1.2.2.3 Dossier product batch information

The following are particulars which clarify the pharmaceutical development of the dosage form, from which data furnished in the undermentioned Modules were derived:

	3.2.P.3	3.2.P.5	3.2.P.8	3.2.R.1	
	Manufacture	Control of final pharmaceutical product	Stability	Bioequivalence	Dissolution
1. *Types of batches					
2. Lot number/s					
3. Lot size/s					
4. Date/s of manufacture					
5. Site/s of FPP manufacture					
6. Formulation and manufacturing process as applied for (Y/N) (clarify if not)					
7.** Site 1 of API 1					
8. Site 2 of API 1					
9.** Site 1 of API 2					
10. Site 2 of API 2					

* Experimental, pilot or production

** Add as many rows as necessary for APIs and API manufacturing sites