PROCESS FOR PREPARATION OF COPOLYMER-1-USED IN THE TREATMENT OF MULTIPLE SCLEROSIS

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Technology

- A novel process for the synthesis of Copolymer-1and its pharmaceutically acceptable salts (which is used in the treatment of multiple sclerosis)
- Using readily available raw materials
- 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
- In treating multiple sclerosis – copolymer-1 could be injected subcutaneously, intra-peritoneally, intravenously, intramuscularly

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Applications

- Copolymer-1is used for treatment of multiple sclerosis
- 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.

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Market Potential

- Over 2.5 million people suffer from multiple sclerosis (MS) worldwide*
- Even though there is no cure for MS, currently drugs are used to slow the progression or reduce the frequency of relapses. In 2007, the market for MS drugs was over $ 7 billion*
- The global market for multiple sclerosis 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 (viewed 10/05/11)
**http://www.prweb.com/releases/multiple_sclerosis_market/autoimmune_disease/prweb3832894.htm (viewed 12/05/11)

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Value

- 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.)
- The process requires 10x less catalyst concentration than conventional systems (lower cost)
- Excellent control over molecular weight
  - Narrow molecular weight distribution
  - 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)
- High purity levels - almost no acid residues (less than 1%)
- Simple and efficient process

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Technology Status, IP Status

- Demonstrated at lab scale
- Ready to be licensed/commercialized
- PCT/Indian patent application filed

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Links & References

- http://www.wikinvest.com/concept/Multiple_Sclerosis_%28MS%29_Drug_Market (viewed 10/05/11)
- 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.
- Spain, R. et *al.*, Recent developments in multiple sclerosis therapeutics, BMC Medicine, 2009, 6 pages.

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Summary

Technology Summary	
Technology title	Process for preparation of copolymer-1
Industry /sector	Pharmaceuticals
Year of development	2006
Related patents (with links)	PCT/Indian patent application filed
Technology readiness level	Demonstrated at lab scale
Licensing status	Ready to be licensed
Encumbrances	None
Availability	Yes

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