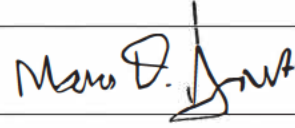
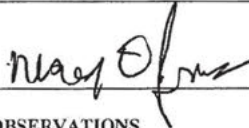


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER United States Food and Drug Administration 12420 Parklawn Dr., Room 2037, Rockville, MD 20857 CDERPAIprogram@fda.hhs.gov		DATE(S) OF INSPECTION 08/18/2025-08/22/2025
Industry Information: www.fda.gov/oc/industry		FEI NUMBER 3008250362
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ms. Sun Yanyan – General Manager		
FIRM NAME Qilu Pharmaceutical (Hainan) Co., Ltd.	STREET ADDRESS No. 273-A Nanhai Avenue, National High-Tech Zone	
CITY, STATE, ZIP CODE, COUNTRY Haikou, Hainan 570314, China	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above. <i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>		
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: Observation #1 Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of drug products. Specifically, a review of master batch records and validation batch records for (b) (4) (b) (4) Capsules strengths (b) (4) mg noted the following: 1) During the numerous (b) (4) processes of (b) (4) performed in the (b) (4) samples are not taken to determine the (b) (4) of the (b) (4) contained on the (b) (4). Only the amount (b) (4) at different time periods was documented. (b) (4) (b) (4) are applied to (b) (4) and the actual amounts contained on the (b) (4) was not determined. 2) Numerous critical processing steps that require (b) (4) only documents the (b) (4) of the (b) (4) obtained from the (b) (4). The (b) (4) of the material that is larger or smaller in size is not measured and no specifications or limits for these materials have been established.		
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3) The quantity of (b) (4) that are used for the (b) (4) steps that are performed in a (b) (4) always varies from each batch with no specifications or limits declared for (b) (4) 4) Time limits have not been established at numerous critical processing steps. For examples, time limits have not been established for (b) (4) times and (b) (4) times. 5) Production operators have to perform numerous complex mathematical calculations using formulas in batch records to determine beginning quantities of materials for critical processing steps.		
Observation #2 Equipment used in the manufacturing of drug products is not of adequate size. Specifically, a review of validation manufacturing batch records for (b) (4) Capsules strengths (b) (4) mg noted numerous (b) (4) are performed during production for these products. These (b) (4) (b) (4) are performed on the (b) (4) Equipment ID # (b) (4) used for the (b) (4) and (b) (4) Equipment ID # (b) (4) used for (b) (4) These two pieces of equipment do not have the capacity to process these (b) (4) in a single operation. Multiple (b) (4) are performed to obtain the desire quantity of (b) (4) and these additional steps increase the likelihood of operational errors and product quality variations.		
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Observation #3 The use of laboratory instruments not meeting established specifications was observed. Specifically, on 8/20/2025, I inspected the firm's QC laboratories located in Building (b) (4) and I observed three Dissolution Tester instruments that had asymmetrical basket apparatus rotation. 1) Instrument ID #PDT2709A/PDT5103B which was used to perform dissolution testing on (b) (4) Capsules was observed to have 2 basket apparatus units out of (b) (4) that had asymmetrical basket apparatus rotation. The last in-house verification for this instrument was on 3/17/2025. 2) Instrument ID #PDT2709B/PDT5103A which was used to perform dissolution testing on (b) (4) Capsules was observed to have 4 basket apparatus units out of (b) (4) that had asymmetrical basket apparatus rotation. The last verification/calibration for this instrument was on 3/19/2025. 3) Instrument ID #PD5103A which was used to perform dissolution testing on (b) (4) Capsules was observed to have 2 basket apparatus units out of (b) (4) that had asymmetrical basket apparatus rotation. The last verification/calibration for this instrument was on 7/16/2025.		
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