ALFA Chemistry

APIs Catalog

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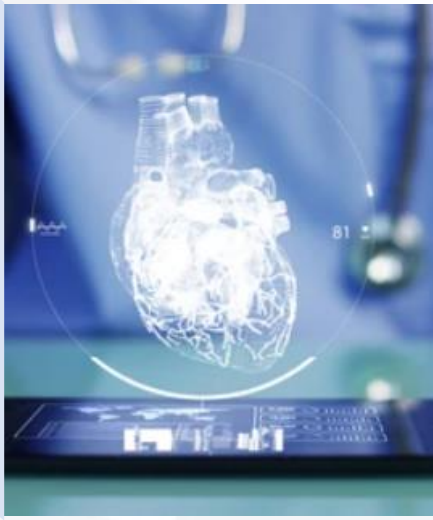
Content

About Us

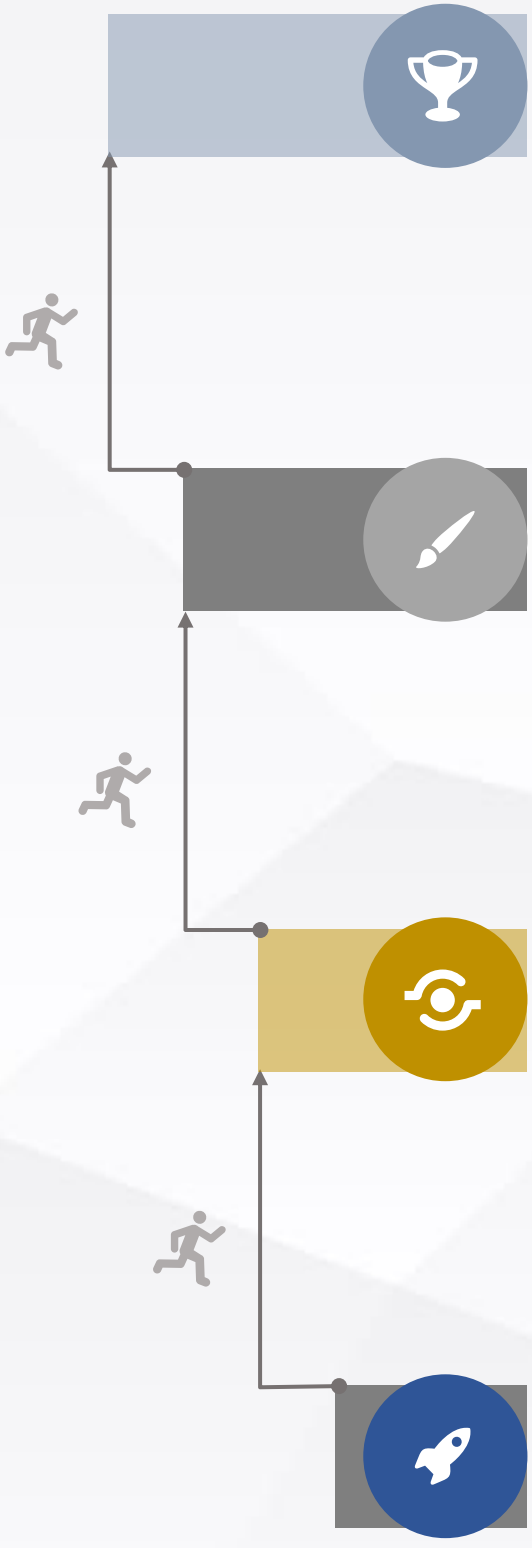
Company Profile

- As a global Contract Research Organization (CRO), headquartered in New York, USA, Alfa Chemistry has served the pharmaceutical and biotechnology industries for years.
- Alfa Chemistry offers a variety of synthetic chemical APIs which can be used in the pharmaceutical preparation. In addition, we offer pre-formulation drug discovery, formulation and process development, custom synthesis, and scale up services.



About Us

Company Value



High Quality

Provide customers with high-quality products

Win-win

Professionalization & Internationalization

Passion

Full support and 24h*7 on call

Honesty

A leading chemical company

About Us

Advantages

Excellent R&D staffs

Highly skilled Ph.D. and
M.S. synthetic chemists

Advanced production & testing equipment

Rich experiences

Over 20 years of
experience
in APIs field

Scale up

From the milligram
to kilogram

About Us

Main sales regions

Our global businesses serve more than 20+ countries or regions, and the main sale regions are listed below:

- United States
- Canada
- United Kingdom
- Germany
- France
- China
- India
- Japan
- South Korea

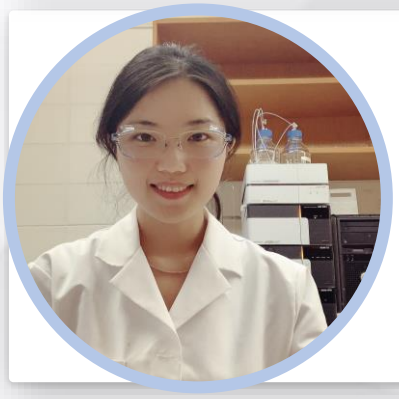
About Us

Core Members

- With many years' experience working with excellent companies, our team is prepared to successfully serve all kinds of customers.
- We have very excellent R&D staffs.
- All of our synthetic chemists are Ph.D.s or masters.
- Our core members are showed below:

Dr. Kong

Doctorate University of Illinois at Chicago in synthetic organic chemistry and material chemistry



Dr. Lin

Ph.D. in Organic Chemistry/University of Georgia

Our APIs

Brief Introduction of APIs

- Active Pharmaceutical Ingredient (API) is any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
- According to the data of China Chamber of Commerce for Import & Export of Medicines & Health Products, in 2019, the global API market size reached USD 167.9 billion, and it will reach USD 306.1 billion by 2027.

