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# Quality assessment of glibenclamide and nifedipine tablets in community pharmacies in lagos state

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- *Abstract:*

### Background

Glibenclamide and Nifedipine are used as mainstay for two common chronic diseases in developing countries, diabetes & hypertension<sup>1</sup>. Often, patients cannot insist on brand faithfulness and many healthcare workers do not think about therapeutic inequivalence. Both drugs belong to the Biopharmaceutical Classification System (BCS) class II with poor water solubility and ultimately variable absorption<sup>2</sup>.

### Methods

Three (3) brands each of glibenclamide & nifedipine were purchased from community pharmacies in Lagos. Physicochemical quality tests were carried out as specified by USP (United States Pharmacopoeia) 2007 and results compared to set guidelines.

### Results

The results showed that the products had acceptable physical quality & percentage content (official requirements, within 90-110% of stated content). None of the glibenclamide brands passed the dissolution test with percentage release varying between 31.5-72.5% at 30 minutes. One brand was equivalent to the innovator. This may have an effect on *in vivo* bioavailability. For nifedipine, two products passed the compendial requirement at 3, 6 and 12 hours respectively while the 3<sup>rd</sup> product failed. None of the brands was similar to the innovator.

### Conclusion

From the results obtained, *in vitro* dissolution inequivalence infers *in vivo* bio-inequivalence. It is recommended that further studies on *in vivo* bio-equivalence of these drugs and in fact, drugs used interchangeably for chronic diseases, be carried out to allow for determination of drug release behavior.

### References

1. Koda Kimble, M. Applied Therapeutics for Clinical Pharmacists. Washington D.C, USA. 1999
2. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). Guidance for Industry Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations. March 2003. Pgs 3, 6-12. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070124.pdf>

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