J Bioequiv Availab 2015, 7:5
http://dx.doi.org/10.4172/0975-0851.S1.022

OMICS International
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6th World Congress on
Bioavailability & Bioequivalence:
BA/BE Studies Summit

August 17-19, 2015 Chicago, USA

## Effect of Atorvastatin and Vitamin D on Rheumatoid Arthritis in experimental animals

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Rheumatoid arthritis (RA) is the most common chronic systemic, immune-mediated inflammatory disorder that attacks flexible joints and also may affect many tissues and organs. The present study was designed to assess the effect of atorvastatin and vitamin D on RA and to compare it with that of methotrexate in female Wistar albino rats. Rheumatoid arthritis was induced by subcutaneous injection of Complete Freund's Adjuvant (CFA). Seventy rats were divided into (7) groups, each of 10 rats. Group I was kept as control. Group II was injected with 0.4 ml CFA for 12 days. Group III, IV and V were injected with CFA then treated with methotrexate, atorvastatin and vitamin D, respectively. Group VI and VII were injected with CFA then treated with atorvastatin plus methotrexate; vitamin D plus methotrexate, respectively. Blood samples were collected after four weeks of the last dose of treatment for hematological examination. Serum samples were used for detection of inflammatory markers and lipid profile. A significantly increase of total leucocytes, neutrophils, lymphocytes, serum tumor necrosis factor α (TNFα), interleukine-6 (IL-6), total cholesterol (TC), triglycerides (TGs) and low density lipoprotein cholesterol (LDL) were observed in arthritis rats with significant decrease in high density lipoprotein cholesterol (HDL). Treatment with atorvastatin and vitamin D significantly decrease TNF α, IL-6 and modulate the leukocytosis and lipid abnormalities comparable to that exerted by methotrexate. The combination therapy was even better than each drug alone and is promising for further clinical trials.

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## Regulatory transparency: Key aspects throughout access BA/BE report

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**Introduction:** Brazil is the 5th biggest pharmaceutical market in the world, and the Brazilian Heath Surveillance Agency (ANVISA) is responsible to evaluate the products quality and safety. Hence, in the field of health regulation, the wide access to data of drugs and related technical documents, especially BA/BE report data, is in expansion at FDA, EMA and ANVISA. A fact to be evaluated is how disclosure policies are built, emphasizing the regulatory impact analysis and detecting the risks and benefits involved. Bioavailability and Bioequivalence Studies (BA/BE) is essentially significant as contain vital information regard drug variability and pharmacokinetic profile over and above is the primary source of information about product efficacy (Generics or multisource products).

**Discussion:** Actually the Brazilian Electronic Database (Sineb) has more than 2000 BA/BE reports of which 30% had negative results, but none of these trials are available for public consultation. Around 300 studies were pilots, performed in order to gain knowledge (Pharmacodynamics/Pharmacokinetic) about the API (Active Product Ingredient). The openness will enable public scrutiny and secondary analysis probably resulting in improvement of the products quality and public health development as well as the social accountability. Over and above the reanalysis will reinforce confidence over Agency´s skills, in the other hand inappropriate re-analysis or methodologically flawed can mislead treatment adherence or public health programs.

**Conclusion:** Responsible public disclosure of BABE reports lead to improve the common knowledge about API characteristics avoiding unnecessary studies as well as protecting voluntaries integrity. However, some boundaries should be respected in order to not frustrate investments on bio-pharmaceutical research and development (R&D) along with not to bias the Agency's decision-making process. After all, decreasing the number of tests imply lowering the registers costs.

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