensuring that an Annual Product Re

view and the report for the Annual Product Review are completed. Where semifinished product is proces sed in multiple Sites, all Sites must participate in the Annual Product Review process by supplying infor mation to the Site of release.
Individual departments, such as Industrial Technologies, API Engineering, Operations, Information Solut ions, Validation, Quality, Compliance, Pharmacovigilance and Regulatory Affairs are responsible for pro viding data and participating in the Annual Product Review process.
The report for the Annual Product Review must be approved by the Senior Site Quality Manager at the C ompany Site or External Manufacturing Unit and distributed to Senior Site Management.

5.0 Reference

5.1 SOP For Annual Product Quality Review

5.2 Good Manufacturing Practices issued By WHO.

6.0 Product Information:

(a) Product Name: DERM CHLORAMPHENICOL CAPSULE

(b) Generic Name: Chloramphenicol capsules 250mg

(c) Dosage Form: Capsules

(d) Pack type: 10 capsules per blister, 10 blisters per box.

(e) Number of batches manufactured: 10

(f) BOM of Raw Material

Sr. No.	Material Code	Ingredient	Grade	Function	Composition	Overage	Theoretical quantity for batch
1	YL-025	Chloramphenicol	BP	Active material	250mg	Nil	250kg
2	FL-17	Pregelatinised starch	BP	Filler	20mg	Nil	20kg
3	FL-01	Maize Starch	BP	Filler	25mg	Nil	25kg
4	FL-08	Magnesium stearate	BP	Lubricant	5mg	Nil	5kg
5	CS-06	Capsule shell	WHO	/	85mg	Nil	85kg
	Total				385mg		385kg

