Module 3. Data requirements table

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
3.0	Module 3 index	Identification of supporting information included within Module 3 to address the data requirements.		• Template Module 3 index	
3.1	Declaration of product formulation (DPF)	The complete product composition and purpose of all formulants in intermediates and finished fabrics.	Implementation guidance (IG) – DPF for spatial emanators	• Template DPF for spatial emanators	
3.2	Product manufacturing details	A key difference between the manufacturing details in Module 3 and the information required in sites master files (SMFs) for Module 6 is that the description of manufacturing process defines all equipment, settings/ranges, speeds and temperatures which must be followed to produce the product as intended. The SMF and quality management system are the system by which a manufacturer ensures that the declared process is followed.	IG – Product manufacturing details – spatial emanators		

[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	Number of batches to test
3.2.1	Declaration of manufacturing sites (DMS)	Identification of the manufacturing sites where source active ingredients (AIs) are produced and the manufacturing sites (including their function(s)) for production and storage of the end-use products prior to release.		• Template DMS	
3.2.2	Control of starting materials	Presentation of the acceptance criteria for use of starting materials in the formulation of the product.			
3.2.3	Batch delineation and formula	Presentation of how batches are defined/delineated for the product and a formula with applicable volumes for a typical batch.			
3.2.4	Description of manufacturing process (DMP)	Complete narrative of the manufacturing process, including the necessary equipment/settings to produce the product as intended.			
3.3	Declaration of product construction, if applicable	Declare the configuration of product components which constitute the final product construction.	May refer to Module 2 Product Summary.		
3.4	Declaration of sampling procedure	Declare the appropriate sampling procedure for data generation and quality control purposes.	IG – Declaration of product sampling		

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3.5	Description of device/ equipment	For active emanators, a description of the device or equipment through which the product is intended to be applied.	May refer to Module 2 Product Summary.		
3.6	Chemical characteristics	The chemical characteristics of the formulated product and the integral components, using established sample preparation and analytical chemistry methods, for the purpose of assessing the following and informing product testing activities by procurers/users.	IG – Physical chemical characterization		5

3.6.1	Verification of the target dose, homogeneity of the formulated product and consistency of production	Chemical analysis of total AI conducted in a manner to capture heterogeneity of the formulated product. Includes identification of the enforcement analytical method.	CIPAC, AOAC or equivalent* *Internationally validated methods (for example, CIPAC or equivalent) must be used for the quantification of AI from product samples. In cases where a new or amended extraction or preparation method is required, an independently validated method should be developed and submitted to support the assessment of AI quantification of samples. New or augmented methods		5

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
			must then be internationally validated for use as the reference method for manufacturing release specifications and other forms of product testing.		
3.6.2	Emanation rate study	Study investigating the emanation rate from the product at different temperatures.	IG – Emanation rate study		5
3.7	Physical characteristics	The physical characteristics of the formulated product based on the formulation type and declared construction of the product (if applicable).	IG – Physical chemical characterization		5
3.8	Storage stability	Storage stability data should be generated using samples which have been subjected to accelerated storage conditions as well as real-time storage conditions. Data from real-time storage samples may be submitted post-prequalification.	IG – Storage stability		3
3.9	Manufacturing release specifications	A set of attributes and quality control tests relying on validated methods and established limits that the product needs to meet to be considered of acceptable quality.	IG – Physical chemical characterization	• Template MRS	

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
3.10	Other related information	To be proposed by applicant as necessary.			