

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		<small>DATE(S) OF INSPECTION</small> 3/10/2025-3/14/2025 <small>FEI NUMBER</small> 3015169752	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Jheng Fong Jhong, Vice President			
<small>FIRM NAME</small> PURIBLOOD MEDICAL CO., LTD		<small>STREET ADDRESS</small> 2F, No. 11, Gongye E. 9th Rd.	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Baoshan Township, Hsinchu County, 30075 Taiwan		<small>TYPE ESTABLISHMENT INSPECTED</small> Manufacturer & Specification Developer	
<p>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.</p> <p><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></p>			
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>Procedures for corrective and preventive action have not been adequately established.</p> <p>Specifically, your firm's procedures to collect and analyze information, identify and investigate existing and potential causes of nonconforming product, or other quality problems have not been adequately established. For example,</p> <p>a. Corrective and Preventive Action Control Procedure, Doc. No. (b) (4)-2-(b) (4) 19, Ver. (b) (4), Effective: 2024.08.12, specifies during Cause Analysis that the responsible department shall investigate and analyze the cause of a deficiency or potential deficiency to identify the real cause leading to the deficiency or nonconformance. However, the procedure does not specify nor document the methods used to determine root cause(s). Also, when a root cause is documented, the corrective and preventive actions may not be commensurate with the root cause determination. As such, the implemented corrective and/or preventive actions to determine CAPA verification of effectiveness does not consistently address the root cause determination to assess whether nonconforming product or other quality problems have been resolved. The procedure also does not specify the use and documentation of risk analysis.</p>			
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<small>Creighton T Tuzon Investigator Signed By: Creighton Tuzon -G Date Signed: 03-14-2025 15:17:49</small>			

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<p>For instance, during review of CAPAs CR240702 and CR240703, which were initiated from Customer Complaints of blood leakage at the (b) (4), the root cause analysis documented contributions from personnel, (b) (4), and (b) (4) and (b) (4) of parts ((b) (4)). The corrective or preventive actions taken include added (b) (4), (b) (4), and (b) (4) and (b) (4) method for (b) (4) that specify a (b) (4). CAPAs CR240702 and CR240703 were determined to be effective based on the (b) (4) follow-up, which documents that the (b) (4) and (b) (4) method for (b) (4) using (b) (4) for storage will be implemented during the (b) (4) of the next batch of (b) (4). There was no documentation of the (b) (4) of the next batch or batches of (b) (4). Additionally, as of 2024.11.29, the (b) (4) documented that the (b) (4) used in the assembly of finished products have not yet adopted the updated (b) (4) method. Although (b) (4) and final product visual inspection was performed, and no defective products were found, there was no specification of the number of (b) (4) of (b) (4) assemblies and the inspection criteria of (b) (4) assemblies that would be evaluated within an adequate timeframe based on (b) (4). Verification of effectiveness (Follow-up) further documents that follow-up monitoring will continue.</p> <p>b. Complaint Handling Procedure, Doc. No. (b) (4)-2-(b) (4), Ver. (b) (4), Effective: 2024.10.30, fails to define a complaint, establish that complaints are evaluated by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner, and that complaints are evaluated to determine whether the complaint represents an event which is required to be reported. For instance, your firm uses Medical Device Reporting and Recall in the United States Guidance, Doc. No. (b) (4)-3-(b) (4), Ver. (b) (4), Effective: 2024.11.06. The procedure however fails to establish whether a device malfunction that is likely to cause or contribute to a death or serious injury as an MDR reportable event.</p> <p>During review of Complaint Files and CAPA Reports from 2022-2024, your firm documented 11 complaint records of which ten (10) complaint records were investigated for root cause determination per your firm's CAPA procedure. During review of complaint files CF240702 and CF240703, CAPAs and associated CAPA investigation reports CR240702 and CR240703 for blood leakage, however, the</p>							
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<p>complaint files and CAPA reports fail to establish the possible failure of a device, labeling, or packaging to meet any of its specifications and whether the device was being used for treatment or diagnosis.</p>					
<p>OBSERVATION 2</p> <p>Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.</p> <p>Specifically, your firm's (b) (4) Procedure, Doc. No. (b) (4) -2-(b) (4), Rev. (b) (4), Effective: 2024.11.5, specifies (b) (4) of classification. (b) (4) are directly related to the (b) (4) (b) (4) and (b) (4) (b) (4) as well as (b) (4). Per procedure, the Quality Management requirements for a (b) (4) is a (b) (4). However, the procedure also specifies that the firm conduct an (b) (4). The (b) (4) however is not specified as a Quality Management requirement although it is used to (b) (4). There are no specifications for when a (b) (4) based on the (b) (4). Furthermore, your firm specified that raw materials are evaluated based on (b) (4); however, there is no documentation of (b) (4) for raw materials of (b) (4). Your firm documented (b) (4).</p> <p>During review of (b) (4) between the (b) (4) and its (b) (4) that provides (b) (4), (b) (4), (b) (4), and (b) (4), there was no specifications as to the type and extent of control over the products, services, (b) (4), and (b) (4) defined.</p>					
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<p>Annotations to Observations</p> <p>Observation 1: Promised to correct</p> <p>Observation 2: Promised to correct</p>			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."