Technical consultation for Getting CTD approval from WHO (prequalified products) /EMA or FDA approval

1. **المستحضرات المقدمة للحصول على النصائح والمشورة الفنية لملف الجودة لمستحضر محلي (Quality Module) لما قبل البدء في خطوات الاعتماد من قبل المنظمة ,**تقوم الشركة بإرسال المحتويات الآتية في الإيميل الموضح عاليه:

A. **First Folder:**

1. Application Sheet (PDF and Word File)
2. Composition
3. Certificate of responsibility
4. Finished product specifications
5. References Product Insert declares pack, Storage conditions, shelf life, and Inactive ingredient.
6. Manufacturing and marketing authorization(s)/international registration
7. Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) (Including any annexes).
8. Letters of access for active pharmaceutical ingredient master files (APIMFs).
9. Good manufacturing practices (GMP) information. (Last report audit on the line of manufacture)
10. Biowaiver requests in relation to conducting a comparative bioavailability Study.
11. Product information:
    - 11.1 Summary of product characteristics (SmPC)
    - 11.2 Labelling (outer and inner labels)

11.3 Package leaflet (also known as patient information leaflet or PIL)

12. Regional summaries:

12.1 Bioequivalence trial information form (BTIF)

12.2 Quality information summary (QIS)

13. Sample of FPP (sample including measuring devices (if applicable))

B. Second Folder (Quality module):

1. Table of contents of Module 3
2. Body of data
3. Literature references

C. Third Folder:

1- Test Validation method and its chromatograms

2- Assay chromatograms

3- Dissolution charts (If required)

4-Statistical analysis data (if present)

2. المستحضرات المقدمة للحصول على النصائح والمشورة الفنية لملف تحضير وتطوير المستحضرات الصيدلية محلية الصنع Pharmaceutical Development لما قبل البدء في خطوات الاعتماد من قبل المنظمة الصحة العالمية او أي من الدول المرجعية المعترف بها من قبل منظمة الصحة العالمية يتم إرسال المحتويات الآتية في الإيميل:

A. **First Folder:**

1. Application Sheet (PDF and Word File)
2. Composition
3. Certificate of responsibility
4. Finished product specifications

5. References Product Insert declares pack, Storage conditions, shelf life, and Inactive ingredient.
6. Manufacturing and marketing authorization(s)/international registration
7. Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) (Including any annexes)/ COA of API supplier.
8. COA of excipients used in Formulation
9. Biowaiver requests in relation to conducting a comparative bioavailability Study.
10. Sample of FPP (1 sample including measuring devices (if applicable))

B. Second Folder (Pharmaceutical Development):

1. Table of contents
2. Body of data
3. Literature references

C. Third Folder:

1- Test Validation method and its chromatograms

2- Assay chromatograms

3- Dissolution charts (If required)

4-Statistical analysis data (if present)

3. المستحضرات المقدمة للحصول على - النصائح والمشورة الفنية لمراجعة ملفَ (QOS) Quality of Summary لما قبل البدء في خطوات الاعتماد من قبل المنظمة يتم إرسال المحتويات الآتية في الإيميل:

A. **First Folder:**

1. Application Sheet (PDF and Word File)
2. Composition
3. Certificate of responsibility

4. Finished product specifications
5. References Product Insert declares pack, Storage conditions, shelf life, and Inactive ingredient.
6. Manufacturing and marketing authorization(s)/international registration
7. Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) (Including any annexes) COA of API supplier.
8. Good manufacturing practices (GMP) information. (Last report audit on the line of manufacture)
9. Biowaiver requests in relation to conducting a comparative bioavailability Study.
10. Regional summaries:
    - 10.1 Bioequivalence trial information form (BTIF)
    - 10.2 Quality information summary (QIS)
11. Samples of FPP (1 sample including measuring devices (if applicable))
12. List of the expression of interest (EOI) including the Finished product.

B. Second Folder (Quality module):

1. Table of contents of Module 3
2. Body of data
3. Literature references

C. Third Folder (QOS–PD):

1- Quality overall summary — product dossier (QOS–PD).

4. النصـــائح والمشـــورة الفنيـة بخصـــوص تقدير المخـاطر الخـاصـــة Risk Assessment بالNitrosamine Impurities لما قبل البدء في خطوات الاعتماد من قبل المنظمة يتم إرســـال المحتويات الآتية في الإيميل:

1. Application Sheet (PDF and Word File)
2. Composition
3. Certificate of responsibility
4. Finished product specifications
5. Manufacturing and marketing authorization(s)/international registration
6. Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) (Including any annexes).
7. Letters of access for active pharmaceutical ingredient master files (APIMFs).
8. Good manufacturing practices (GMP) information. (Last report audit on the line of manufacture)
9. List of the expression of interest (EOI) including the Finished product.

B. Second Folder (QOS–PD):

1- Quality overall summary — product dossier (QOS–PD).

2- COA of excipients including information about presence /absence of nitrosamine

C. Third Folder:

1- Nitrosamine risk assessment

2-Test Validation method and its chromatograms

3- Assay chromatograms

4- Confirmatory testing & reports