

Crystallization in the pharmaceutical industry

Balbir Negi

SHAH TC Overseas Pvt. Ltd, India

Crystallization has the vital role in the pharmaceutical industry as it is started from intermediates separation process and the final manufacture step as active pharmaceutical ingredients. Crystallization is a key component of almost all processes in the manufacturing of pharmaceuticals. Whether for purification of intermediates, formation of the product, or prevention of crystallization in amorphous products, crystallization is essential in both processing & development. Crystallization can be natural or artificial process of formation of solid crystal precipitating from a solution melts or more rarely deposited directly from a gas. Crystallization is also a chemical solid-liquid separation technique, in which mass transfer of a solute from the liquid solution to a pure solid crystalline phase occurs. If we take an example of third generation, semi synthetic, broad-spectrum cephalosporin Ceftriaxone sodium, which belongs to β -lactam antibiotics. This is most in demand able anti-infectious production India and abroad. The continuous methodical studies and development of R& D have been performed to resolve the problems faced in the industry manufacture of ceftriaxone sodium, for example the low yield of batches, less commercial batches and non uniform of the quality so on. With the help of R & D the problem is studied and continuous lab batches taken and data evaluated. A new process of dilution crystallization has been successfully used for industry manufacture of ceftriaxone sodium, and the product quality, yield and size were enhanced much more than that of the old technology. In past the India has done more studies and research on the crystal formation of ceftriaxone sodium. By evaluating the type of equipment for crystallization, solvent quality, maintaining temperature, recovering solvent, time for reflux, effects of seeds, stirring RPM control, purification and concentration of mother liquor the crystallization process is developed. After intensive work on the crystallization of ceftriaxone sodium has been determined, and the product quality, yield and size are improved.

Biography

Balbir Singh Negi has completed his M.sc Chemistry in 1990 at the age of 23 years from Hemwati Nandan Bahuguna Garhwal University and M.B.A in Project Management from Sikkim Manipal University completed in 2011. In 1996 received D.sc Honorary degree from the Open International University of Complementary Medicine, Srilanka. He is the GM Regulatory Affairs in Shah Trading Corporation Overseas Private Limited, Delhi, INDIA, an APIs trading company having office in India and China. Coordinating the licensing authority Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India and Central Drug Testing laboratory Mumbai India. He has total 22 yrs experience from reputed MNC Ranbaxy labs Ltd, Venus Remedies Ltd and CliniRx Research P Ltd in field of APIs- Manufacturing, Quality Assurance, Regulatory Compliance, Formulation - Regulatory Compliance and CRO - Project Management.

balbir@shahtc.com