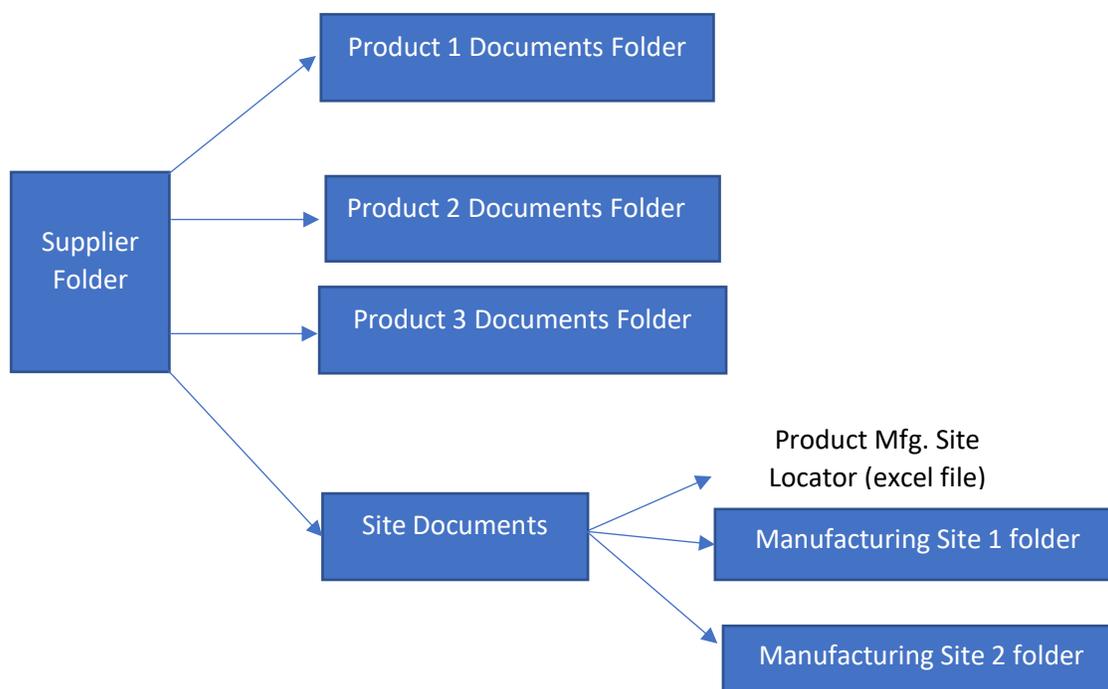


1. For a link to the UNICEF Supplier Document Library on SharePoint send a request to Rennie Shonhiwa-Chikwanha (email: rshonhiwa@unicef.org) including full name and address of the bidder, INN descriptions of products of interest and their respective manufacturing sites (name, physical address, city & country) and contact details of person(s) in the company that should have access to the SharePoint library.
2. The **Product (Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPQ)-Automated pdf version)** and the **Manufacturer (Annex 2a UNICEF Technical Questionnaire for manufacturers)** questionnaires are the basis of the UNICEF technical evaluation.
3. Please ensure you upload the **Product and Manufacturers questionnaires in their original format. i.e. please DO NOT upload printed/scanned versions. The forms are automated hence cannot be processed if a scanned version is uploaded.**
4. In the UNICEF Supplier Document library, each supplier has its own folder, which contains Named Product folders (for each INN and strength) and Site documents folder. Only one Site Documents folder is allocated to each supplier and it contains a Product Manufacturing Site Locator (excel file) and Manufacturing site folders 1,2...etc.) as depicted in figure 1 below.

Figure 1: Supplier folder structure



Please note that product folders are created for each product strength (for e.g., Amoxicillin 250mg and Amoxicillin 500mg) and you need to upload documents into respective Product documents and Site documents folders even if they are similar or have been already uploaded in the other product folder having different strengths e.g., you need to again upload the same documents (if applicable) in each strengths folder for e.g., Amoxicillin 250 mg and Amoxicillin 500 mg for e.g. even if API, mfg. site is same for both the strengths.

INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT

5. For each Named Product folders (for each INN and strength) please upload the required documents as mentioned in the Table 1 below in the section “Product Documents”.
6. Product Mfg. Site Locator (excel file located in Site Documents folder) needs to be completed. This file is used for locating specific Manufacturing Site (e.g., 1 or 2 or 3) for a specific product *and its strength*. The product and its mfg. site must match with the details mentioned in the Product (Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)-Automated pdf version).
7. For each manufacturing site – please upload the required documents as mentioned in Table 1 below in the section “Site Documents (for each mfg. Site)”.
8. Please upload only pdf or word Doc or Jpeg (for pictures/ Images) files in Product documents and Site documents folder. Do not upload any “zip folders” or “folders” in Product documents and Site documents folder. (e.g., COA’s or stability reports for 3 batches should be scanned as one file). Scanned files for the annexes of the IAPPQ can be uploaded.
9. If you do not have any Annex (for product or site or other documents) to upload for any reason, please mention the specific reason for the same on a word /pdf file and upload the same in that respective Annex upload. e.g. Not Applicable or Will submit the document later (by XXXX date) or Document cannot be provided or Not available or any other reason as applicable.

