

Module 2. Data requirements table

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.		<ul style="list-style-type: none"> Template Module 2 index
2.1	Description of product development	A narrative description of the product development process which includes, but is not limited to, information about the rationale for active ingredient and formulant selection, optimization and finalization of the formulation, development of the manufacturing process, scalability of manufacturing process to commercial production, etc.		
2.2	Product summary	<p>Description of the product, components/equipment for deployment, intended use pattern, and justification for the claim of duration of intended useful life.</p> <p>Also includes specific summary information for Modules 3, 4 and 5.</p>	Implementation guidance - Product Summary	<ul style="list-style-type: none"> 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.

Spatial emanators guidance

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2.3	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.		
2.5	Other related information	To be proposed by applicant as necessary.		