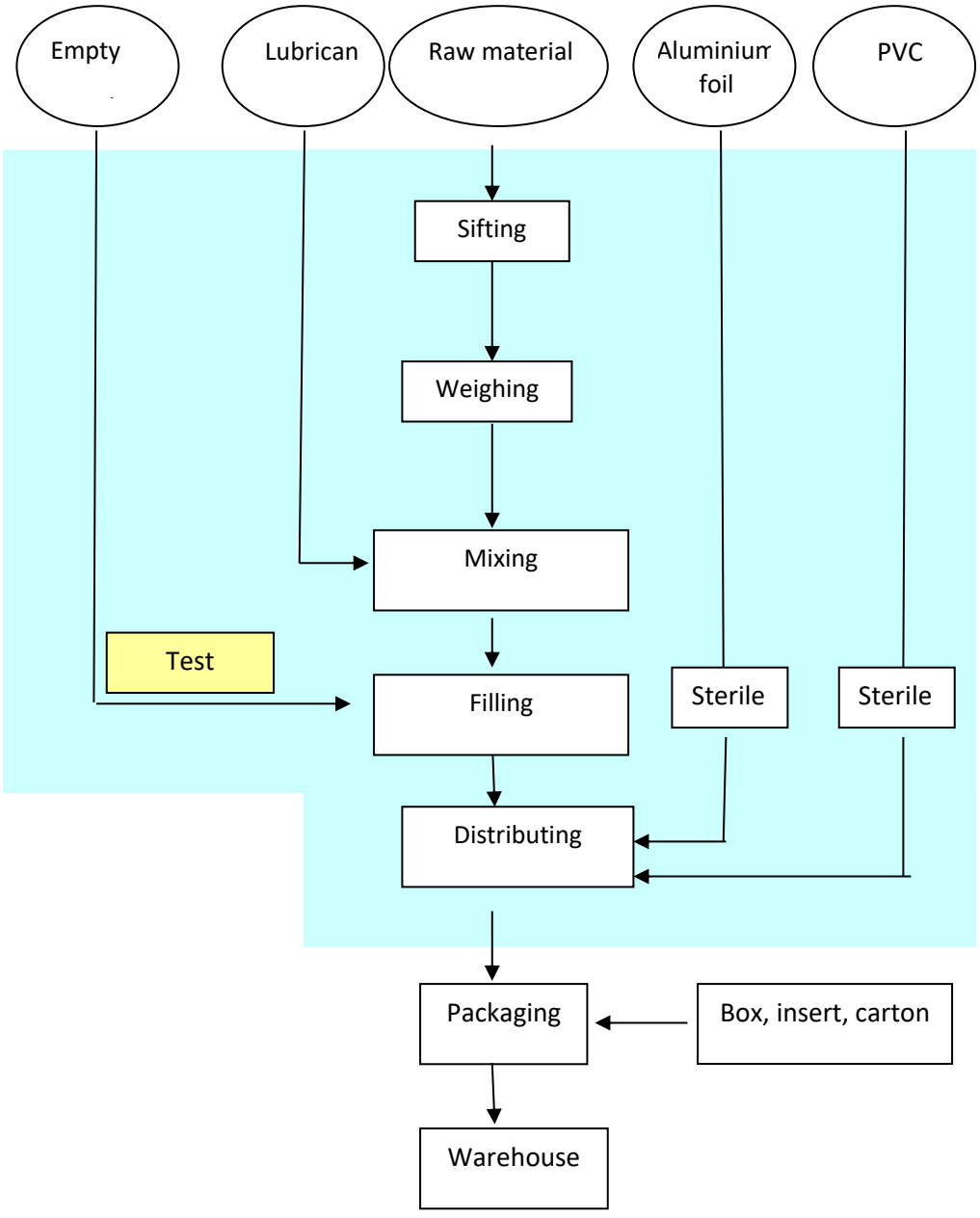
(g) BOM of Packing Material

PACK STYLE: 10 capsules per blister, 10 blisters per box**,** 100 boxes/ Carton

Sr. No.	**Item Code**	**Item**	**Item Descriptions**	**Standard Quantity**

				Quantity	UOM
1	BZ075-01	Alu printed foil	Pack style: 10’s/blister	180	kg
2	BZ075-02	Alu-PVC panel	Pack style: 10’s/blister	40	kg
5	BZ175-001	Leaflet	Printed	10000	PCS
6	BZ175-002	Box	Pack style:10X1Ampoules	10000	PCS
7	BZ175-003	Carton	Pack style:10Middle boxs	100	PCS

(K) Flow Chart



7.0 Review of starting materials and packaging materials.

All the raw material and packing material used for manufacturing are from approved vendors.

Raw Material Vender

Raw Material Name	Consignment Received	Number of Consignment Passed	Number of Consignment Rejected	Vendor review comment	Vendor Approved/ Not Approved
Chloramphenicol	02	02	00	Satisfactory	Approved
Pregelatinised starch	01	01	00	Satisfactory	Approved
Maize Starch	01	01	00	Satisfactory	Approved
Magnesium stearate	01	01	00	Satisfactory	Approved
Capsule shell	10	10	00	Satisfactory	Approved

All purchased batches are qualified and in good condition for production.Please refer to Attachment -1 Starting raw material data for the details.

Packing Material Vender

Packing Material Name	Consignment Received	Number of Consignment Passed	Number of Consignment Rejected	Vendor review comment	Vendor Approved/Not Approved
Alu printed foil	10	10	00	Satisfactory	Approved
PVC	01	01	00	Satisfactory	Approved
Leaflet	10	10	00	Satisfactory	Approved
Box	10	10	00	Satisfactory	Approved
Carton	10	10	00	Satisfactory	Approved

All purchased batches are qualified and in good condition for production. lease refer to Attachment -2 Packing material data for the details.

8.0 Review of OOS/changes/refuse

8.1 Review of all batches that failed to meet established specification(s) and their investigations (OOS).

No OOS Observed

8.2 Review of all significant deviations or non - conformance, their related investigations, and the effectiveness of corrective and preventive actions taken.

No deviation Observed

8.3 Review of all changes carried out.

No change control observed.

8.4 Review of marketing authorizations variations submitted/granted/refuse (where ever applicable).

Not applicable.

9.0 Review of Quality control

9.1 Review of the result of the stability monitoring programmer and any adverse trend.

Batch No. C00101 first batch of the year result found satisfactory.

9.2 Review of all quality (related returns, complaints and recalls).

Not Applicable.

9.3 Review of process validation status.

No Process Validation batches planned in year 2022.

9.4 Review of findings of internal audits and the corrective action implemented.

Satisfactory.

10.0 Review of the qualification status of relevant equipment and utilities

10.1 Purified Water System Qualification Review

Purified water system is Qualified. Purified water generation, storage and distribution system is capable of consistently producing the good quality of Purified water which meets the predefined BP/TP specification and suitable for intended use. Purified water trend was reviewed and found satisfactory.

10.2 HVAC SYSTEM

HVAC qualification for HVAC No. was performed by external agency as per predefined schedule.

10.3 Compressed Air System Review

As per the frequency,Compressed Air System is Qualified at all user points.

10.4 Equipment Qualification Review

All the equipment's used during the manufacturing of the product are qualified.