Table 1: Documents to be provided by Suppliers

Site Documents (for each mfg. Site) (for a specific manufacturing site where the product is produced)	Product Documents (refers to product specific documents)		
Annex 2a UNICEF Technical Questionnaire for manufacturers	Annex 2c Interagency Finished Pharmaceutical Product Questionnaire (IAFPPQ)-Automated pdf version	Annex 2h Interagency Finished Pharmaceutical Product Questionnaire for BTPs and SBPs	Annex 2f UNICEF Technical Offer form
Site Master File (pdf or word document)	Annex 2d IAFPPQ Commitment and authorization - Section 5	Annex 2d IAFPPQ Commitment and authorization - Section 5	Annex 2g UNICEF Technical commitment declaration form
Manufacturing License from your National Regulatory Authority.	Annex A Batch Formula	Annex A Batch Formula	CoA
Copy of the latest inspection report.	Annex B Primary Packaging	Annex B Primary Packaging	CoPP (Certificate of Pharmaceutical Product)
Most recent GMP Certificate(s).	Annex C Secondary Packaging	Annex C Secondary Packaging	Copy of product registration & market status
List of all the recent GMP inspections performed at the site.	Annex D Manufacturing License (FPP & API)	Annex D SMF of all manufacturers	Labelling (Primary & Secondary)
Copy of relevant closing letters from the GMP inspections.	Annex D1 Copy of product registration & market status- License No.	Annex E Product registration and market status	SmPC and PIL

INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT

List of products currently supplied to UNICEF.	Annex E CoPP (Certificate of Pharmaceutical Product)	Annex F CoPP (Certificate of Pharmaceutical Product)	Annex 2i Letter of Authorization permitting UNICEF and PAHO to access information
List of products submitted for tender.	Annex F Acceptance/Deficiency letter issued by PQP/SRA	Annex G Historical deficiency/acceptance letter for Product Dossier issued by WHO PQ/SRA	
	Annex G WHO Prequalification letter	Annex H -List of other countries where product is registered/marketed	
For Wholesalers Only	Annex H WHO acceptance letter for Product Dossier	Annex I -WHO Prequalification acceptance letter	
Annex 2b UNICEF Technical Questionnaire for wholesalers (required only for wholesalers)	Annex I Labelling (Primary & Secondary)	Annex J - WHO acceptance letter for product dossier with WHO reference number	
Evidence from wholesaler that they are authorized by manufacturer to distribute the product.	Annex J SmPC and PIL	Annex K -SRA acceptance letter for product dossier with reference number	
	Annex K API GMP certificate	Annex L -primary and secondary packaging/label	
	Annex L API specification (FPP Mfc. Internal specif.)	Annex M -Patient information leaflet/package insert	
	Annex M Method Validation for API	Annex N -GMP certificate of the API manufacturer(s) from the country of origin	
	Annex N Data on validation for sterile API	Annex O - Inspection reports related to GMP inspections conducted in the last 3 years	
	Annex O API COA (API Mfgr. & FPP Mfgr.)	Annex P - Description of the raw and starting material	
	Annex P1 CEP certificate for API	Annex Q - Summary of the viral validation studies	
	Annex P2 Technical file (DMF)	Annex R - summary of clearance data gathered using model viruses	
	Annex Q FPP GMP certificate	Annex S - Summary of the risk minimization measures (animal spongiform encephalopathy agents)	
	Annex R FPP Specifications (release & shelf life)	Annex T -Copy of the internal API(s) specification(s)	
	Annex S FPP COA (3 batches)	Annex U - DS manufacturer justification of specifications	
	Annex T Process Flow Sheet (FPP- mfg. process)	Annex V - Validated analytical methods for API with in-house analytical method	

INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT

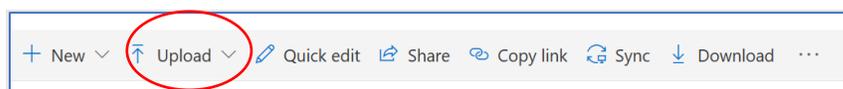
	Annex U Data on validation of sterile aspects for sterile FPP products	Annex W - Data on validation of the aseptic manufacturing of the product	
	Annex V Stability Data -FPP (long term & Accl.)	Annex X -certificate(s) of analysis of the API from the API and FPP manufacturer	
	Annex W Stability Declaration (API used)	Annex Y - Recent/valid GMP certificates of the FPP	
	Annex X Status of On-going Stability	Annex Z - GMP inspection reports related to inspections conducted in the last three years	
	Annex Y In-use Stability Data	Annex AA - Copy of In-house specification if it is different from BP, USP and Ph.Int	
	Annex Z Summary of pharmacology, toxicology and efficacy of the product.	Annex AB - Copy of the certificate of analysis for the three last batches	
	Annex AA Graphic summary of BE results	Annex AC- Flow diagram and narrative (FPP- mfg. process)	
	Annex AB BE study Report	Annex AD - Summary of the evaluation, justification and coding of the major manufacturing changes	
	Annex AC Schematic representation of BE study design	Annex AE - Summary of the comparability exercise	
	Annex AD Therapeutic Equivalence Protocol	Annex AF - Summary of the microbiological control strategy	
	Annex AE Power of Attorney	Annex AG - Data on validation of the aseptic process validation of the product	
	Annex 2e UNICEF API Declaration form to be filled by FPP manufacturer	Annex AH - Protocol and Stability Data -FPP (long term & Accl.)	
	Annex 2i Letter of Authorization permitting UNICEF and PAHO to access information	Annex AI -Stability Declaration (API used)	
		Annex AJ - Status report of any ongoing stability studies	
		Annex AK - In-use stability data and storage conditions after reconstitution for oral powder for suspension, powder for injection, or injection that may be further diluted, or multidose containers	
		Annex AL - Summary of pharmacology, toxicology and efficacy of the product	

INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT

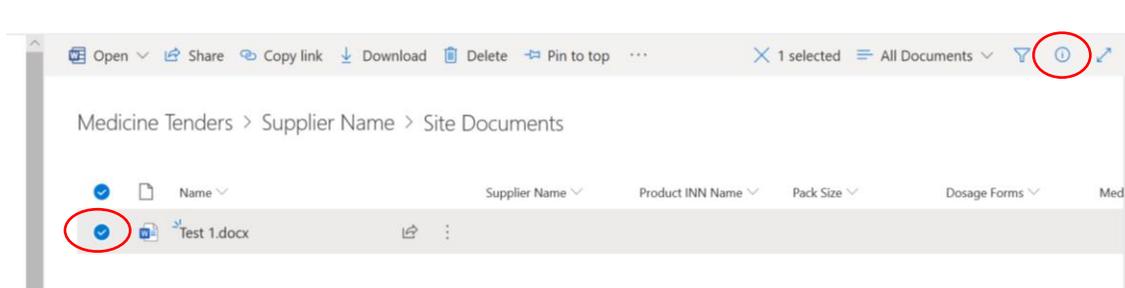
		Annex AM - summary of the demonstration of biosimilarity (quality, safety and efficacy)	
		Annex AN - Results for demonstration of biosimilarity of the SBP (quality)	
		Annex AO - summary of the safety and efficacy data	
		Annex AP - summary of the PK/PD studies	
		Annex AQ - Copy of the power of attorney	
		Annex 2e UNICEF API Declaration form to be filled by FPP manufacturer	
		Annex 2i Letter of Authorization permitting UNICEF and PAHO to access information	

10. To upload files on our SharePoint:

- i. Click on the link provided. It will take you to your supplier folder.
- ii. Click on the appropriate type of folder for the document to be uploaded (Site Documents or Product Documents)
- iii. Click on "Upload".



- iv. Select "Files" and choose the file you want to upload.
- v. Once the file is uploaded, select the file by ticking the circle that appears on left when you mouse over the files and click on the "i" icon (*open details pane*) on the top right corner.



- vi. Using the vertical slide bar at the far right, scroll down to "Properties" and click on "Edit All".



vii. Complete the relevant fields. *NB ensure to complete only the Medicine Product Documents field for medicines or Medicine Site Documents for manufacturing site but do not complete both fields for one document.*

Content Type
UNICEF Document

Name *
Test 1 .docx

Medicine Product Documents
Select options

Medicine Site Documents
Select options

Dosage Forms
Select options

Pack Size
Enter value here

Save Cancel

viii. When entering the pack size value, the following format must be used; for blister packs e.g. 10 x10, 5 x 10 etc. & loose or bulk packs e.g. 100, 1000 etc. Also indicate whether it's a vial, ampoule, bag etc.

Pack Size
Enter value here

- ix. Click on "Save".
- x. Repeat for all the documents. These will be secured for future tenders, so the documents uploaded will remain in this file for each tender unless amended. Updates can be made if needed.
- xi. When uploading documents for more than one product, please ensure that you upload the files in the correct product folder.