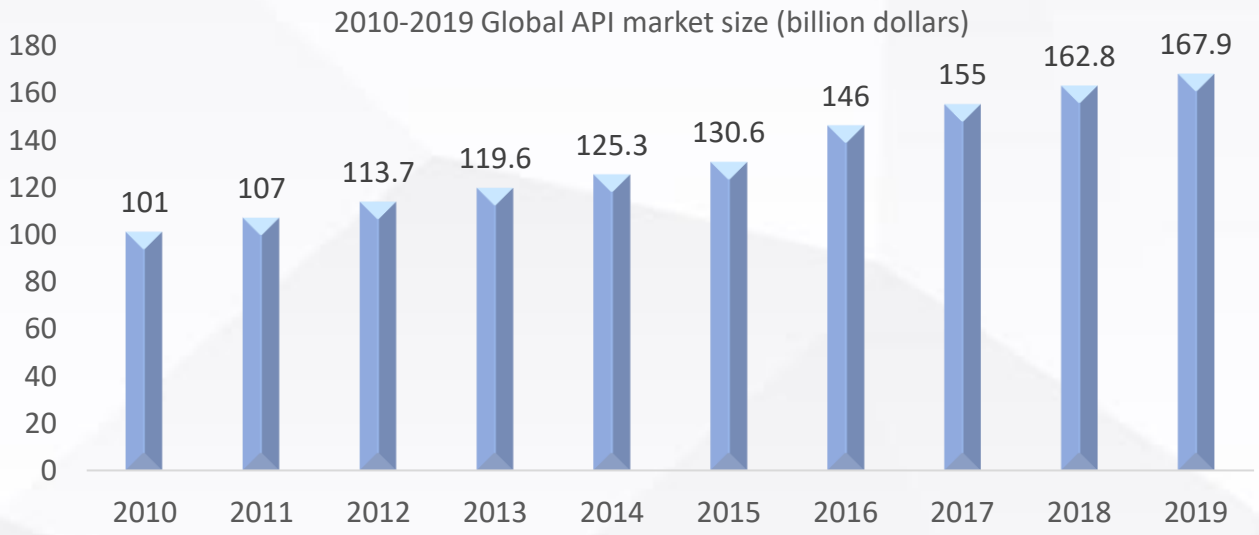


Fig. 1 2010-2019 Global API market size

- APIs may exist in the form of liquids, powders, crystals that obtained by chemical synthesis, biotechnology, or plant extraction. Alfa Chemistry offers a variety of **synthetic chemical APIs** which can be used in the pharmaceutical preparation.

Our APIs

APIs Catalog

- As for now, Alfa Chemistry offers a variety of synthetic chemical APIs which can be used in the pharmaceutical preparation, including :

Our APIs

Donepezil

- Donepezil is a white or almost white crystalline powder and is freely soluble in chloroform, soluble in water and in glacial acetic acid, slightly soluble in ethanol and in acetonitrile, and practically insoluble in ethyl acetate and in n-hexane. Donepezil is a potent, selective, noncompetitive, and rapidly reversible inhibitor of acetylcholinesterase (AChEI) licensed for the treatment of Alzheimer disease (AD) and other types of dementia.
- The commonly accepted cholinergic hypothesis proposes that a portion of the cognitive and behavioral decline associated with Alzheimer's are the result of decreased cholinergic transmission in the central nervous system.
- Donepezil binds reversibly to acetylcholinesterase and inhibits the hydrolysis of acetylcholine, thus increasing the availability of acetylcholine at the synapses, enhancing cholinergic transmission (see Figure 2)

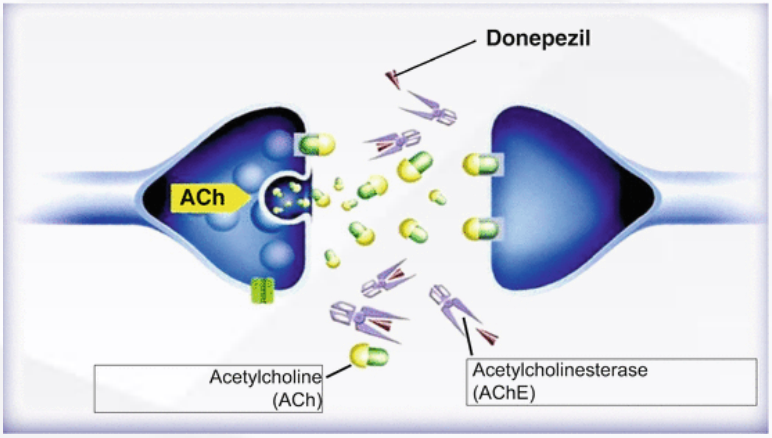


Fig. 2 Donepezil impedes AChE resulting in an increase of Ach level in the synaptic cleft

Our APIs —Donepezil

- Product Name: Donepezil
- Catalog No.: ACM120014064
- CAS No.: 120014-06-4

Test	Specification
Appearance	White or almost white, crystalline powder.
UV	According to the UV-Vis spectrophotometry, this product should have the maximum ab-sorption at 229nm, 266nm ,309nm wave-length and the minimum absorption at 219nm, 242nm ,281nm wavelength.
IR	The IR spectrum of the sample should match that of the Reference Standard.
Chromatogram	The principal peak in the chromatogram obtained with the sample solution obtained in the Assay is similar in retention time to the principal peak in the chromatogram obtained with standard solution.
Chlorid	Should be qualified (Should not be more than 0.02%)
Related substances	Impurity H≤0.10%
	Impurity B≤0.10%
	Impurity C≤0.10%
	Impurity E≤0.10%
	Impurity L≤0.10%
	Impurity M≤0.10%
	Impurity K≤0.10%
	Other maximum single impurity≤0.10%
	Total impurities≤0.5%
Residual solvents	Methanol≤3000ppm
	Ethanol≤5000ppm
	Acetone≤5000ppm
	Methyl tert-butyl ether≤5000ppm
	Ethyl acetate≤5000ppm
	Toluene≤890ppm
	Isopropyl alcohol≤5000ppm
Loss on drying	Should not be more than1.0%
Residue on ignition	Should not be more than 0.1%
Heavy metal	Should conform with the regulation (Should not be more than 0.001%)
Assay	It contains not less than 98.0% and NMT the equivalent of 102.0% of C24H29NO3, calculated with reference to the dried substance.
Standard	The results comply with the above requirements.

Our APIs

Dexmedetomidine Hydrochloride

- Dexmedetomidine hydrochloride is a white or almost white powder that is a potent α2-adrenoceptor agonist, which produces and analgesia, about 8 times higher selective affinity for the α2/α1-adrenoceptor than clonidine.
- Dexmedetomidine hydrochloride selectively binds to and activates presynaptic alpha-2 adrenoceptors located in the brain, thereby inhibiting the release of norepinephrine from synaptic vesicles. This leads to an inhibition of postsynaptic activation of adrenoceptors, which inhibits sympathetic activity, thereby leading to analgesia, sedation and anxiolysis. Physiology of the α 2-adrenoceptor agonists receptor is showed in figure 3.