Equipment Name	Equipment I. D. No.	Qualification Status	Qualification Done On	Qualification Due On
Electronic balance	10-001	Qualified	Nov.01, 2020	Oct.31, 2023
Three dimensional motion mixer	10-002	Qualified	Nov.01, 2020	Oct.31, 2023
Auto-capsule filling machine	10-003	Qualified	Nov.01, 2020	Oct.31, 2023
Polishing machine	10-004	Qualified	Nov.01, 2020	Oct.31, 2023
PVC-Alu blister packing machine	10-005	Qualified	Nov.01, 2020	Oct.31, 2023
Packing machine	10-006	Qualified	Nov.01, 2020	Oct.31, 2023

11.0 Review of Environmental Monitoring

During manufacturing, packing and analysis of said product, Environmental Monitoring was found within Acceptance Criteria.

Batch No.	Area	Environmental condition					
		Temperature (18~26℃)		Relative Humidity (45%~65%)		Air Pressure difference (≥10Pa)	
		Min	Max	Min	Max	Min	Max
C00101	Sifting,Weighing	22.5	24.6	48	55	10.8	12.5
	Mixing,Filling	22.2	24.8	47	52	11.0	12.8
	Inner packing	21.8	23.9	49	53	10.6	12.9
C00102	Sifting,Weighing	22.3	25.1	50	54	10.5	12.7
	Mixing,Filling	21.9	24.9	48	53	10.8	13.0
	Inner packing	22.1	25.0	49	53	10.5	12.8
C00103	Sifting,Weighing	22.1	24.9	50	55	10.7	12.5
	Mixing,Filling	22.3	24.5	49	53	11.1	12.6
	Inner packing	22.5	25.2	49	54	10.5	12.6
C00104	Sifting,Weighing	22.2	24.7	48	55	10.6	12.8
	Mixing,Filling	21.8	24.6	47	53	11.0	12.9
	Inner packing	22.0	25.2	48	53	10.5	12.8
C00105	Sifting,Weighing	21.7	24.8	49	55	10.8	13.1
	Mixing,Filling	22.0	24.6	48	52	11.2	13.3
	Inner packing	22.4	25.4	49	53	10.4	12.7
C00106	Sifting,Weighing	22.5	24.6	50	54	10.5	12.6
	Mixing,Filling	22.2	24.8	47	52	11.0	12.9
	Inner packing	21.8	23.9	48	53	10.5	12.8
C00107	Sifting,Weighing	22.1	25.1	48	55	11.1	13.2
	Mixing,Filling	22.3	24.8	47	53	11.0	12.8
	Inner packing	22.6	25.3	49	54	10.5	12.9
C00108	Sifting,Weighing	21.8	24.5	50	55	10.6	12.7
	Mixing,Filling	22.1	24.6	48	52	11.0	12.7
	Inner packing	22.3	25.3	49	53	10.5	12.9
C00109	Sifting,Weighing	22.2	25.5	49	54	10.6	12.8
	Mixing,Filling	22.4	24.6	48	52	11.0	12.9
	Inner packing	21.8	25.0	49	53	10.7	12.7
C00110	Sifting,Weighing	22.2	24.7	48	54	10.8	12.6
	Mixing,Filling	22.0	24.8	47	53	11.2	12.9
	Inner packing	21.9	25.2	49	54	10.7	12.8

12.0 Review of critical in-process controls

Some critical process parameters during Filling have been reviewed for all the batches manufactured during the review period. All the parameters are tabulated here with specification.

Specification of in-process controls

Tests	Acceptance Criteria

Description	White or almost white powder
Assay	95.0%-105.0% of the stated amount.

Results of In Process Test
Please refer to Attachment -3 Intermediate Product Result for details

Evaluation
All the Analysis results of all the batches of in process product are reviewed and it is observed that all the batches were manufactured as per approved manufacturing process and results are complying with acceptance criteria.

13.0 Review of finished product results.
Finished testing results have been reviewed for the all batches manufactured during the review period. Some critical parameters of Finish product have been reviewed for all the batches, manufactured during the review period. All the parameters are tabulated here with specification.

Specification of finished product

Tests	**Acceptance Criteria**
Description	White or almost white powder
Uniformity of mass	Not more than 2 of the individual masses deviate from the average mass by 7.5% and none deviates by more than twice that percentage. (n=20)
Assay	95.0%-105.0% of the stated amount.
Material balance	98.0-101.0%

Results of Finished product Test
Please refer to Attachment -4 Finished product Result for details

Evaluation
All the Analysis results of all the batches of Finish products are reviewed and it is observed that the results are complying with approved specification.

14.0 A review of any contractual arrangements or technical agreement to ensure that they are up to date.
All technical agreements are within period.

