ZAMBIA MEDICINES REGULATORY AUTHORITY

New Dossier Submission Checklist

A completed copy of the checklist should be included in the dossier.

1. Supporting documents

Supporting documents	Yes (Y)/ No (N)/ Not applicable (N/A)	Comment	*For ZAMRA Use Only*
Letter of application			
Proof of payment			
Samples			
Samples CoA			
WHO-type CPP			
Package insert and patient information leaflet			
Label			

2. Dossier

CTD sections	Description	Yes (Y) No (N)	Comment	*For ZAMRA Use Only*
Module 1, section1.2.1	Administrative information			
Module 1, section 1.3	Product Profile			
Module 2	Expert Reports			
Module 3	Chemical and Pharmaceutical Information			
Module 3, section 3.2.P.1	Composition			
Module 3, section 3.2.P.2	Development Pharmaceutics			
Module 3, section 3.2.S, 3.2.R and 3.2.P.4	Control of starting Materials			
Module 3, section 3.2.P.7	Packaging Material			
	Control Tests on Intermediate Products			
Module 3, section 3.2.P.5	Control tests on the Finished Product			
Module 3, section 3.2.P.3	Method of Preparation for the Finished Product			

Module 3, section 3.2.P.8	Stability Tests on the Finished Product			
Module 4	Summary of Toxico-pharmacological Documentation of a Medicine			
Module 5	Bioavailability/ Bioequivalence Data			
Module 5	Summary of Clinical Studies			