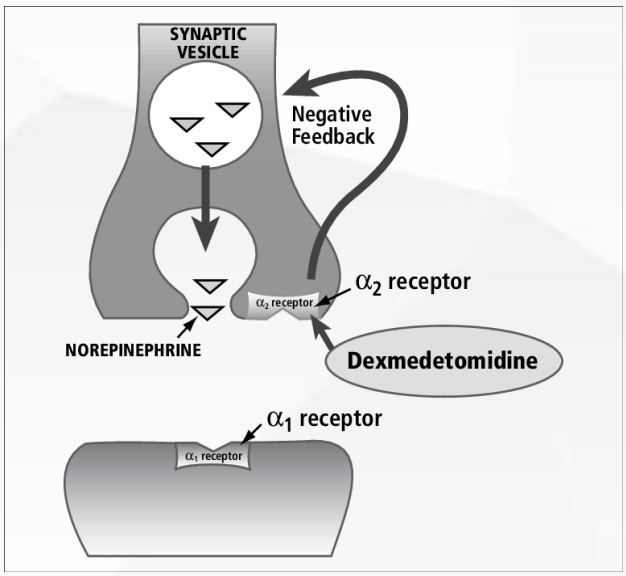


Fig. 3 Physiology of the α 2-adrenoceptor agonists receptor

Our APIs —Dexmedetomidine Hydrochloride

- Product Name: Dexmedetomidine Hydrochloride
- Catalog No.: ACM145108583
- CAS No.: 145108-58-3

Test	Specification
Appearance	White or almost white, hygroscopic, crystalline powder.
Solubility	Very soluble in water, freely soluble in methylene chloride and in N,N-dimethylformamide, slightly soluble in acetonitrile.
Melting point	154 °C to 158 °C
Specific optical rotation	+48° to +54°
Chemical reaction	It gives reaction (a) of chlorides
IR	The IR spectrum of the sample should match that of the Reference Standard.
HPLC	The principal peak in the chromatogram obtained with the sample solution obtained in the Assay is similar in retention time to the principal peak in the chromatogram obtained with standard solution. (The absolute value of relative error between retention time of the principal peak obtained with the sample solution and that obtained with standard solution should not be more than 5%).
Clarity and colour of solution	The solution should be clear and colorless; if the solution develops turbidity it should not be more opalescent than reference suspension I; if the solution shows any colour, it should not be more intensely coloured than reference solution B9.
pH	3.5 to 5.5
Related substances	Impurity A: NMT 0.07%
	Impurity B: NMT 0.07%
	Any individual unspecified impurity: NMT 0.10%
	Total Impurities :NMT 0.3%
Enantiomeric purity	Levomedetomidine hydrochloride: NMT 0.15%
Residual solvents	Ethanol: NMT 5000 ppm
	Acetone: NMT 5000 ppm
	Ethyl acetate: NMT 5000 ppm
	n-Heptane: NMT 5000 ppm
	Tert-butanol: NMT 3500 ppm
	Methanol: NMT 3000 ppm
	Methylene chloride: NMT 600 ppm

Our APIs —Dexmedetomidine Hydrochloride

Test	Specification
Loss on drying	NMT 1.0%
Sulfated ash	NMT 0.1%
Microbial contamination	Aerobic bacteria: NMT 103 CFU/g
	Fungi and yeasts: NMT 102 CFU/g
	Specified Microorganism (Escherichia coli): Should be absent per gram
Bacterial endotoxins	Less than 5 EU/mg
Assay	It contains not less than 98.0% and NMT the equivalent of 102.0% of C13H16N2·HCl, calculated with reference to the dried substance.
Standard	CP & EP

Our APIs

Lenalidomide

- Lenalidomide is a light-yellow powder which is used to treat various types of cancers. It works by slowing or stopping the growth of cancer cells. It is also used to treat anemia in patients with certain blood/bone marrow disorders (myelodysplastic syndromes-MDS).
- Lenalidomide can be used in the treatment of various of cancers and anemia in patients with certain blood/bone marrow disorders, including:

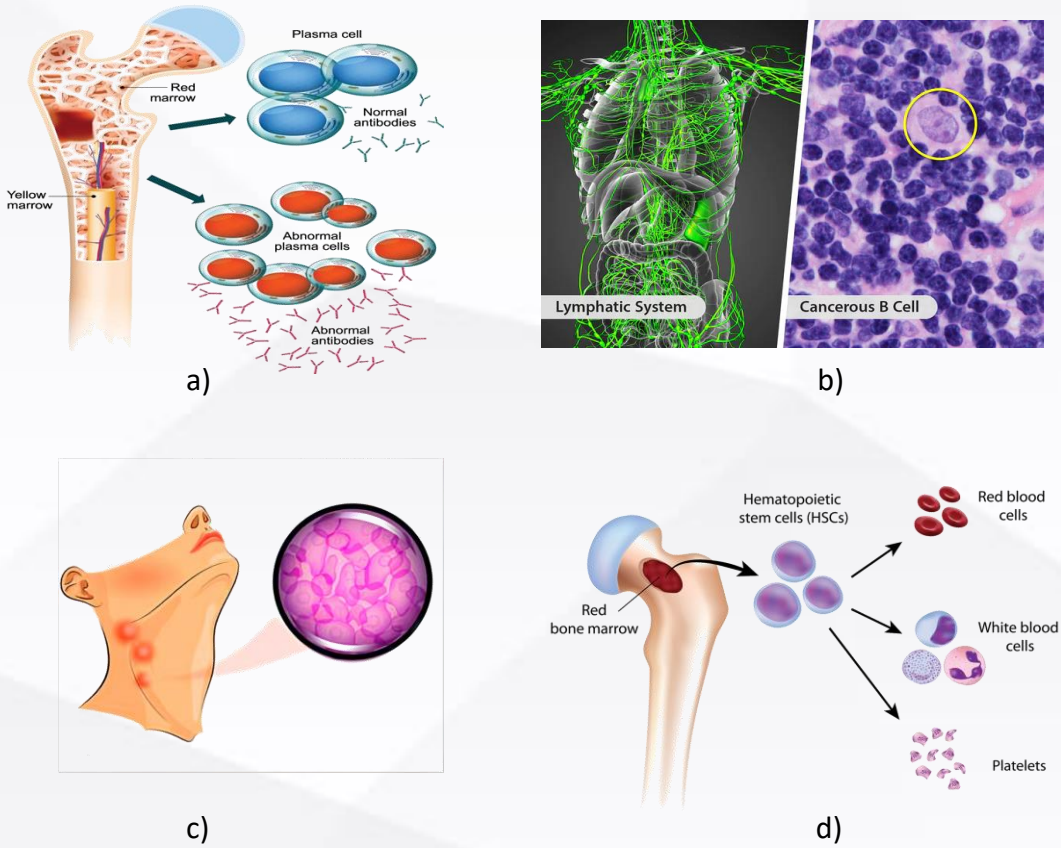


Fig. 4 Cancers and syndromes can be treated with lenalidomide
a) Multiple myeloma (MM)
b) Mantle cell lymphoma (MCL)
c) Follicular lymphoma (FL) or marginal zone lymphoma (MZL)
d) Myelodysplastic syndromes (MDS)

