药品 GMP 符合性检查告知书

编号：冀药监化药符（2024）27 号

任务编号	2024 年 7 号	检查类型	常规检查
被检查单位名称	石家庄龙泽制药股份有限公司	药品生产许可证号	冀 20180034
检查地址	深泽县工业园区（西环路 16 号）		
检查范围及相关车间、生产线	片剂 （201 车间 片剂生产线） 硬胶囊剂（201 车间 硬胶囊剂生产线）		
检查依据	《药品生产质量管理规范（2010 年修订）》及其附录		
检查时间	2024 年 3 月 6 日-8 日		
结论	符合要求		
附件			
主送	石家庄龙泽制药股份有限公司		
抄送	石家庄迪康龙泽药业有限公司		

河北省药品监督管理局

2024 年 4 月 2 日

GMP Compliance Inspection Notification

No: Hebei Drug Administration Pharmaceutical Correspondence No. 27 (2024)

Task No.	2024 No.7	Inspection Type	Routine Inspection
Inspected Unit	Shijiazhuang Lonzeal Pharmaceutical Co., Ltd	Drug Production License No.	Ji20180034
Inspection Address	Industrial Zone, Shenze (No. 16 West Ring Road)		
Inspection Scope and Related Workshops and Production Lines	Tablet (Tablet production line in Workshop 201) Hard Capsules (Hard capsule production line in Workshop 201)		
Basis of Inspection	Good Manufacturing Practice for Drugs (Revised in 2010) and its annexes		
Inspection Date	March 6-8, 2024		
Conclusion	In compliance		
Attachments			
Primary Recipient	Shijiazhuang Lonzeal Pharmaceutical Co., Ltd		
Copies to	Shijiazhuang Dikang Longze Pharmaceutical Co., Ltd.		

Hebei Medical Products Administration

2 April, 2024

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 46 27
Fax direct: +41 22 791 47 30
E-mail: prequalinspection@who.int

In reply please refer to: P5-447-3/DC/JT/1

Your reference:

Mr Yaling Cao
Shijiazhuang Lonzeal
Pharmaceuticals Co Ltd
Workshop No. 201 No. 16 West Ring Road
Shenze
Shijiazhuang Hebei 52560
Chine (République populaire de)

6 June 2024

Dear Mr Cao,

WHO Prequalification Unit (PQT) Inspection Services Team
Closing of Inspection: Shijiazhuang Lonzeal Pharmaceuticals Co Ltd (Shenze)-FPP

I refer to the inspection that was performed by the World Health Organization (WHO) Prequalification Unit (PQT) Inspection Services Team (INS) and specifically Dr D. Catsoulacos and Dr M. Kladi the details of which are outlined below:

Name: Shijiazhuang Lonzeal Pharmaceuticals Co Ltd (Shenze)-FPP
Address: Workshop No. 201 No. 16 West Ring Road, Shenze Shijiazhuang, Hebei, 52560, China
Date: 12-13 and 16-17 October 2023

Thank you for your emails dated 2 January, 17 February, 22 March, and 17 April 2024 and the corrective actions to the deficiencies listed in the inspection report. The inspectors have reviewed the actions taken, or proposed to be taken, to correct the deficiencies.

In general, they are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, the Prequalification Inspection Group has recommended that the site can be considered to be compliant with the standards of Good Manufacturing Practices (GMP) published by the World Health Organization (WHO) for the scope activities listed below:

- Manufacture of tablets

The inspection findings and your response allow us to recommend to the Prequalification Assessment Group that the site inspected may continue to be named as a manufacturing site in the dossier for the following product:

PQT Number	*Product*	*Strength*	*Dosage Form*	*Applicant*
HP030	Tenofovir disoproxil fumarate	300mg	Tablet, Film-coated	Shijiazhuang Lonzeal Pharmaceuticals Co Ltd

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

Mr Vimal Sachdeva
Acting Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division