Process for Preparation of Copolymer-1-used in the treatment of multiple sclerosis

EXECUTIVE SUMMARY

A novel process for the synthesis of Copolymer-1 and its pharmaceutically acceptable salts, which is used in the treatment of Multiple Sclerosis (MS). This process yields precisely tailored, non-toxic end products with readily available raw materials at a much reduced cost.

BACKGROUND

Out of the many processes available today for synthesis of Copolymer- 1, no process provides control over the specific molecular weight (m. wt.) especially since the m.wt of 22KDa and above is considered toxic and without residual levels of acids.

TECHNOLOGY DESCRIPTION

A novel process using readily available raw materials, for the synthesis of Copolymer-1 and its pharmaceutically acceptable salts is described here. The process uses a polymer bound catalyst as an initiator (which requires 10X less catalyst concentration than conventional systems). The resulting polymer has a narrow molecular weight distribution, with m.wt can be tailored to be in the range of 8-19KDa. Copolymer-1 could be injected subcutaneously, intra-peritoneally, intravenously, intramuscularly for the treatment MS.

MARKET POTENTIAL

- Over 2.5 million people suffer from MS worldwide*
- Even though there is no cure for MS, currently drugs are used to slow the progression or reduce the frequency of relapses
- The global market for MS therapeutics has been projected to exceed $12.5 billion by 2015**
- US has been termed as a growing market for MS therapeutics with the highest demand**

*http://www.wikinvest.com/concept/Multiple_Sclerosis_%28MS%29_Drug_Market
**http://www.prweb.com/releases/multiple_sclerosis_market/autoimmune_disease/prweb3832894.htm

VALUE/ADVANTAGES

- A simple, cost-effective process using easily available raw materials
- Yields a product with high degree of purity (without requiring additional steps of separation, purification etc.)
- Molecular weight can be tailored to be in the range of 8-19KDa (hence overcoming toxicity issues; m. wt of over 20 KDa are known to be toxic)- with excellent control over the m. wt distribution
- High purity levels - almost no acid residues (less than 1%)

APPLICATIONS

- Copolymer-1 is used for treatment of MS
- Suggested application in the treatment of non-autoimmune neurodegenerative disorders such as glaucoma, acute CNS injuries, Alzheimer's disease*

*Kipnis, J. and Schwartz, M., Dual action of glatiramer acetate (Cop-1) in the treatment of CNS autoimmune and neurodegenerative disorders, TRENDS in Molecular Medicine , Vol.8, 2002, Pg. 319-323

TECHNOLOGY STATUS

- Demonstrated at the lab scale
- On the lookout for potential partners for licensing
- Patent applications filed: PCT #- IN2009/000320, Indian #- 0599/DEL/2008

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