Our APIs —Lenalidomide

- Product Name: Lenalidomide
- Catalog No.: ACM191732726
- CAS No.: 191732-72-6

Test	Specification
Appearance	Almost White to light yellow powder.
Solubility	Freely soluble in N-methylpyrrolidone, soluble in N,N-dimethylformamide or dimethyl sulfoxide, slightly soluble in 0.1mol/L hydrochloric acid solution, very slightly soluble in methanol, insoluble in water.
IR	The IR spectrum of the sample should match that of the Reference Standard.
HPLC	The principal peak in the chromatogram obtained with the sample solution obtained in the Assay is similar in retention time to the principal peak in the chromatogram obtained with standard solution.
Chemical reaction	Should have orange yellow precipitate generated.
Crystalline	There should be a characteristic diffraction peak with a diffraction Angle of 7.8°, 14.3°,15.8°, 17.6°, 20.5°and25.9° in the X-ray powder diffraction pattern.
Clarity and colour of solution	The solution should be clear and colorless; if the solution develops turbidity, it should not be more opalescent than reference suspension I; if the solution shows any colour, it should not be more intensely coloured than reference solution B9.
Chloride	Should not be more than 0.02%
Related substances	Deduction of chromatographic peak of N,N-dimethylformamide and dimethyl sulfoxide, the peak area of Impurity A (Peak area after correction) Should not more than 1.5 times to the major peak area of the reference solution (0.15%).
	Deduction of chromatographic peak of N,N-dimethylformamide and dimethyl sulfoxide, the peak area of Impurity B (Peak area after correction) Should not more than 1.5 times to the major peak area of the reference solution (0.15%).
	The peak area of Impurity SM2 (Peak area after correction) Should not be more than the major peak area of the reference solution (0.1%).
	The peak area of Impurity C (Peak area after correction) Should not be more than the major peak area of the reference solution (0.1%).
	The peak area of Impurity D (Peak area after correction) Should not be more than the major peak area of the reference solution (0.1%).
	The peak area of Impurity M-1 (Peak area after correction) Should not be more than the major peak area of the reference solution (0.1%).
	The single impurity peak area should not be more than the major peak area of reference solution (0.10%).
	The peak area of Total impurities (Peak area after correction)Should not more than 5 times to the major peak area of the reference solution (0.5%).

Our APIs —Lenalidomide

Test	Specification
Impurity E*	Should not be more than 0.006%
Impurity F*	Should not be more than 0.006%
Impurity SM1*	Should not be more than 0.006%
Residual solvents-1	Triethylamine: Should not be more than 0.032%
	Isopropyl acetate: Should not be more than 0.5%
	Ethanol: Should not be more than 0.5%
Residual solvents-2	N,N-dimethylformamide: Should not be more than 0.088%
	Dimethyl sulfoxide: Should not be more than 0.5%
Loss on drying	Should not be more than 0.5%
Residue on ignition	Should not be more than 0.1%
Heavy metal	Should conform with the regulation (Should not be more than 0.001%)
Palladium	Should conform with the regulation (Should not be more than 0.001%)
Microbial limit	Aerobic bacteria count: not more than 103 cfu/g
	Fungi and yeasts count: not more than 102 cfu/g
	Escherichia coli: absence in 1 g Not Detected
Assay	It contains not less than 98.0% and NMT the equivalent of 102.0% of C13H13N3O3, calculated with reference to the dried substance.
Standard	CP & EP & USP

Our APIs

Parecoxib Sodium

- Parecoxib sodium is a white or almost white crystalline powder which is an amide prodrug of the cyclooxygenase II (COX-2) selective, non-steroidal anti-inflammatory drug (NSAID) valdecoxib, with anti-inflammatory, analgesic, and antipyretic activities.
- Upon intravenous or intramuscular administration, parecoxib is hydrolyzed by hepatic carboxyesterases to its active form, valdecoxib. Valdecoxib selectively binds to and inhibits COX-2. This prevents the conversion of arachidonic acid into prostaglandins, which are involved in the regulation of pain, inflammation, and fever. Figure 5 shows the schematic of NSAID mechanism of action

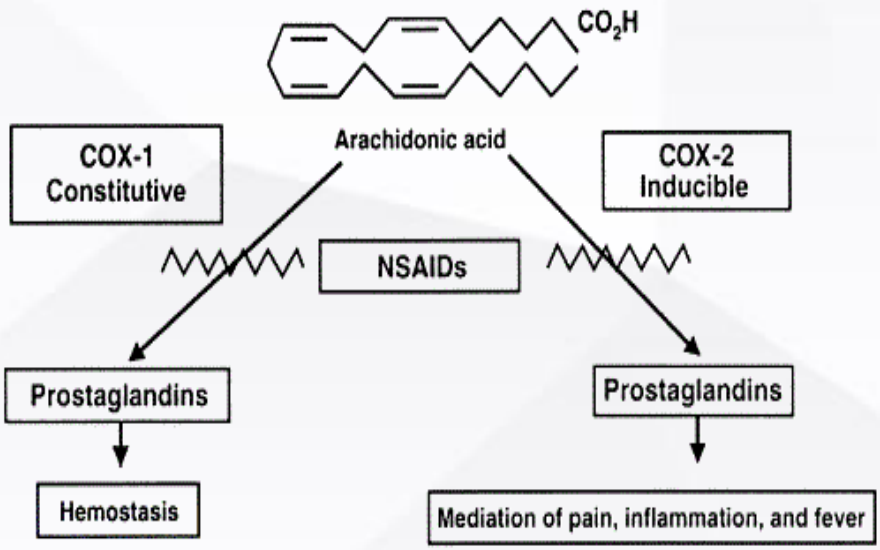


Fig. 5 Schematic of NSAID mechanism of action

Our APIs —Parecoxib Sodium

- Product Name: Parecoxib sodium
- Catalog No.: ACM198470858
- CAS No.: 198470-85-8

Test	Specification
Appearance	White or almost white crystalline powder, odourless, hygroscopic.
Solubility	Freely soluble in water, methanol, N,N-dimethylformamide, slightly soluble in ethanol, and practically insoluble in dichloromethane.
Infrared absorption (IR)	The IR spectrum of the sample should match that of the Reference Standard.
Chemical reaction	It gives reaction (a) of chlorides
HPLC	The principal peak in the chromatogram obtained with the sample solution obtained in the Assay is similar in retention time to the principal peak in the chromatogram obtained with standard solution.
Clarity and Colour of solution	The solution should be clear and colorless; if the solution develops turbidity it should not be more opalescent than reference suspension I.
Alkalinity	pH 7.5 to 8.5
Chloride	Should conform with the regulation (Should not be more than 0.02%)
Sulphate	Should conform with the regulation (Should not be more than 0.02%)
Sodium propionate	NMT 0.5%
Residual solvents	Ethyl benzenel: NMT 0.089%
	Ethyl acetate: NMT 0.5%
	Triethylamine: NMT 0.032%
	Dichloromethane: NMT 0.06%
	N-hexane: NMT 0.029%
	Ethanol: NMT 0.5%
	Tert-butyl methyl ether: NMT 0.5%
	tetrahydrofuran: NMT 0.072%
	Benzene: NMT 0.0002%