15.0 Evaluation of process capability index:

Test	**Results**				
	Minimum & Maximum Value		**Avg. (Mean)**	**SD**	**$C_{pk.}$**
Assay Chloramphenicol capsules 250mg (95.0%–105.0%)	Minimum	99.4%	100.0%	0.45	3.68
	Maximum	100.8%			

16.0 Conclusion:

Manufacturing process of Chloramphenicol capsules 250mg is capable of consistency and reproducibly producing the product of predetermined specification and consistent quality attributes:
Ten batches were manufactured during the review period. API and package for Chloramphenicol capsules 250mg were reviewed and found satisfactory. No OOS or OOT was reported during review period. No market complaint was reported during review period. No product return or recall was initiated during review period. No batch was rejected or reworked during review period. All the equipment used during manufacturing are qualified as per schedule. All the in-process parameter at manufacturing stage were reviewed and found satisfactory and well within the trend.

17.0 LIST OF ATTACHMENT

Sr. No.	Subject
Attachment-1	Starting raw material
Attachment-2	Primary packing material
Attachment-3	Intermediate Product data.
Attachment-4	Statistical data of finish product results and yield in tabular form

PROTOCOL APPROVAL SHEET

Activity	Department	Name	Designation	Sign/Date
Prepared By	Quality Assurance	Zhang Zhenhua	QA Chemist	
Reviewed By	Quality Assurance	Liu Ran	QA Chemist	
Reviewed By	Quality Assurance	Mao Jinglian	QA Chemist	
Reviewed By	Quality Assurance	Mao Jinglian	QA Chemist	
Approved By	Quality Assurance	Zhang Zhiying	QA Manager	

Attachment-1 Starting raw material

Sr. No.	Batch No.	Name of Raw Material	Batch No. of Raw Material	Manufacture	Specification	Assay in %	Status	Remark
1.	C00101	Chloramphenicol	C08-W2110118	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.7%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
2.	C00102	Chloramphenicol	C08-W2110118	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.7%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
3.	C00103	Chloramphenic	C08-	Wuhan Wuyao	97.5% to 102.0% (dried	99.7%	Pass	Satisfactory

		ol	W2110118	Pharmaceutical Co., Ltd.	substance)			
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
4.	C00104	Chloramphenicol	C08-W2110118	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.7%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
5.	C00105	Chloramphenicol	C08-W2110118	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.7%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical	/	/	Pass	Satisfactory

				Excipients Co. Ltd.				
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
6.	C00106	Chloramphenicol	C08-W2203082	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.9%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
7.	C00107	Chloramphenicol	C08-W2203082	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.9%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng	/	/	Pass	Satisfactory

				Huayang Excipent Co., Ltd.				
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
8.	C00108	Chloramphenicol	C08-W2203082	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.9%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory
9.	C00109	Chloramphenicol	C08-W2203082	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.9%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%;	Complies	Pass	Satisfactory

				Excipients Co. Ltd	Sum of stearic acid and palmitic acid: minimum 90.0%.			
10.	C00110	Chloramphenicol	C08-W2203082	Wuhan Wuyao Pharmaceutical Co., Ltd.	97.5% to 102.0% (dried substance)	99.9%	Pass	Satisfactory
		Pregelatinised starch	21121205	Anhui Sunhere Pharmaceutical Excipients Co. Ltd.	/	/	Pass	Satisfactory
		Maize Starch	202108009	Shandong Liaocheng Huayang Excipent Co., Ltd.	/	/	Pass	Satisfactory
		Magnesium stearate	20210196	Anhui Sunhere Pharmaceutical Excipients Co. Ltd	Magnesium:4.0%~5.0% Stearic acid: minimum 40.0%; Sum of stearic acid and palmitic acid: minimum 90.0%.	Complies	Pass	Satisfactory

Prepared by: 刘然 Checked by: 张清翠 Verified by:

Attachment-2 Primary packing material

Sr. No.	Batch No.	Name or Packing Material	Specification	Manufacture	Status	Remark
01.	C00101	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
02.	C00102	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
03.	C00103	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
04.	C00104	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
05.	C00105	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
06.	C00106	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
07.	C00107	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory

		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
08.	C00108	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
09.	C00109	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory
10.	C00110	Alu printed foil	In-house	Wuxi Meijian Huaqiang plastic printing Co., Ltd.	Pass	Satisfactory
		PVC	In-house	Yixing Jiecheng medicine package material Co., Ltd.	Pass	Satisfactory
		Leaflet	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Box	In-house	Zhangqiu Renhe Printing Co., Ltd	Pass	Satisfactory
		Carton	In-house	Jining Ruijialin Industry and Trade Co., Ltd	Pass	Satisfactory

Prepared by: 刘然 Checked by: 张清翠 Verified by:

