



## 产品规格书 /PRODUCT DATA SHEET

### 抗坏血酸/Ascorbic acid

参考标准 Reference standard	EP/BP/USP/FCC/E300	版本 Version	2022/05
生效日期 Official date	May 1st, 2022	页码 Total page	3

### 描述/ Description

东北制药生产的抗坏血酸的标准参考欧洲药典、英国药典、美国药典、美国食品化学法典、欧洲食品的所有要求。

The specification of Ascorbic acid, which produced by Northeast Pharmaceutical Group Co., Ltd., is established with reference of all requirements of the European Pharmacopeia (EP), British Pharmacopoeia (BP), United States Pharmacopeia(USP), Food Chemicals Codex(FCC) and E300.

### 产品识别/Product identification

化学名称 /Chemical names: (5R)-5-[(1S)-1,2-Dihydroxyethyl]-3,4-dihydroxyfuran-2(5H)-one

别名 /Synonyms: L-ascorbic acid; L-xyllo-ascorbic acid; L-(+)-ascorbic acid; vitamin C

CAS号/CAS No.: 50-81-7

Einecs 号 /Einecs No.: 200-066-2

E号 /E No.: E300

分子式 /Molecular formula: C<sub>6</sub>H<sub>8</sub>O<sub>6</sub>

分子量 /Molecular mass: 176.1

### 标准 / Specifications

项目 /Items	要求 /Requirements	方法/Test methods
性状 /Characteristics	白色或类白色结晶性粉末或无色结晶 White or almost white, crystalline powder or colorless crystals	欧洲药典 EP
鉴别 /Identification	IR:符合规定 /IR: Complies; 化学鉴别: 呈正反应 /CA: Positive	欧洲药典 2.2.24 EP 2.2.24 美国药典专论 USP monograph
熔点 /Melting Point	约 190°C , 同时分解 /About 190 °C, with decomposition	中国药典 0612 ChP 0612
比旋度 /Specific Rotation	+20.5 ° ~ +21.5 ° /+20.5 ° ~ +21.5 °	欧洲药典 2.2.7 EP 2.2.7
酸度 /Acidity (pH)	2.1~ 2.6 (5%水溶液) /2.1 ~ 2.6 (5% aqueous solution)	欧洲药典 2.2.3 EP 2.2.3
酸度 /Acidity (pH)	2.4 ~ 2.8 (2%水溶液) / 2.4~ 2.8 (2% aqueous solution)	企业内控 In-house
含量	99.0% ~ 100.5%	欧洲药典专论



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/Assay	/ 99.0% ~ 100.5%	EP monograph
干燥失重 /Loss on Drying	≤0.40% /≤0.40%	企业内控 In-house
*草酸 (杂质 E) /Oxalic Acid Impurity E)	≤0.2% /≤0.2%	欧洲药典专论 EP monograph
*有关物质 /Related Substances	杂质 C、D : ≤0.15% / Impurity C, D: ≤0.15% 任一非特定杂质: ≤0.10% / Unspecified Impurities: ≤0.10% 除 C、D 外总杂质: ≤0.2% / Total Impurities other than C, D: ≤0.2%	欧洲药典 2.2.29 EP 2.2.29
*重金属 /Heavy Metals	≤10ppm /≤10ppm	企业内控 In-house
*铜 /Copper	≤5ppm /≤5ppm	欧洲药典 EP 2.2.23
*铁 /Iron	≤2ppm /≤2ppm	欧洲药典 EP 2.2.23
砷 / Arsenic	≤3ppm /≤3ppm	企业内控 In-house
铅 /Lead	≤2ppm /≤2ppm	企业内控 In-house
汞 /Mercury	≤1ppm /≤1ppm	企业内控 In-house
硫酸灰分 /Sulphated Ash	≤0.1% /≤0.1%	欧洲药典 2.4.14 EP 2.4.14
溶液澄清度 /Clarity of Solution	澄清 /Clear	欧洲药典 2.2.1 EP2.2.1
溶液颜色 /Color of Solution	≤BY <sub>7</sub> /≤BY <sub>7</sub>	欧洲药典 2.2.2 EP2.2.2
*残留溶剂 /Residual Solvents	甲醇≤0.3% / Methanol ≤0.3%	企业内控 In-house
细度 /Particle-Size	40 目筛上≤30% /≤30% more than 40 mesh 从 40 目到 80 目≥45% /≥45% between 40 and 80 mesh.	企业内控 In-house
*需氧菌总数 /The total aerobic microbial count(TAMC)	≤10 <sup>3</sup> cfu/g /≤10 <sup>3</sup> cfu/g	中国药典 1105 ChP 1105



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*霉菌和酵母菌总数 /The total combined yeasts and moulds count(TYMC)	≤10 <sup>2</sup> cfu/g /≤10 <sup>2</sup> cfu/g	中国药典 1105 ChP 1105
*大肠埃希菌 / Escherichia coli	不得检出/g Not detected /g	中国药典 1106 ChP 1106
*金黄色葡萄球菌 /Staphylococcus aureus	不得检出/g Not detected /g	中国药典 1106 ChP 1106
*沙门菌 /Salmonella	不得检出/10g Not detected /10g	中国药典 1106 ChP 1106

备注：上面带\*的项目为抽检。

Note:\*These items as above are sampling test.

**包装和贮存 /Packaging and storage**

贮存：密封、遮光、非金属容器中。

Store : Preserve in tightly closed non-metallic containers from light.

包装：25kg/箱。

Packing: Corrugated carton net weight 25kg.

复验期：3年。

Retest date: 3 years.

**稳定性和贮存 /Stability and storage**

产品在干燥空气中相对稳定，对热敏感。产品在室温条件下，未拆封的原包装容器中可以贮存36个月。

This product is reasonably stable in air if protected from humidity, but is somewhat sensitive to heat. The product may be stored for 36 months from the date of manufacture in the unopened original container and at room temperature.

**使用/Uses**

产品适用于食品级。

This product is especially suited for food grade.

**遵守药典/Compendial compliance**

当按照欧洲药典/英国药典、美国药典、美国化学法典、欧洲食品进行检验时，抗坏血酸符合以上有效的概述的所有要求。

The Ascorbic acid meets all requirements of the following valid compendia when tested accordingly: EP/BP, USP, FCC, E300.

**安全/Safety**

产品在预定用途下是安全的。采用合适的保护措施，避免吸收和吸入或直接接触灰尘。需要全面的安全信息和必要的预防措施参考产品安全数据。

This product is safe for the intended use. Avoid ingestion, inhalation of dust or direct contact by applying suitable protective measures and personal hygiene. For full safety information and necessary precautions, please refer to the respective Material Safety Data Sheet.