Our APIs —Parecoxib Sodium

Test	Specification
Related substances	Ignore the chromatographic peak of retention time 2.5 minutes ago (solvent peak, 4-dimethylaminopyridine peak and propionic acid peak), vadioxib should not exceed 0.10%。
	Ignore the chromatographic peak of retention time 2.5 minutes ago (solvent peak, 4-dimethylaminopyridine peak and propionic acid peak), impurity D should not exceed 0.10%.
	Ignore the chromatographic peak of retention time 2.5 minutes ago (solvent peak, 4-dimethylaminopyridine peak and propionic acid peak), impurity Q should not exceed 0.10%.
	Ignore the chromatographic peak of retention time 2.5 minutes ago (solvent peak, 4-dimethylaminopyridine peak and propionic acid peak), impurity K should not exceed 0.10%.
	Individual Impurity: NMT 0.10%
	Total Impurities: NMT 0.4%
Moisture content	NMT1.0%
Heavy metal	Should conform with the regulation (not more than 10 parts per million)
Ammonium salt	Should conform with the regulation (not more than 0.02%)
Microbial contamination	Aerobic bacteria count: NMT 10^3 CFU/g
	Fungi and yeasts count: NMT 10^2 CFU/g
Bacterial endotoxins	Less than 2.9 EU/g
Na content	In terms of anhydrous matter, the sodium content should be 5.6% ~ 6.2%.
Assay	It contains not less than 98.5% and NMT the equivalent of 101.5% of C19H17N2NaO4S, calculated with reference to the dried substance.
Standard	CP & EP

Our APIs

Rivaroxaban

- Rivaroxaban is an orally active direct factor FXa inhibitor drug which can catalyze the cleavage of prothrombin and thus possesses an anticoagulant activity and the inhibition of thrombin generation. Therefore, rivaroxaban as antithrombotic drug is widely described to treat and prevent various thromboembolic diseases.
- Rivaroxaban is a selective inhibitor of FXa, it does not require a cofactor (such as Anti-thrombin III) for activity and can directly inhibit both free and bound factor FXa in the prothrombinase complex. By inhibiting FXa, rivaroxaban decreases thrombin generation, interrupts the intrinsic and extrinsic pathway of the blood coagulation, and then it inhibits the thrombin as well thrombi formation (Figure 6)

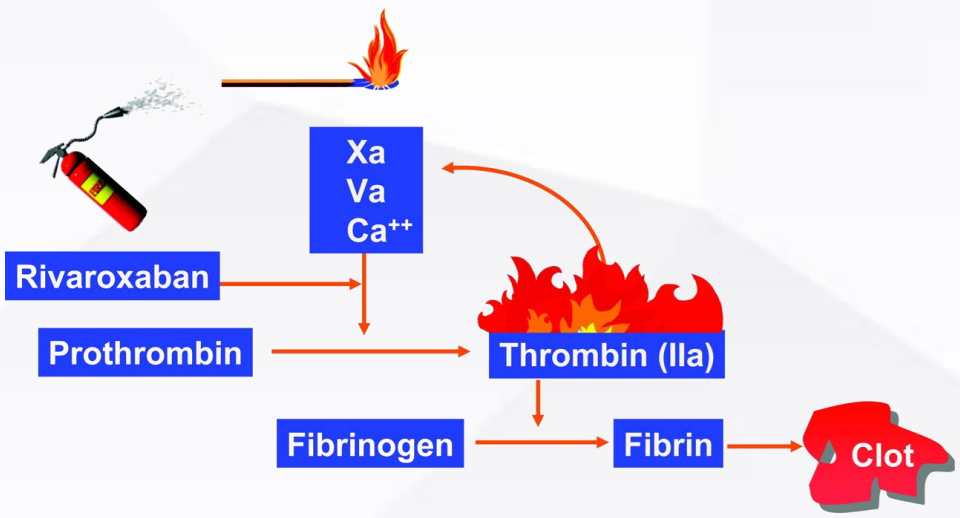


Fig. 6 Mechanism of action of rivaroxaban

Our APIs —Rivaroxaban

- Product Name: Rivaroxaban
- Catalog No.: ACM366789028
- CAS No.: 366789-02-8

Test	Specification
Appearance	White to yellow powder, odorless.
Solubility	Practically insoluble in water, 0.1mol/L hydrochloric acid solution and ethanol.
IR	The IR spectrum of the sample should match that of the Reference Standard.
HPLC	The principal peak in the chromatogram obtained with the sample solution obtained in the Assay is similar in retention time to the principal peak in the chromatogram obtained with standard solution.
Crystal type	The characteristic diffraction peak of the sample should be consistent with that of the reference material and should contain characteristics Peak： 16.5 °±0.2 °, 19.5 °±0.2 °, 19.9 °±0.2 °, 22.5 °± 0.2 °, 25.6 °±0.2 °, 26.7 °±0.2 °.
Colour of solution	
Isomer	Isomer peak area should not outweigh the main peak area of reference solution （0.15%） .
Sulfated ash	NMT 0.1%
heavy metal	Should conform with the regulation (not more than 20 parts per million)
Loss on drying	NMT 1.0%
Nickel	Should conform with the regulation (Should not be more than 0.0005%)
Residual solvents I	Methanol: NMT 0.3%
	Ethanol: NMT0.5%
	Dichloromethane: NMT 0.06%
	N,N-dimethylformamide: NMT 0.088%
Residual solvents II	Acetic acid should not be more than 0.5%

Our APIs —Rivaroxaban

Test	Specification
Grass amine	The corrected peak area (Multiply by correction factor 1.6) of Grass amine should not be more than the major peak area of the reference solution (0.10%).
Related substances	Amide solution compounds: NMT 0.10%
	Dioxalamide Urea: NMT 0.15%
	Decchlorination compounds: NMT 0.15%
	Oxygen Phthalimide: NMT 0.15%
	Any individual unspecified impurity: NMT 0.10%
	Total Impurities: NMT 0.50%
Microbial contamination	Aerobic bacteria count: NMT 10^3 CFU/g
	Fungi and yeasts count: NMT 10^2 CFU/g
	Escherichia coli: Should be absent per gram
Assay	It contains not less than 98.0% and NMT the equivalent of 101.5% of C19H18ClN3O5S, calculated with reference to the dried substance.
Standard	CP

Our APIs

Tofacitinib Citrate

- Tofacitinib citrate is a white or almost white powder which is a novel, oral Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis.
- Tofacitinib citrate inhibits the phosphorylation and activation of JAKs. JAKs cannot phosphorylate the cytokine receptors. Consequently, the receptors cannot dock STATS. These latter are not phosphorylated and activated. Therefore, they cannot translocate to the nucleus. Gene transcription and cytokine production are inhibited. Figure 7 shows the simplified action mechanism diagram.

