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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 35956-2018

**Detection and determination of N-nitrosodiethanolamine
(NDELA) in cosmetics -- HPLC-MS-MS**

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard uses the translation method equivalent to the use of ISO 15819.2014

"Cosmetics analysis methods cosmetics N-nitrosodiethanolamine

(NDELA) Determination of High Performance Liquid Chromatography-Tandem Mass Spectrometry (English).

This standard has made the following editorial changes.

- a) Change the standard name to "Determination of N-nitrosodiethanolamine (NDELA) in Cosmetics by High Performance Liquid Chromatography-Tandem Mass Spectrometry law";
- b) Delete the preface and introduction of international standards;
- c) Add informative Annex NA.

This standard is proposed by China Light Industry Federation.

This standard is under the jurisdiction of the National Standardization Technical Committee on Fragrance & Fragrance Cosmetics (SAC/TC257).

This standard was drafted by. Shanghai Institute of Daily Chemical Industry, Jiangsu Provincial Institute of Product Quality Supervision and Inspection (National Cosmetic Quality

Supervision and Inspection Center), Beijing P & G Technology Co., Ltd.

1 Scope

This standard describes a method for the detection and quantification of NDELA in makeup and its raw materials. This method does not apply to detection and/or

Or quantitative determination of nitrosoamines other than NDELA, nor is it suitable for the determination of products other than cosmetics and their raw materials

NDELA. If a product is likely to be contaminated with NDELA from its raw material or NDELA is produced from its raw material, then this

The standard method should be used to quantify NDELA. This method is not used for routine determination of cosmetics. Because there are many classes within the scope of application

For other cosmetics, this method may require the adoption and adaptation of certain substrates (see ISO 12787). Therefore, it is

Do not develop other international standards that will apply to the determination of other nitrosamines in cosmetics. If other measuring parties

The method can be proved to be suitable for determination of NDELA in terms of recovery rate and quantification, and these methods can also be used.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article

Pieces. For undated references, the latest version (including all amendments) applies to this document.

ISO 3696.1987 Analytical laboratory water specifications and test methods
(Waterforanalytical laboratoryuse-Speci-

Ficationandtestmethods)

ISO 12787.2011 Cosmetic analysis methods using chromatographic techniques for confirming analytical results (Cosmetics-Ana-

lyticalmethods-Validationcriteriaforanalyticalresultsusingchromatographictechniques)

3 Principle

In the presence of the deuterated d8-NDELA internal standard, NDELA in cosmetic samples was extracted with water. Purification steps can be used

C18 loaded SPE cartridges (purified by solid phase extraction, see 6.3.1), or when the sample is not dispersed in water, dichloromethane-liquid extraction may be used.

Take (DCM purification, see 6.3.2). The extracts were analyzed by HPLC-MS-MS (high

performance liquid chromatography tandem mass spectrometry).

NDELA was identified using molecular ions and two characteristic ions. By comparing NDELA and d8-NDELA on the standard curve

The ratio of the main fragment ions to quantify NDELA.

According to ISO 12787, a second analysis can be used to confirm that NDELA does not exist in the sample. The standard addition method at the target value can be

Used to assess the detection limit of NDELA in the sample.

For a particular cosmetic, if its matrix effect is found to have a significant effect on the implementation of the test method (sensitivity, accuracy, etc.),

Standard calibration procedures can be used (refer to ISO 12787).

4 Reagents

In analytical tests, only analytically pure reagents and distilled water or Class 1 water according to the ISO 3696.1987 standard were used unless otherwise stated.

The solvent should have a quality suitable for HPLC-MS.