

Focus on Quality, Topscience Biotech Breaks Through The Sodium Hyaluronate Market With Professionalism.

There is a saying in the industry: worldwide, China Sodium Hyaluronate is the first, in China, Shandong Sodium Hyaluronate should be the first. According to the *2020 Research Report of Global and China Sodium Hyaluronate (HA) Industry Market* released by Frost&Sullivan, the top four sales in the global Sodium Hyaluronate raw material market are all Chinese companies. However, most companies are concentrated in Sodium Hyaluronate cosmetic and food grade, and less involved in the field of pharma grade raw materials. This is due to that the technical requirements and access threshold of pharma grade products are high. Besides, not all Sodium Hyaluronate enterprises can produce and sell pharma grade raw materials. Therefore, new entrants in the industry mostly focus on the cosmetic grade and food grade raw materials markets with low added value.

As one of the main suppliers of sodium hyaluronate in the world, Topscience Biotech may have no advantage in overall production capacity compared with some companies, but after continuous breakthroughs in technical barriers, it has become one of the two largest pharma grade sodium hyaluronate manufacturers in China. Different from other domestic pharma grade sodium hyaluronate manufacturers, Topscience Biotech has always been focusing on the R&D of sodium hyaluronate raw materials with the goal of "specialized in pharma grade sodium hyaluronate", Topscience has been committing to providing customers with the most guaranteed sodium hyaluronate raw materials.

01. Professionalism and Specialization

Topscience Biotech produces high-quality pharma grade sodium hyaluronate.

Throughout the medical aesthetic market, the trend of light medical aesthetic is obvious, the proportion of non-surgical medical aesthetic has increased, and the market scale of injection projects accounts for nearly 60% of the industry, of which sodium hyaluronate is the most popular. According to the big data from Soyoung, the market scale of injection medical and beauty projects accounts for the largest proportion of the industry, about 57.04% in 2019. Among them, sodium hyaluronate injection accounted for 66% and botulinum toxin injection accounted for 33%. Therefore, there is huge room for development in the medical aesthetic finished market, especially for injection products based on sodium hyaluronate raw materials. According to the report data of Orient Securities, in 2019, the end market scale of domestic pharma grade sodium hyaluronate products has reached 7.83 billion yuan, of which the compound growth rate in the field of medical aesthetic is much higher than that of orthopedic treatment and ophthalmic treatment. The proportion of medical aesthetic sales has increased year by year, from 42% in 2015 to 55% in 2019.

However, the entry barrier of sodium hyaluronate API is very high. For enterprises, from product development to market launch, not only the quality audit, confirmation verification and stability investigation that meet the requirements of GMP (Good Manufacturing Practice), but also the drug production license, API registration number and other license certificates are necessary. The whole

process generally takes 2-5 years.

As one of the two largest pharma grade sodium hyaluronate manufacturers in China, all products of Topscience Biotech are produced by microbial fermentation and non-animal origin. It has the advantages of ultra-low impurity level, ultra-low bacterial endotoxins level, ultra-low metal impurity residue, ultra-low microbial contamination and so on. So far, the three core impurity indexes of bacterial endotoxins, nucleic acid and protein of Topscience Biotech pharma grade sodium hyaluronate have reached the industry-leading level.

Taking bacterial endotoxins as an example, the bacterial endotoxins of sodium hyaluronate mainly comes from the materials used in the production process and the gram-negative bacteria that may be introduced in the environment. The bacterial endotoxins is produced when the bacteria is autolyzed or lysed. At present, the level of bacterial endotoxins in the industry is generally controlled at <0.05 IU/mg in accordance with the pharmacopoeia standard, but the bacterial endotoxins of Topscience Biotech pharma grade sodium hyaluronate can be stably controlled at ≤ 0.001 IU/mg, which is 1 / 50 of the value specified in the international standard of European Pharmacopoeia, and is in a leading position in the industry.