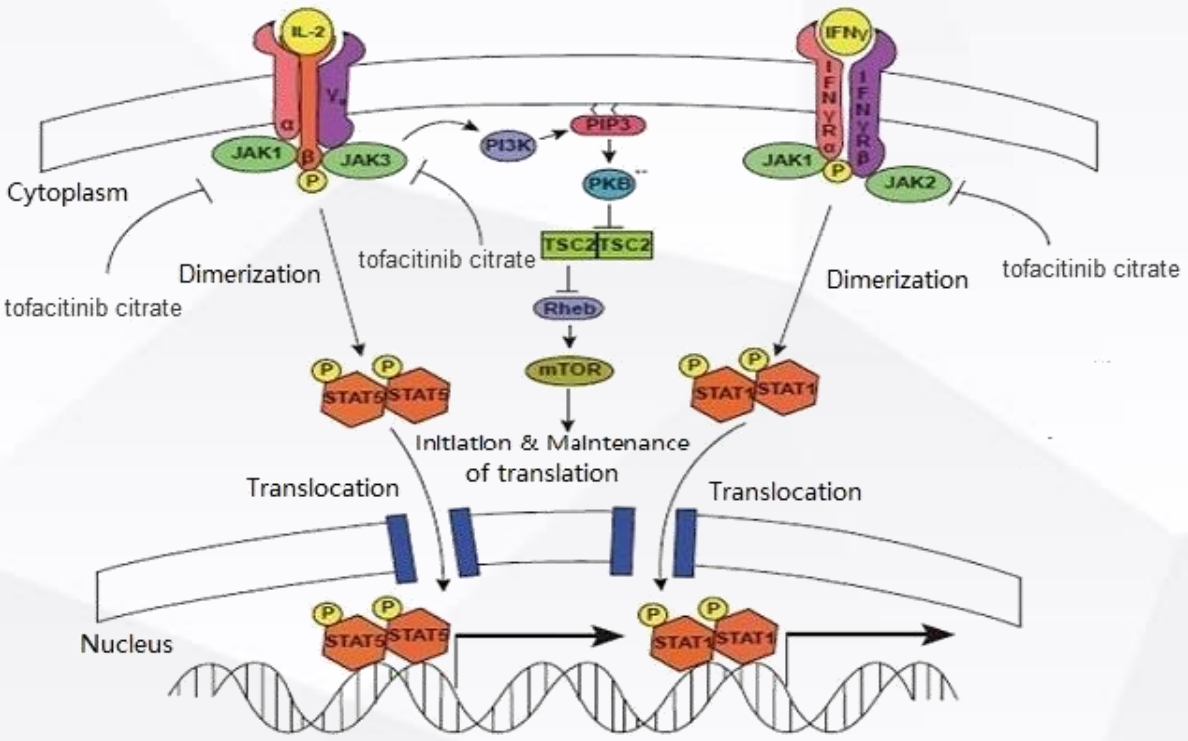


Fig.7 Action Mechanism of tofacitinib citrate

Our APIs —Tofacitinib Citrate

- Product Name: Tofacitinib citrate
- Catalog No.: ACM540737299
- CAS No.: 540737-29-9

Test	Specification
Appearance	White or almost white powder.
Solubility	Slightly soluble in water， very slightly soluble in methanol, and practically insoluble in acetone.
HPLC	The principal peak in the chromatogram obtained with the sample solution obtained in the Assay is similar in retention time to the principal peak in the chromatogram obtained with standard solution.
IR	The IR spectrum of the sample should match that of the Reference Standard.
Chemical reaction	There should be a positive reaction.
Chloride	Should be qualified (Should not be more than 0.02%)
Enantiomeric purity	The peak area of the enantiomer Should not be more than 0.5%of the sum of the peak area of Tofacitinib and the peak area of the enantiomer.
Related substances	Except for the chromatographic peak at the same position as the blank solution， peak area of a single impurity Should not more than 0.2 times to the major peak area of the reference solution (0.10%).
	The sum of the peak areas of each impurity Should not more than the major peak area of the reference solution (0.5%).
Residual solvent	Ethanol: NMT 0.5%
	Acetone: NMT 0.5%
	Toluene: NMT 0.089%
	Dimethyl sulfoxide: NMT 0.5%
Loss on drying	NMT 0.5%
Sulfated ash	NMT 0.1%
heavy metal	Compliance be comply
Microbial contamination	Aerobic bacteria count: NMT 2000CFU/g
	Fungi and yeasts count: NMT 200CFU/g
	Escherichia coli: Should be absent per gram
Assay	It contains not less than 98.0% and NMT the equivalent of 102.0% of C16H20N6O· C6H8O7 , calculated with reference to the dried substance.
Standard	CP

Our APIs

Tamoxifen Citrate

- Tamoxifen citrate is an estrogen receptor antagonist and partial agonist which has been shown to induce apoptosis in human malignant glioma cells and to block VEGF production in breast cancer cells.
- Tamoxifen is a type of hormonal therapy known as a selective estrogen receptor modulator (SERM). The drug attaches to hormone receptors (specific proteins) in breast cancer cells. Once the medication is inside the cells, it stops the cancer from accessing the hormones they need to multiply and grow.
- Two metabolites of tamoxifen Citrate, 4-hydroxy-tamoxifen and 4-hydroxy-N-desmethyltamoxifen, exhibit much greater anti-estrogenic effects compared with tamoxifen. They are all antiestrogens that inhibit the binding of estradiol to the estrogen receptor.

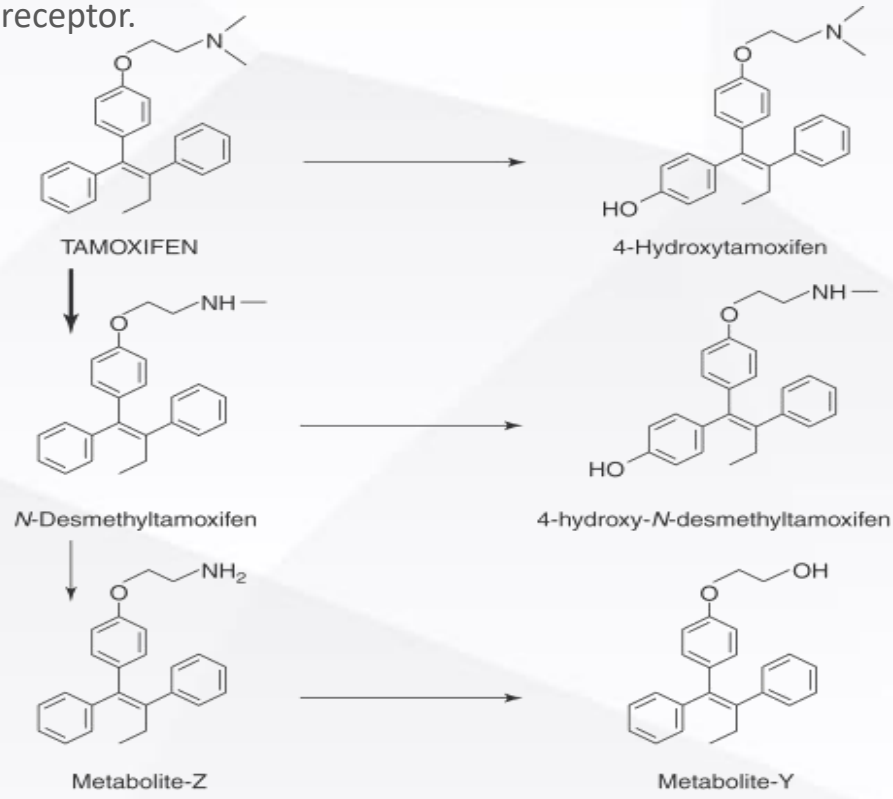


Fig. 8 The metabolism of tamoxifen is humans

Our APIs —Tamoxifen Citrate

- Product Name: Tamoxifen Citrate
- Catalog No.: ACM54965241
- CAS No.: 54965-24-1

