Publications Template

#	Research Title	Field	Abstract	Year of Publication Publishing	Publishing Link "URL"
1	**Basant A. Abou-Taleb**, Maha Bondok, Mohamed Ismail Nounou, Nawal Khalafallah and Saleh Khalil; **Are multisource levothyroxine sodium tablets marketed in Egypt interchangeable?**; Annales d'Endocrinologie, 79 (2018) 23–29	Pharmacy & Pharmacology	A clinical study was initiated in response to patients' complaints, supported by the treating physicians, of suspected differences in efficacy among multisource levothyroxine sodium tablets marketed in Egypt. The study design was a multiple dose (100 µg levothyroxine sodium tablet once daily for 6 months) and involved 50 primary hypothyroidism female patients (5 equal groups). Tablets administered included five tablet batches (two brands, three origin locations) purchased from local pharmacies in Alexandria. Assessment parameters (measured on consecutive visits) included the thyroid stimulating hormone, total and free levothyroxine. Tablet dissolution rate was determined (BP/EP 2014 & USP 2014). In vitro vs in vivovs correlations were developed. Clinical and pharmaceutical data confirmed inter-brand and inter-source differences in efficacy. Correlations examined indicated potential usefulness of in vitro dissolution test in detecting poor performing levothyroxine sodium tablets during shelf life.	**2018**	https://www.sciencedirect.com/science/article/abs/pii/S0003426617309095

2	**Basant A. Abou-Taleb**, Maha Bondok, Mohamed Ismail Nounou, Nawal Khalafallah and Saleh Khalil; **Effect of batch age on potency and dissolution of levothyroxine sodium tablets: Impact of BP and USP monograph differences on dissolution results.** Drug Development and Industrial Pharmacy, 2018, 44:11, 1762-1769, DOI:10.1080/03639045.2018.1496446	Pharmacy & Pharmacology	Controversies surround levothyroxine sodium as a drug and product, and are reflected in compendia (USP vs BP) differences in levothyroxine sodium tablets specifications concerning potency limit and dissolution test conditions, and in lack of consensus on several issues such as whether the drug BCS class I or III. We have recently published a clinical study in patients comparing the efficacy of multisource 100 mcg levothyroxine sodium tablets (three sources, two brands, a total of five batches). Clinical efficacy and dissolution rate data varied among the tablet batches studied and indicated that brand/source interchangeability could not be claimed. The efficacy parameters showed good correlation with dissolution data generated under BP 2014, but not under USP 2014 dissolution test conditions. In the present study, we decided to expand the number of tablet batches studied in vitro to a total of 12, to report potency and content uniformity data missing in the clinical study, and to further examine the discrepancy in dissolution results based on the medium used. The wide range of batch age in the studied samples allowed investigating the effect of batch age on in-vitro tablet performance parameters. Generated potency values indicated the prevalence of super-potent tablet batches. The dissolution data reflected the effect of compendia monograph differences in dissolution medium. The results also indicated an inverse relationship between tablet potency and batch age and, between dissolution and batch age. The possible effect of potency results on the generated dissolution data was discussed. Statistical significance of correlations examined was assessed by linear and non-linear regression analysis. Statistical significance was evident for the relation between batch age and BP 2014 dissolution data, compared to USP 2014 dissolution results.	**2018**	https://www.tandfonline.com/doi/abs/10.1080/03639045.2018.1496446

3	**Basant A. Abou-Taleb**, Magdy H. Megallaa, Nawal Khalafallah and Saleh Khalil; **In-vitro and in-vivo performance of locally manufactured glimepiride tablet generics compared to the innovator (Amaryl®) tablets** Drug Development and Industrial Pharmacy, 2020 Feb 1;46(2):192-9. DOI:10.1080/03639045.2020.1716369	Pharmacy & Pharmacology	Both physicians and patients in Egypt often express concern as to the clinical efficacy of locally manufactured glimepiride tablet generics whenever adequate control of blood sugar is not achieved with these products. The present study addresses this issue. The pharmaceutical quality of four glimepiride 3mg tablet generics purchased in Egypt from local pharmacies was assessed relative to the innovator product (Amaryl®), 3mg tablets. Uniformity of Content, dissolution rate, disintegration time and hardness were determined. Products were subjected to a 6-month stability study under stress condition (40° c/75%RH). The same brands were evaluated in vivo in a clinical study conducted in the Main Alexandria University Hospital involving 100 patients (20 patients per brand including innovator). Patients recruited were newly diagnosed type II diabetics. Glimepiride tablets were used as a monotherapy. Fasting blood glucose (FBG) and glycosylated hemoglobin (HbA1C) were measured over a period of 3months. The results indicated differences ($p \leq .05$) in the in vitro and in vivo performance of the tested products; innovator and tested generics substitution was not evident. The stability study indicated that the tablets were prone to deterioration in their physical characteristics, particularly dissolution profiles, upon storage of blisters in a hot humid climate. In vitro/in vivo correlations were investigated seeking to identify an in vitro test to serve as a performance indicator for glimepiride tablets in the post-marketing period. The similarity factor (f2) of the dissolution data proved to be a good indicator of in vivo performance of the tablets.	**2020**	https://www.tandfonline.com/doi/abs/10.1080/03639045.2020.1716369