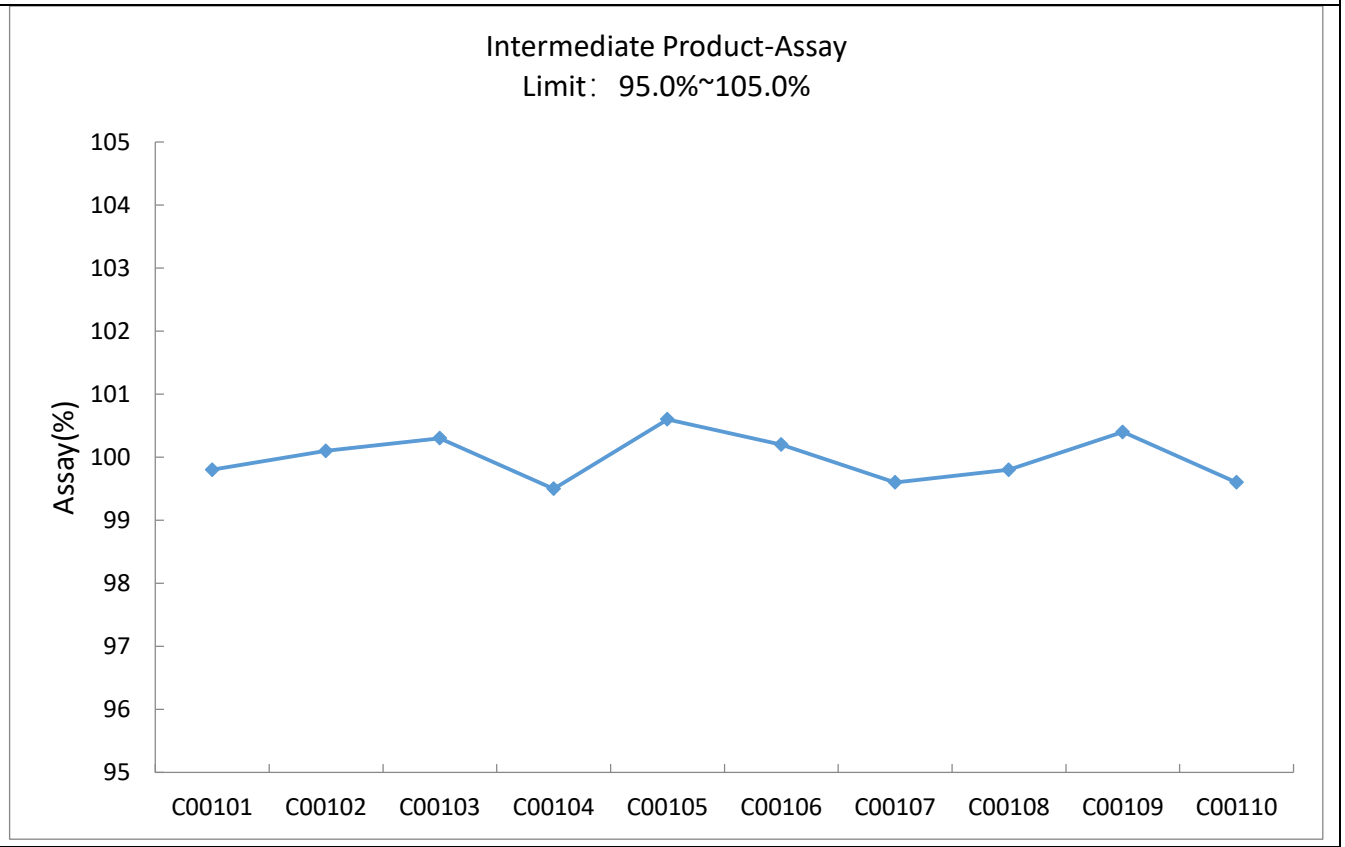
Attachment-3 Intermediate Product data

Intermediate Product Result(During Filling)		
Batch No.	Description	Assay Limit：95.0-105.0%
C00101	White or almost white powder	99.8%
C00102	White or almost white powder	100.1%
C00103	White or almost white powder	100.3%
C00104	White or almost white powder	99.5%
C00105	White or almost white powder	100.6%
C00106	White or almost white powder	100.2%
C00107	White or almost white powder	99.6%
C00108	White or almost white powder	99.8%
C00109	White or almost white powder	100.4%
C00110	White or almost white powder	99.6%
Average	/	100.0%
Min	/	99.5%
Max	/	100.6%
SD	/	0.38

Prepared by: 刘然 Checked by: 张清翠 Verified by:

Attachment-3 Intermediate Product data

Intermediate Product Result	
Batch No.	Assay Limit：95.0-105.0%
C00101	99.8%
C00102	100.1%
C00103	100.3%
C00104	99.5%
C00105	100.6%
C00106	100.2%
C00107	99.6%
C00108	99.8%
C00109	100.4%
C00110	99.6%
Average	100.0%
Min	99.5%
Max	100.6%
SD	0.38



