

# 2<sup>nd</sup> International Conference and Exhibition on Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

### **Medical Device Regulatory Profile for India**

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Many in the international investment community have identified healthcare in India as a major business opportunity as the sector expands to meet the needs of India's growing middle-class, a population of around 300 million with rising income, increasing expectations and greater access to healthcare services. Despite India's relatively low per capita expenditure on healthcare to date, India's market for medical devices is in the world's top twenty - in 2007 India's medical equipment market was estimated at about \$1.56 billion. The market is expected to grow about 8 percent annually and approach \$2.3 billion by 2012 [source: Espicom Business Intelligence].

Although India has a growing domestic medical device manufacturing sector the country still imports more than half of its healthcare equipment, in particular high technology products.

India has both government and private healthcare providers, however most growth in recent years has occurred in the private sector (which currently contributes about 80 percent to growth in the healthcare delivery market). Medical equipment distribution in India is through regional distributors who have networks of sub-distributors, and the use of a local, well-qualified distributor helps in establishing good relationships influencing buying decisions. Smaller medical electronics manufacturer may find it difficult to compete with the larger, branded medical electronics manufacturers unless the product has niche applications. Regardless of the electronics equipment being imported, a rigorous after-sales servicing plan is expected.

### Biography

He has completed his B.Pharmacy education at Maharashtra College of Pharmacy in 2003. He completed his Masters at Vinayaka Mission Research Foundation in 2009. He served as a Sr. officer- Regulatory Affairs and Compliance in Wockhardt Limited, Gujarat. He also served as Regulatory Specialist (People Manager) Novartis Healthcare Pvt Ltd, Hyderabad. Currently he is working as Manager-Regulatory Affairs India Medtronic Pvt Ltd, New Delhi.

## Method development and validation of the assay and dissolution of a fixed dose combination of tenofovir and efavirenz tablet

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reverse phase-high performance liquid chromatographic method was developed and validated for the simultaneous Adetermination of tenofovir disoproxil fumarate and efavirenz in tenofovir and efavirenz finished formulation product. The method was developed by altering various organic solvents such as acetonitrile and methanol, column, detection, flow rate and temperature. An isocratic elution mode with a mixture of acetonitrile and water in the ratio of (55:45 % v/v) was selected for the mobile phase with a C18 (4.6 mm x 250 mm x 5 m) column as stationary phase for simultaneous separation of tenofovir disoproxil fumarate and efavirenz. The separation was achieved at a flow rate of 1 mL/min and detection wavelength of 252 nm at room temperature. Further, different dissolution media were investigated for optimal release of tenofovir disoproxil fumarate and efavirenz from lamivudine, tenofovir and efavirenz tablets. The optimization of dissolution medium was preceded by establishment of the sink concentration for efavirenz (which is class-II drug) which was found at 0.5% sodium dodecyl sulphate in water with a release of more than 75% of each of the three active pharmaceutical ingredients at 37°C with a paddle method, 75 rpm at 45 min. The analytical method was validated and the linear range was found in the concentration range of 0.05 to 0.12 mg/mL of tenofovir disoproxil fumarate and efavirenz with regression coefficient (r2) of 0.9984 which met the acceptance criteria of r2 equal or greater than 0.98. The % rsd for the intra-day precision were 1.23% and 1.46% for tenofovir disoproxil fumarate and efavirenz respectively. The % rsd for the inter-day precision were 1.99% and 1.67% for tenofovir disoproxil fumarate and efavirenz respectively. The test method had an acceptable level of accuracy for the assay of tenofovir disoproxil fumarate and efavirenz in tenofovir and efavirenz tablets from 50 % to 120 % of test concentration with % rsd less than 2% for all three active pharmaceutical ingredients. The test solution remained stable when stored at 4°C for 72 hours. The method was robust as it remained largely unaffected by small variations in temperature and mobile phase. All of these assessed parameters complied with the acceptance criteria hence indicated the usefulness of the reverse phase-high performance liquid chromatographic method for determination of assay and dissolution release testing for finished formulation product which contain tenofovir disoproxil fumarate and efavirenz active substances.