Test	Specification
Appearance	The product should be white or almost white, crystalline powder; odorless.
Solubility	The product should be soluble in methanol, slightly soluble in ethanol or acetone, very slightly soluble in methenyl trichloride, almost insoluble in water and easily soluble in glacial acetic acid.
Melting Point	Should be 142℃ ~148℃ (Dissolve and decompose at the same time)
Chemical Reaction	Should be positive reaction
UV	This product should have the maximum absorption at 238nm wavelength and 278nm wavelength.
IR	The IR spectrum should be the single absorption peak in the range of 1700~1740cm-^{1}; IR spectrum between sample and standard (Spectrum 265) should be the same after the acetone crystallization.
Chloride	Should be qualified (Should not be more than 0.01%)
Related substance Ⅰ	Except Tamoxifen Citrate peak, Impurity A:Should not be more than 0.10%.
	The peak area of Impurity F (Relative Retention Time approximately 0.9) Should not more than 2 times to the major peak area of the reference solution (0.2%).
	The corrected peak area (Multiply by correction factor 1.2) of Impurity I (Relative Retention Time approximately 1.6~1.8) should not be more than the major peak area of the reference solution (0.10%).
	The peak area of Impurity D (Relative Retention Time approximately 0.7) Should not more than the major peak area of the reference solution (0.10%).
	The peak area of Impurity K (Relative Retention Time approximately 2.9) Should not more than the major peak area of the reference solution (0.10%).
	The single impurity peak area should not be more than the major peak area of reference solution (0.10%).

Our APIs —Tamoxifen Citrate

Test	Specification
Related substance II	The corrected peak area (Multiply by correction factor 2.8) of Impurity O (Relative Retention Time approximately 1.30) should not more than the major peak area of the reference solution (0.10%).
	The peak area of Impurity L (Relative Retention Time approximately 1.08) Should not more than the major peak area of the reference solution (0.10%).
	The peak area of Impurity P (Relative Retention Time approximately 1.27) Should not more than the major peak area of the reference solution (0.10%).
Total impurities	Total impurities in related substances I and the impurity L, O and P should not be more than 0.5%.
Residual solvents	Methyl Alcohol: Should not be more than 0.3%
	Ethanol: Should not be more than 0.5%
	Acetone: Should not be more than 0.5%
	Isopropanol: Should not be more than 0.5%
	Acetic Ether: Should not be more than 0.5%
	Butylene oxide: Should not be more than 0.072%
	Methylbenzene: Should not be more than 0.089%
	Benzene:Should not be more than 0.0002%
Loss on drying	Should not be more than 0.5%
Residue on ignition	Should not be more than 0.1%
Heavy metal	Should conform with the regulation (Should not be more than 0.001%)
Microbial limit	Aerobic bacteria count: not more than 100 cfu/g
	Fungi and yeasts count: not more than 50 cfu/g
	Escherichia coli: absence in 1 g Not Detected
	Live mites should not be detected
Assay	Not less than 99.0% of C26H29NOC6H8O7, calculated on the anhydrous basis.
Standard	CP & USP

Our APIs

Epalrestat

- Epalrestat is a carboxylic acid derivative and a noncompetitive and reversible aldose reductase inhibitor used for the treatment of diabetic neuropathy, which is one of the most common long-term complications in patients with diabetes mellitus.

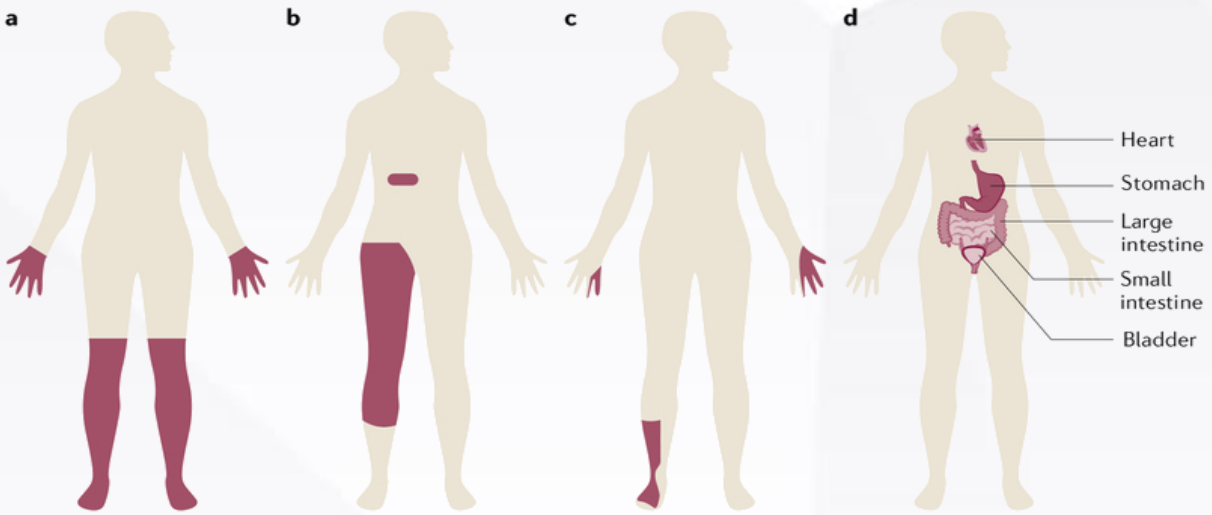


Fig. 9 Types of diabetic neuropathy
a) Peripheral symmetric neuropathy b) Thoracic and lumbar root, or proximal, neuropathy
c) Mononeuropathies d) Autonomic neuropathy

- Epalrestat, an uncompetitive aldose reductase inhibitor, significantly reduces intracellular sorbitol accumulation in sciatic nerve, erythrocytes and ocular tissues from animal models, and in erythrocytes in humans, with diabetes mellitus, without affecting glucose levels. Epalrestat also increased sodium-dependent myoinositol uptake into sciatic nerve tissue in rats and skin fibroblasts from patients with diabetes, and attenuated nerve conduction velocity and retinal changes commonly seen in patients with diabetic neuropathy and retinopathy, respectively.

