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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0576-2024

Replacing YY/T 0576-2005

Columbia blood agar medium

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document replaces YY/T 0576-2005 Columbia Blood Agar Medium. Compared with YY/T 0576-2005, except for the structural adjustment In addition to editorial changes, the main technical changes are as follows:

--- Changed the scope of the standard (see Chapter 1, Chapter 1 of the.2005 edition);

--- Changed the "culture medium" in the terms and definitions (see Chapter 3, Chapter 3 of the.2005 edition);

4.2 Preparation Method" (see Chapter 4);

---Changed "loss on drying" to "water content", added appearance, thickness, pH, microbial limit and growth in "plate culture medium" The performance index requirements of the test have been expanded to include the "stability" performance index requirements (see Chapter 5, Chapter 5 of the.2005 edition);

--- The test method has been changed (see Chapter 6, Chapter 6 of the.2005 edition);

--- Deleted "Instructions for Use" (see Chapter 7 of the.2005 edition);

--- Changed the signs and labels (see Chapter 7, Chapter 8 of the.2005 edition);

--- Changed packaging, transportation and storage (see Chapter 8, Chapter 9 of the.2005 edition);

--- Columbia blood agar growth test (see Appendix A, Appendix A of the.2005 edition) has been changed. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Clinical Testing Laboratories and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: China Food and Drug Inspection Institute,

Henan Provincial Drug and Medical Device Inspection Institute (Henan Provincial Vaccine Approval Center), Shanghai Institute of Medical Device Inspection, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Zhengzhou Antu Bioengineering Co., Ltd., Zhengzhou Bo Sai Biotechnology Co., Ltd., Zhongxiu Technology Co., Ltd., Qingdao High-tech Industrial Park Haibo Biotechnology Co., Ltd., Beijing San Pharmaceutical Technology Co., Ltd. The main drafters of this document are. Yu Ting, Li Fengchun, Deng Min, Yi Qiaolian, Yang Yongkang, Ding Kunfeng, Tan Weili, Cai Xiangrong, Wang Jinheng, Bao Xueyin, Zhang Caiyu, Qu Shoufang, Sun Nan, Hu Zebin, Jia Zheng, Zhang Juanli, Li Guilin, and Zhang Xiaoguo. The previous versions of this document and the documents it replaces are as follows:

---First published in.2005 as YY/T 0576-2005;

---This is the first revision. Columbia blood agar

1 Scope

YY/T 0576 is the product standard for Columbia blood agar, one of the workhorse culture media of the clinical microbiology laboratory. It specifies the main components and the preparation method, the requirements, the labels and instructions for use, and the packaging, transport and storage, together with the corresponding test methods. A culture medium is regulated in China as an in vitro diagnostic product, and its performance is judged on what grows: the growth rate of target organisms, the selectivity against others, and the haemolysis patterns that a technologist reads directly from the plate.
Batch-to-batch consistency matters more here than in most products, because the reader is comparing appearance against experience. For a manufacturer or a distributor of prepared media for the Chinese market, this is the governing product standard.

This document specifies the main components and preparation, requirements, identification, labeling and instructions for use, packaging, transportation, etc. of Columbia blood agar medium. and storage, and describes the corresponding test methods. This document applies to Columbia blood agar culture medium, including dry powder culture medium and plate culture medium.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 191 Pictorial markings for packaging, storage and transportation

GB/T 29791.2 Information provided by the manufacturer of in vitro diagnostic medical

devices (labeling) Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 culture medium Prepared by artificial methods, containing natural and/or synthetic ingredients, for the cultivation, separation, identification, research and preservation of microorganisms Liquid, semi-solid or solid mixed nutrient products.

3.2 Quality control strain quality control strain Microorganisms used for quality control and performance testing of culture media.

3.3 colony forming unit; CFU In the counting of live bacteria culture, the colonies formed by the growth and reproduction of a single bacterium or multiple bacterium clusters on a solid culture medium are called It expresses the number of viable bacteria.

4 Main ingredients and preparation method (applicable to dry powder culture medium)

4.1 Main ingredients Trypticase or tryptone 10.0g Beef heart powder 3.0g Corn starch 1.0g Peptone 5.0g