Prepared by: 刘然 Checked by: 张清翠 Verified by:

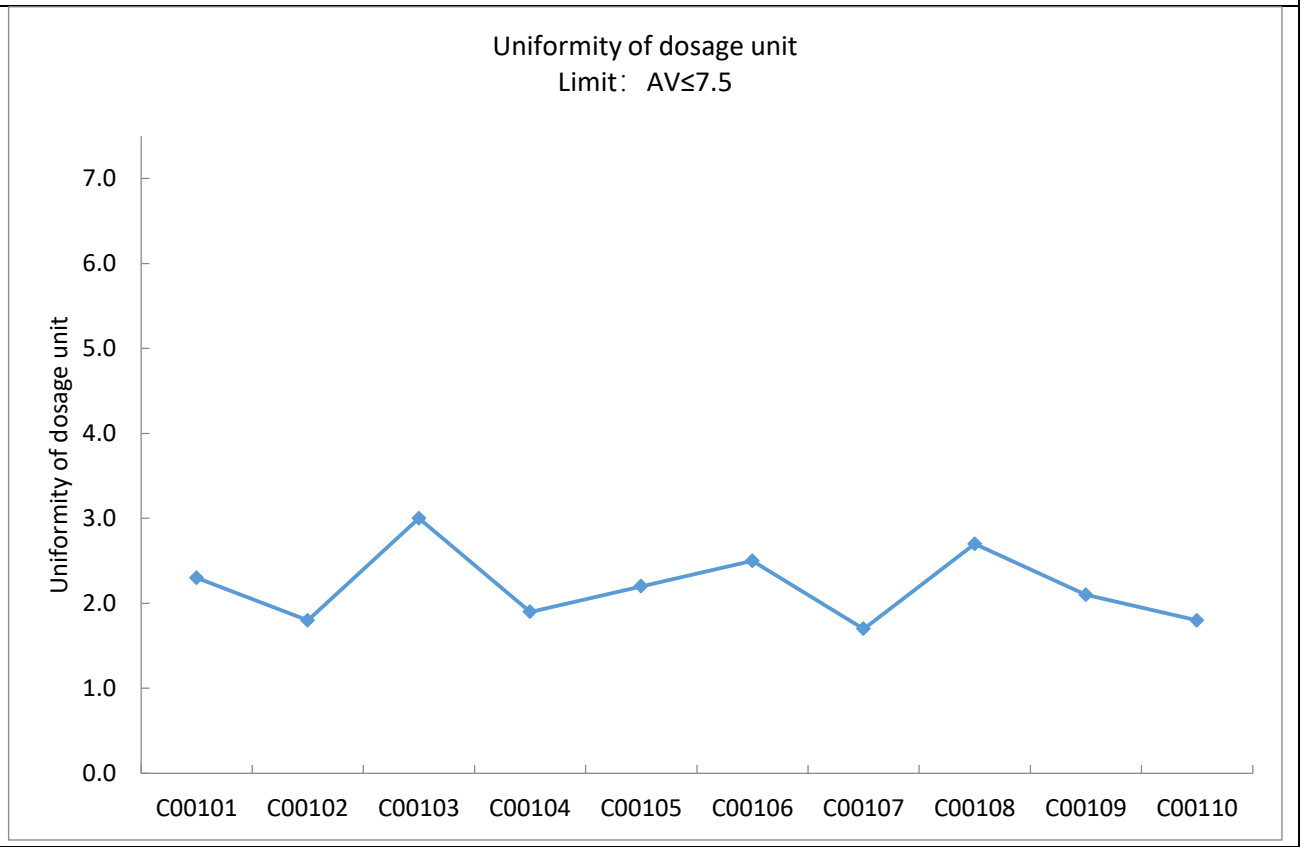
Attachment-4 Statistical data of finish product results and yield in tabular form

Batch No.	Appearance	Uniformity of dosage unit Limit：AV≤7.5	Assay Limit：95.0-105.0%	Material balance Limit：98.0-101.0%
C00101	White or almost white powder	2.3	99.7%	99.3%
C00102	White or almost white powder	1.8	100.4%	99.6%
C00103	White or almost white powder	3.0	100.2%	99.5%
C00104	White or almost white powder	1.9	99.6%	99.8%
C00105	White or almost white powder	2.2	100.0%	100.0%
C00106	White or almost white powder	2.5	99.4%	99.4%
C00107	White or almost white powder	1.7	100.8%	99.7%
C00108	White or almost white powder	2.7	100.3%	99.1%
C00109	White or almost white powder	2.1	99.5%	99.6%
C00110	White or almost white powder	1.8	99.8%	100.1%
Average	/	2.2	100.0%	99.6%
Min	/	1.7	99.4%	99.1%
Max	/	3.0	100.8%	100.1%
SD	/	0.43	0.45	0.31