Our APIs —Epalrestat

- Product Name: Epalrestat
- Catalog No.: ACM82159099
- CAS No.: 82159-09-9

Test	Specification
Appearance	Orange-red crystalline powder, have a specific odor.
Solubility	Freely soluble in tetrahydrofuran, soluble in N,N-dimethylformamide, sparingly soluble in acetonitrile, slightly soluble in methanol or ethanol, practically insoluble in water.
Melting point	221 °C to 225 °C
UV	At 220nm ~ 500nm, the UV-VIS spectrum of the sample should match that of the Reference Standard.
IR	The IR spectrum of the sample should match that of the Reference Standard.
Related substances	The single impurity peak area should not be more than 0.2 times to the major peak area of reference solution (0.2%).
	Total impurity peak area should not be more than the major peak area of reference solution (1.0%).
Loss on drying	Should not be more than 0.5%.
Residual solvents	Ethanol: Should not be more than 0.5%
	Acetone: Should not be more than 0.5%
Acetic acid	The peak area is calculated by the external standard method, acetic acid should not be more than 0.5%
Residue on ignition	Should not be more than 0.1%
Heavy metal	Should conform with the regulation (Should not be more than 0.001%)
Microbial limit	Aerobic bacteria count: not more than 100 cfu/g
	Fungi and yeasts count: not more than 50 cfu/g
	Escherichia coli: absence in 1 g Not Detected
	Live mites should not be detected
Assay	It contains not less than 98.0% and NMT the equivalent of 101.0% of C15H13NO3S2, calculated with reference to the dried substance.
Standard	CP & JP

Our APIs

Edaravone

- Edaravone is a white crystalline powder which is available as a clear, colorless liquid provided as a sterile injection solution supplied for intravenous (IV) infusion.
- Researchers think that oxidative stress due to free radicals is one of the causes of nerve cell death in Amyotrophic lateral sclerosis (ALS) .
- Edaravone acts to increase prostacyclin production, decrease lipoxygenase metabolism of arachidonic acid by trapping hydroxyl radicals, and inhibit alloxan-induced lipid peroxidation and quench active oxygen species. It targets various kinds of cells, including neurons, endothelial cells and myocardial cells.

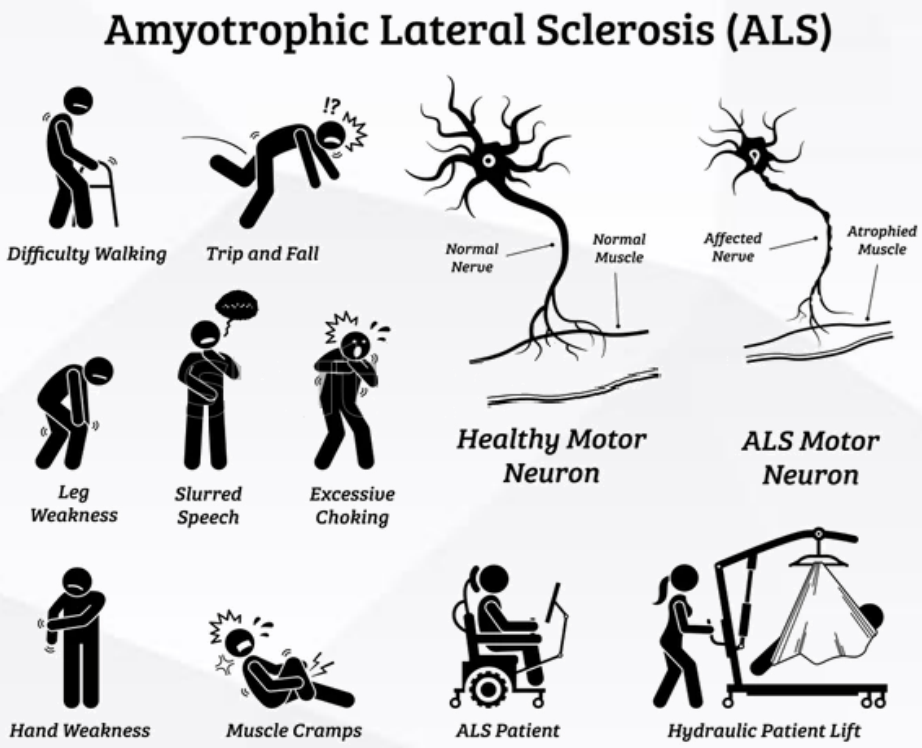


Fig. 10 The symptoms of ALS

Our APIs —Edaravone

- Product Name: Edaravone
- Catalog No.: ACM89258
- CAS No.: 89-25-8

Test	Specification
Appearance	White or almost white, odourless, crystalline powder.
Solubility	Freely soluble or soluble in methanol, soluble in ethanol, very slightly soluble or practically insoluble in water.
Melting point	126 °C to130 °C
Absorption coefficient	770~810
Chemical reaction	It should give positive reaction
UV	This product should have the maximum absorption at 244nm wavelength.
IR	The IR spectrum of the sample should match that of the Reference Standard.
pH	4.5 to 5.5
Clarity and colour of ethanol solution	The solution should be clear and colorless; if the solution shows any colour, it should not be more intensely coloured than reference solution B9.
Related substances	Calculated according to principal component self - comparison method ,the impurity I (RT≈3.0) peak area should not be more than the major peak area of reference solution (0.1%)
	The single impurity peak area should not be more than the major peak area of reference solution (0.1%).
	Total impurity peak area should not be more than the 3 times to the major peak area of reference solution (0.3%).
Phenylhydrazine	Should not be more than 0.0025%
Residual solvents Ⅰ	Ethanol: Should not be more than 0.5%
	Ethyl acetate: Should not be more than 0.5%
Residual solvents Ⅱ	Benzene: Should not be more than 0.0002%
Loss on drying	Should not be more than 0.5%
Residue on ignition	Should not be more than 0.1%
Heavy metal	Should conform with the regulation (Should not be more than 0.001%)

Our APIs —Edaravone

Test	Specification
Bacterial endotoxins	Less than 0.5 EU/mg
Microbial limit	Aerobic bacteria count: not more than 200 cfu/g
	Fungi and yeasts count: not more than 20 cfu/g
	Escherichia coli: absence in 1 g Not Detected
Assay	Not less than 99.0% of C10H10N2O , calculated on the anhydrous basis.
Standard	CP

Customer Services

- Alfa Chemistry has accumulated strong synthetic expertise through our vast range of catalog products. We also provide a full range of custom synthesis and manufacturing services to our clients worldwide for years.

- Our highly skilled Ph.D. and M.S. synthetic chemists will help solve problems you may have in your research. With many years' experience working with APIs companies, our team is prepared to successfully complete any challenging custom synthesis opportunity, from the milligram to kilogram scale in our custom synthesis lab.

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Customer Services

Equipment in our lab

Oven

Ultraviolet Spectrophotometer

HPLC

GC

Microscope

SEM

Our Customer

- As a global Contract Research Organization (CRO), headquartered in New York, USA, Alfa Chemistry has served the pharmaceutical and biotechnology industries for years. Some of our customers are listed below:

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