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

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Pyrazosulfuron-ethyl wettable powder

吡嘧磺隆可湿性粉剂

(English Translation)

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Table of Contents

Foreword

1 Scope

2 Normative references

3 Requirements

4.1 Sampling

4.2 Identification Test

4.3 Topiramate ethyl mass fraction determination

4.4 Determination of the suspension rate

4.5 Determination of Moisture

4.7 Determination of wetting time

4.8 Fineness

4.9 Thermal storage stability test

4.10 Product inspection and acceptance

5 Marking, labeling, packaging, storage and transportation

Foreword

The standard Chapter 3, Chapter 5 are mandatory, the rest are recommended.

The standard proposed by China Petroleum and Chemical Industry Association.

This standard by the National Standardization Technical Committee on Pesticides (CSBTS/T C133) centralized.

1 Scope

This standard specifies the topiramate ethyl wettable powders requirements, test methods and marking, labeling, packaging, storage and transportation.

This standard applies to the processing by the original drug topiramate ethyl, fillers and additives made of a suitable topiramate ethyl wettable powder.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to

the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB/T 1600 Determination of Water Pesticides Determination of GB/T 1601 Pesticides pH value GB/T 1604 Goods pesticide regulations for acceptance GB/T 1605-2001 Sampling Method commercial pesticides GB 3796 pesticide packaging General GB/T 5451 WP Pesticide wettability measurement method GB/T 14825 method for determination of pesticide suspension GB/T 16150 pesticide powder, wettable powder fineness measurement method GB/T 19136 Determination of Pesticide Thermal storage stability

3 Requirements

3.1

Composition and appearance. This product should meet the standards of the original drug topiramate ethyl with suitable additives and fillers processed and, as an integral loose uniform Powder, there should be no lumps.

3.2

topiramate ethyl WP should meet the requirements of Table 1.

Table 1 topiramate ethyl WP Control Project Index

Item Index

Topiramate ethyl mass fraction /% 7.5 ± 0.8 10.0 ± 1.0 Suspension rate /% ≥ 75 Moisture /% ≤ 2.0 pH range of 5.0 to 8.0 Wetting time/s ≤ 90 Fineness (through 44 μ m standard sieve) /% ≥ 98 Thermal storage stability test a qualified when a normal production, heat storage stability test every three months at least once.

Test Method 4

4.1 Sampling

According to GB/T 1605-2001 "on solid preparation sampling" approach. Determining sample package using a random number table method; the final sample size not less than 300g.

4.2 Identification Test

HPLC --- The identification test can be carried out simultaneously with the determination of topiramate ethyl content. Under the same chromatographic operating conditions, Retention time with the standard solution in the sample solution to a peak of topiramate ethyl chromatographic retention time, the relative difference should be 1.5% Fewer.

4.3.1 Method summary

Samples dissolved in methanol, - water as the mobile phase, use ODSHypersil, 5 μ m as filler columns and variable wavelength UV Detectors, sample of topiramate ethyl liquid chromatography separation and determination.

4.3.2 Reagents and solutions

Methanol. HPLC grade;

Water. The new secondary steam distilled water;

Topiramate ethyl standard. a known mass fraction $\geq 98.0\%$.

4.3.3 Instruments

LC. a variable wavelength UV detector and quantitative injection valve;

Chromatographic data processor or chromatography workstation;

Column. 4.6mm (i.d.) x 200mm stainless steel column, built ODSHypersil, 5 μ m filler (or with the same column efficiency Other reversed phase columns);

Filter. pore size of about 0.45 μ m;

Ultrasonic bath;

Micro Injector. not less than 50 μ L.

4.3.4 HPLC operating conditions

Mobile phase. psi (CH₃OH.H₂O) = 70.30 (adjusted with phosphoric acid to pH = 3);

The mobile phase flow rate. 1.0mL/min;

Column temperature. room temperature (temperature change should not exceed 2 °C);

Detection wavelength. 241nm;

Injection volume. 10 μ L;

Retention time. topiramate ethyl approximately 8.0min.

HPLC operating conditions described above, the Department of typical operating parameters. According to the characteristics of different instruments, given operating parameters adjusted as appropriate, in order to obtain the best results. Typical liquid chromatogram topiramate ethyl WP shown in Figure 1.

1 --- topiramate ethyl.

Figure 1 topiramate ethyl WP liquid chromatogram

4.3.5.1 Preparation of standard solution

Weigh topiramate ethyl standard 0.05g (accurate to 0.0002g), placed in 100mL flask, add 80mL of methanol, add ultrasound Wave bath sonication 5min. Remove cooled to room temperature, add methanol to volume, shake; pipette imbibe 10.00mL, set in a 50mL volumetric flask, add methanol to volume, shake.

4.3.5.2 Preparation of the sample solution

Weigh containing topiramate ethyl 0.05g sample (accurate to 0.0002g), a 50mL volumetric flask, add 40mL of methanol, into Ultrasonic bath sonication 5min. Removed, cooled to room temperature, add methanol to volume, shake; a membrane pore size of more than about 0.45 μ m Filter.

4.3.5.3 Determination

Under the above chromatographic operating conditions, after the instrument is stable, continuous injection of several doses of the standard solution until the two adjacent needles topiramate ethyl relative peak area After the change of less than 1.0%, according to the order of the standard solution, sample solution, sample solution, standard solution injection analysis.

4.3.6 Calculation

The two needle sample solution measured before and after the peak area of the sample and two doses of the standard solution of ethyl topiramate were averaged. Sample topiramate Ethyl mass fraction of 1 (%) according to equation (1).

Where.

A1 --- standard solution Metsulfuron mean peak area pyrazosulfuron;

A2 --- sample solution topiramate ethyl Metsulfuron mean peak area;

--- Topiramate ethyl standard samples topiramate ethyl mass fraction, expressed as a percentage.

4.3.7 Allowable difference

The difference between two parallel determination results shall not be greater than 0.3%, the arithmetic mean value as a measurement result.

4.4.1 Measuring step

According to GB/T 14825 performed. Weigh containing topiramate ethyl 0.10g sample (accurate to 0.0002g). With 60mL methanol cylinder the remaining 25mL of the suspension