

CCS C21

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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0206-1995

Pharmaceutical excipients - Disodium edetate

药用辅料 乙二胺四乙酸二钠

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Foreword

This document was issued on 11 March 1995 by the National Medical Products Administration and takes effect on 1 August 1995.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It is classified under Chinese classification C21.

1 Scope

YY 0206 is the pharmaceutical excipient standard for disodium edetate, the chelating agent added to formulations to bind trace metal ions that would otherwise catalyse oxidation, and used as a stabiliser and preservative adjunct across injectables, ophthalmics and topicals. It specifies the technical requirements, the test methods, the inspection rules and the packaging, labelling, storage and transport. An excipient standard governs a material that is not the active ingredient and is therefore easy to treat as a commodity, which is exactly why its identity, purity and heavy metal limits are specified: the impurity profile of the excipient becomes the impurity profile of the product. For a manufacturer or a supplier of EDTA disodium for pharmaceutical use in China, this is the material specification.

About this edition

YY 0206-1995 is the current edition. It was issued on 11 March 1995 and has been in force since 1 August 1995.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up documentation before the new text becomes the one that applies. The date on this page is

the official one from the record of the Standardization Administration.

Classification and status

Its Chinese Standard Classification code is CCS C21. CCS is the domestic scheme, a letter for the sector and two digits for the subject within it, and it is the code by which the standard is filed and searched in China.

The YY prefix marks an industry standard, issued by the authority for its sector rather than by the national body. It applies within that industry, and it becomes binding in the same ways a recommended national standard does: when a contract, a regulation or a declaration of conformity names it.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

YY 0206-1995 runs to 15 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.

About this English translation

The English edition of YY 0206-1995 is a full translation of the official Chinese text, not a summary, an abstract or a machine rendering left unchecked. Clause and subclause numbers, table and figure numbers and annex letters are those of the original, because they are what a specification, a purchase order or a test report cites.

Technical terms are translated against the vocabulary standards of the same field, so that a term used in YY 0206-1995 reads the same way as in the other Chinese standards it is used beside. Where a term has an established English form in an ISO or IEC document on the same subject, that form is used; where China's term has no foreign counterpart, it is translated literally and the Chinese is kept alongside it rather than replaced by an approximation.

Quantities, units and symbols are carried over unchanged. Chinese standards use SI, so a value in the translation is the value in the original document, not a conversion, and a limit read from the English text is the limit that will be applied by a Chinese inspection body reading the Chinese one.

This page is compiled from the official publication record: the standard number and both titles, the issuing bodies, the dates of issue and effect, the ICS and CCS classification. The requirements, limits, tables and test conditions are in the document itself.

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