WHO Prequalification of Vector Control Products

Data requirements table – Module 2

DR code	Requirement	Description/notes	Method[1]/reference	Form/template
2.0	Module 2 index	Identification of supporting information included within Module 2 to address the data requirements.		• Template Module 2 index
2.1	Description of product development	The rationale for choosing specific ingredients in the formulation; their concentration informed by assessments of quality, safety, and efficacy; their compatibility with the active ingredient(s) and polymers; optimization of the formulation and manufacturing process, etc.		
2.2	Summary of test samples	Summary of identifying information about product samples used in testing, such as batch IDs, formulation codes, and manufacturing process for all product samples used in data generation and the corresponding studies.		
2.3	Discipline summaries	This is the applicant's opportunity to provide a summary of the supporting information provided for each discipline and communicate the applicant's interpretation of the supporting information.		
2.3.1	Quality summary	Summary of data submitted in support of the product quality and interpretive analysis.		• Template Quality dossier summary

[1] Methods identified should be used for the generation of data. Additional and/or alternative methods may be proposed by applicants provided that complete description of the method and validation is included.

DR code	Requirement	Description/notes	Method[1]/reference	Form/template
2.3.2	Safety summary	Summary of risk conclusions in support of the product safety, and identification of any recommended/required mitigative approaches for reducing potential risks.		
2.3.3	Efficacy summary	Summary of data submitted in support of the product efficacy and interpretive analysis across the available studies.		
2.4	Other related information	To be proposed by applicant as necessary.		