

Faculty	Natural Sciences			
Home Department	School of Pharmacy			
Module Topic	Regulatory Sciences and Generics and Biosimilars			
Generic Module Name	Regulatory Sciences			
Alpha-numeric Code	PAR 813			
NQF Level	9			
NQF Credit Value	10			
Duration	Semester			
Proposed semester to be offered.	First Semester			
Programmes in which the module will be offered	MSc (Pharmacy Administration and Policy Regulation) (3859)			
Year level	8			
Main Outcomes	<p>On completion of this module students should be able to:</p> <ul style="list-style-type: none"> • Interpret the regulation of Generic medicines and Biosimilars. • Contribute to the further development of the above-mentioned regulations. • Provide valuable assistance to those applicants aiming to market these two groups of medicines. 			
Main Content	<ul style="list-style-type: none"> • The study of the continual advancement and development of the legislation, regulations and science - especially of the Biosimilars • The investigation of aspects of quality, safety and efficacy of these medicinal products and the effects of these factors on the access by patients of these agents and finished products 			
Pre-requisite modules	None			
Co-requisite modules	None			
Prohibited module Combination	None			
Breakdown of Learning Time	Hours	Timetable Requirement per week		Other teaching modes that does not require time-table Online Course. No Timetable Requirements.
<i>Contact with lecturer / tutor:</i>	20	<i>Lectures p.w.</i>	0	
<i>Assignments & tasks:</i>	35	<i>Practicals p.w.</i>	0	
<i>Practicals:</i>	0	<i>Tutorials p.w.</i>	0	
<i>Tutorials:</i>	10			
<i>Tests & Examinations:</i>	0			
<i>Selfstudy:</i>	0			
<i>Other:</i>	35			
Total Learning Time	100			
Methods of Student Assessment	Continuous Assessment (CA): 50% Final Assessment (FA): 50%			
Assessment Module type	Continuous and Final Assessment (CFA)			