In addition, the continuous batch test results of Topscience Biotech PHARMAHYA® INJ sodium hyaluronate (injection grade) show that the impurity level of nucleic acid is less than 0.01 (A260nm), which is also 1 / 50 of the values specified in the international standards of the European Pharmacopoeia. At the same time, the content of protein is lower than the detection limit (0.03%), which is also in the leading position in the industry. From the three indicators, Topscience Biotech not only meets the standard, but also surpasses the standard. It is also one of the few domestic manufacturers of sodium hyaluronate API with Chinese GMP certificate, and the API registration number is in status A. It is worth mentioning that the pharma sodium hyaluronate products produced by the company include injection grade, eye-drop grade, pharmaceutical grade, excipients grade and other specifications. The molecular weight of the product covers all the molecular weight ranges of high, medium and low, which can meet various medical purposes. As can be seen from the above, in the high threshold field of pharma grade sodium hyaluronate, the product quality of Topscience Biotech is very high and is in the leading position in the industry. Topscience Biotech has been deeply involved in the industry for more than ten years, and has been focusing on the R&D, production and sales of biochemical raw materials and cosmetic raw materials, and has continuously been winning the trust and support of customers with professional strength.

02. Strong R&D strength and dedicated product line

Support the continuous products breakthrough of Topscience Biotech.

From the overall perspective of the medical aesthetics industry chain, the degree of differentiation on the raw material side of sodium hyaluronate is not high. As a key factor in manufacturer competition, product R&D capability can support the company's product coverage and basic application. Besides, a deep R&D team and an efficient and collaborative industrialization team can help companies continue

to move to a deeper level.

Shandong Topscience Biotech Co., Ltd. is located in Rizhao City, Shandong Province, covering a total area of 100 thousand m². Specifically, the R&D team of Topscience Biotech has been injecting new vitality into the continuous innovation of the company's products. At present, there are 31 people with intermediate or above professional titles and 35 licensed pharmacists; Secondly, from the perspective of hardware facilities, there are 10 production workshops that meet GMP standards, 3 GLP standardization laboratories, and 1 SPF animal laboratory for rats and mice. In addition, a complete quality system has been established in accordance with ICH, GMP and other international standards. From the collection of raw materials to the release of products, strict and efficient control is implemented to ensure the quality of the products. At the same time, Topscience Biotech has successfully passed the on-site audits by the drug regulatory agency and many well-known European and American companies.

From the team to the infrastructure, to the quality system, a complete and professional process is destined to make Topscience Biotech a representative enterprise of professional raw material manufacturers in the industry. Now Topscience Biotech has more than 30 patents, 8 R&D platforms such as engineering laboratories above the provincial level, 3 international advanced scientific and technological achievements, 4 new products, 11 national third-class new drugs, and 7 various international certifications such as Europe and the United States. There are 35 brand trademarks, and one is involved in the revision of national pharmacopoeia standards. On the whole, there is no doubt about the R&D strength of Topscience Biotech.

While striving to improve its own R&D capabilities, Topscience Biotech also continues to contribute to the development of the industry. As one of the few companies in the country that can do pharma grade sodium hyaluronate, Topscience Biotech uses practical actions to help the industry's scientific R&D. Besides, it also presents the highest-quality pharma grade sodium hyaluronate samples to scientific research institutions and universities for free. It has made an important contribution to the promotion of the development of the industry.

In addition, with many upstream enterprises continue to extend downstream of the industrial chain and expand to various application fields, Topscience Biotech has always been focusing on the field of sodium hyaluronate raw materials.

On the one hand, Topscience enhances scientific research strength and the professionalism and competitiveness of product; on the other hand, Topscience won't form a competitive relationship with customers. Therefore, whether it is based on the hard power of the R&D side or the distribution of benefits on the sales side for customers, the advantages of Topscience Biotech are obvious. Based on the entire medical aesthetics industry, the current development of sodium hyaluronate preparation technology is relatively mature. Besides, the trend of product homogeneity is obvious and the market concentration is relatively high. However, as a raw material manufacturer, production technology has always been the core advantage. Continuous research in the field of technology and R&D is the foundation of enterprise development. Since its establishment for more than ten years, Topscience

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Shandong Topscience Biotech Co., Ltd.



Biotech has always been focusing on the R&D and innovation of sodium hyaluronate and continuously improving its hard strength. Under high standards and strict requirements, Topscience Biotech will have a bright future.