Prepared by: 刘然 Checked by: 张晶晶 Verified by:

Attachment-4 Statistical data of finish product results and yield in tabular form

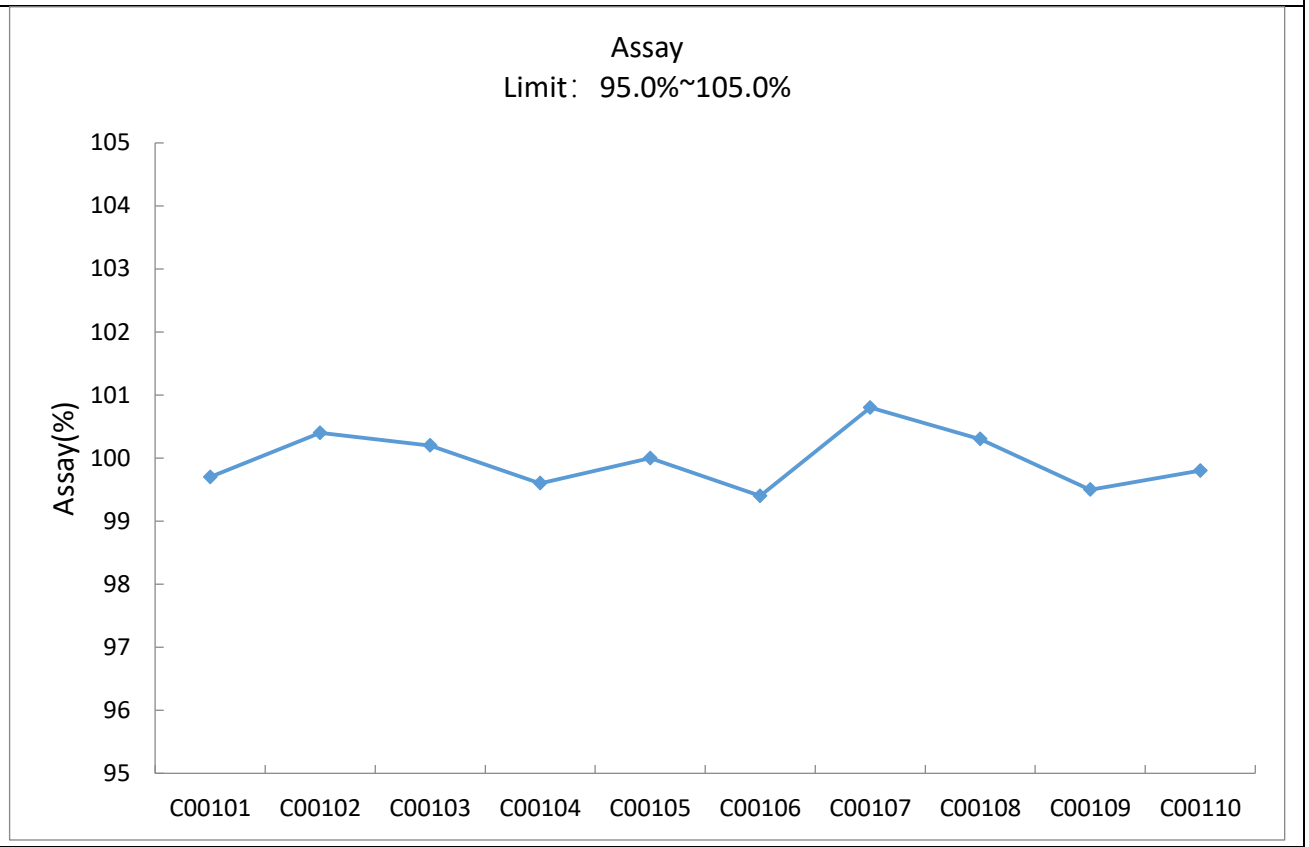
STATISTICAL FINISHED DATA RESULT	
Batch No.	Uniformity of dosage unit Limit：AV≤7.5
C00101	2.3
C00102	1.8
C00103	3.0
C00104	1.9
C00105	2.2
C00106	2.5
C00107	1.7
C00108	2.7
C00109	2.1
C00110	1.8
Average	2.2
Min	1.7
Max	3.0
SD	0.43



Prepared by: 刘然 Checked by: 张清翠 Verified by:

Attachment-4 Statistical data of finish product results and yield in tabular form

