Please find below documentation (certificates, analysis, etc.) that may be requested by UNRWA in case of tendering exercise at a later stage.

1) **Documentation to be submitted for products not registered in stringent regulatory authorities (SRA) [1] :**
   - Formulation of the product (complete qualitative and quantitative composition including active ingredient(s) and excipients.
   - Description and composition of primary packaging materials.
   - Description and composition of secondary packaging materials.
   - Copy of primary and secondary packaging/label.
   - Patient information leaflet/package insert.
   - Copy of product registration and market status.
   - Certificate of pharmaceutical product (CPP) according to the WHO certification scheme (WHO technical report series, no. 863. An earlier version is not acceptable)
   - List of countries where the product is registered and is currently marketed
   - Good manufacturing product (GMP) certificate of the active pharmaceutical ingredient (API) manufacturer(s) from the country of origin
   - Validated analytical methods if analytical methods for API are in-house analytical method, different from British pharmacopoeia (BP), United States pharmacopoeia (USP) and international pharmacopoeia (Ph.Int)
   - Recent/valid GMP certificates/letter of compliance of the finished pharmaceutical product (FPP) manufacturer
   - If analytical methods for FPP are in-house, different from BP, USP and Ph.Int., attach a copy of the analytical method and analytical validation data
   - Sample of the finished pharmaceutical product with copy of the certificate of analysis for the three last batches released
   - Protocol and report for accelerated and long term stability testing
   - Declaration that stability studies have been done or are being done with all declared API sources
   - Copy of the power of attorney

2) **Documentation to be submitted for products registered in Stringent regulatory Authorities (SRA):**
   - Sample of the finished pharmaceutical product with the Certificate of Analysis (CoA) of the sample.
   - Package insert if applicable and patient information leaflet (PIL) with evidence of SRA or WHO pre-qualification team approval
   - Certificate of pharmaceutical product (CPP) according to the WHO certification scheme-WHO technical report series no. 863.
   - List of countries where product is registered, including the specific product name and license number in each country
   - Registration certificate from SRA or approval letter from WHO pre-qualification team.
   - Copy of GMP certificate by WHO/SRA1 /PIC.s/UN agency

[1] The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA). For details on ICH, please look at www.ich.org