APPENDIX 5: SUPPORTING DOCUMENTS REQUIRED FOR CHANGE OF MANUFACTURING SITE (COS) APPLICATION

Supporting documents required for change of manufacturing site (COS) application

No.	Document to be submitted	Type I	Type II	Type III	Type IV	Type V
1	Letter of authorisation/ appointment from the product owner to authorise Product Registration Holder to submit the change of site application. In case of a contract manufacturer, a letter of acceptance from the proposed contract manufacturer to manufacture the product.	√	√	√	√	√
2	Letter from the manufacturer/ product owner to clarify/ explain the need to change site of manufacture.	√	√	√	√	√
3	Written declaration from the manufacturer to certify that the manufacturing process, and the release and expiry (check) specifications of the product as the same as already approved. *OR* If there are minor changes, to declare the "minor changes" & justify the need for such changes.	√	√	√	√	√

4	"Release" and "end-of-shelf life" specifications from proposed site.	√	√	√	√	√
5	Original copy of the Certificate of Free Sale (CFS) / Certificate of Pharmaceutical Product (CPP) and notarised Good Manufacturing Practice (GMP) from the source country of the new manufacturing site in the case of an imported product *OR* Letter of confirmation on GMP status or valid manufacturer's licence for the new manufacturing site.	√	√	√	√	√
6	Specification of the drug substance	√	√	√	√	√
7	Product formula/ Batch Manufacturing Formula	√	√	√	√	√
8	Original copy of Certificate of Analysis (CoA) from the new manufacturing site.	√	√	√	√	
9	Comparative batch analysis data of drug product of at least two production batches (or one production batch and two pilot batch) from the proposed site and last three batches from the current site; batch analysis data on the next two full	√	√	√	√	

	production batches should be available upon request or reported if outside specifications (with proposed action).					
10	"Accelerated" and on-going stability data as per ASEAN Guideline on Stability Study of Drug Product and a letter of commitment to submit real time stability data.	√	√	√	√	
11	Amended immediate label, outer label and package insert for the product from the proposed site.	√	√	√	√	√
12	Process validation report as per ASEAN Guideline On Submission Of Manufacturing Process Validation Data For Drug Registration.	√	√	√	√	
13	Holding time studies testing of bulk pack during storage and transportation between the bulk production site and primary packager (where applicable).	√	√	√	√	
14	Letter of commitment to submit stability data, certificate of analysis, process validation report (where applicable) and sample for laboratory testing within 6 months of approval of site change.					√

15	A written plan for assessing the effect of the change of site on the quality of the product with the objective of demonstrating that the pre- and post-change products are equivalent.	√	√		√	