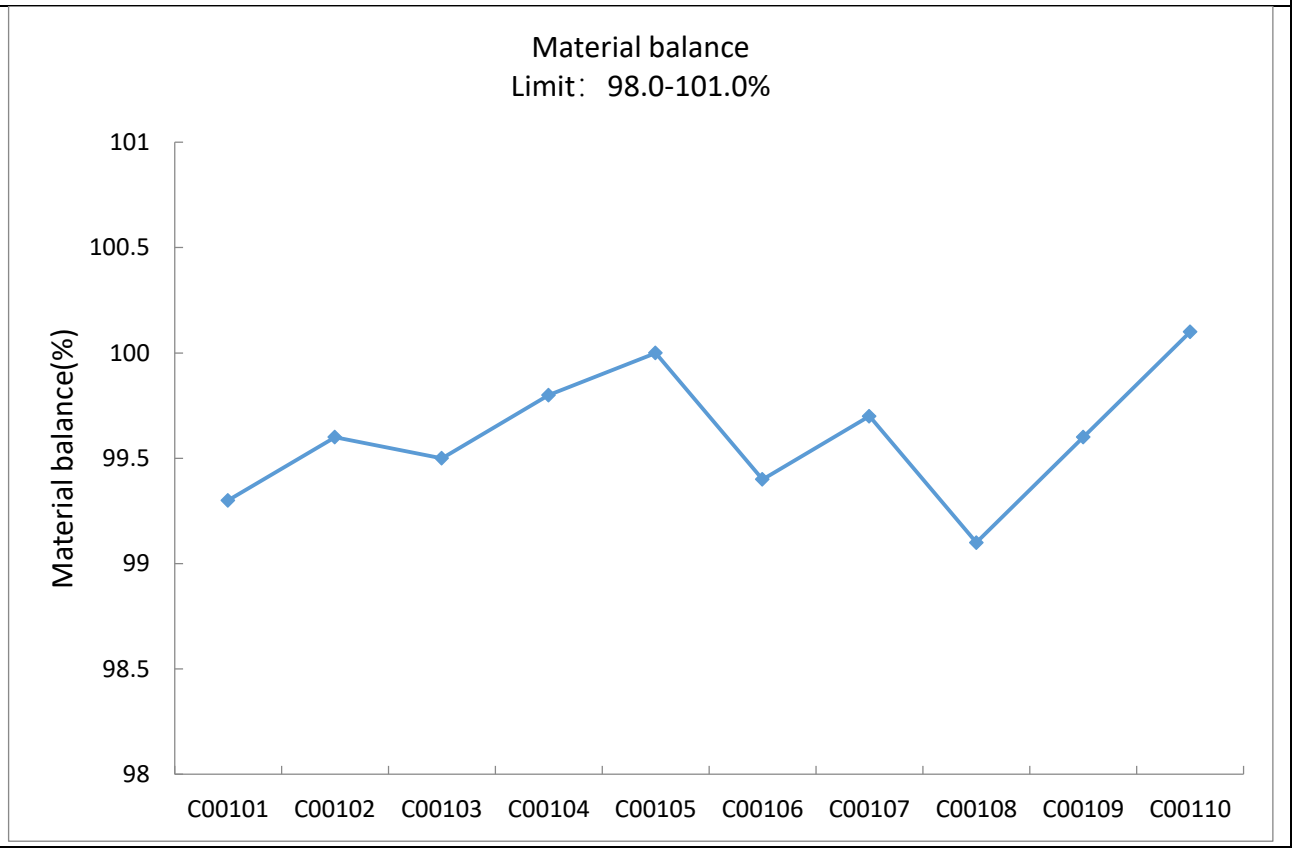
STATISTICAL FINISHED DATA RESULT	
Batch No.	Assay Limit: 95.0-105.0%
C00101	99.7%
C00102	100.4%
C00103	100.2%
C00104	99.6%
C00105	100.0%
C00106	99.4%
C00107	100.8%
C00108	100.3%
C00109	99.5%
C00110	99.8%
Average	100.0%
Min	99.4%
Max	100.8%
SD	0.45



Prepared by: 刘然 Checked by: 张清翠 Verified by:

Attachment-4 Statistical data of finish product results and yield in tabular form

STATISTICAL FINISHED DATA RESULT	
Batch No.	Material balance Limit：98.0-101.0%
C00101	99.3%
C00102	99.6%
C00103	99.5%
C00104	99.8%
C00105	100.0%
C00106	99.4%
C00107	99.7%
C00108	99.1%
C00109	99.6%
C00110	100.1%
Average	99.6%
Min	99.1%
Max	100.1%
SD	0.31



Prepared by: 刘然 Checked by: 张嘉琪 Verified by: