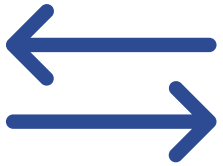
The world faces a curious paradox: despite unparalleled scientific advancements, such as the development of life-saving medicines, we still witness the tragic reality of preventable deaths in some parts of the world.




# What's this all about ?



1. What’s new / changed?

2. What’s next / coming?

3. How can you contribute or becoming actively involved?

# WHO's constitutional mandate to establish norms and standards that are fit-for purpose for all Member States

Constitutional mandate to establish norms and standards

- *Article 2 (u) ..to* develop, establish and promote international standards with respect to food, biological, **pharmaceutical** and similar products;

GPW 13 Output 1.3.3 – *country and regional regulatory capacity strengthened and improved the supply of quality-assured and safe health products*

# The 10th edition of WHO's Quality Assurance of Pharmaceuticals Compendium, Volume 2, is a key resource for safeguarding the quality, safety, and effectiveness of medicines.

*Compendium empowers countries to establish robust regulatory systems and uphold international standards in pharmaceutical quality assurance.*

*reflects the latest guidelines adopted by the Expert Committee on Specifications for Pharmaceutical Preparations (54th, 55th, 56th meetings).*

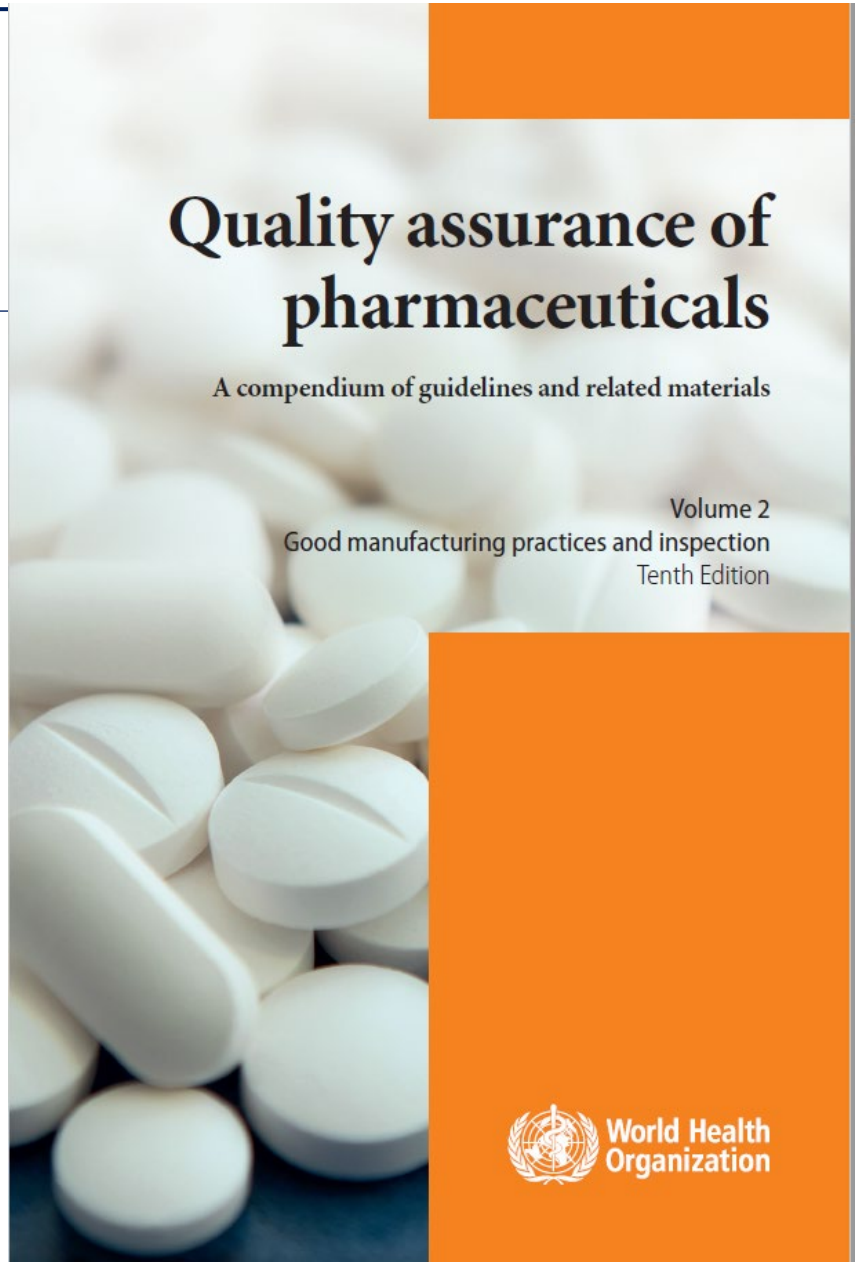
***45*** *guidelines*

**10** *revised guidelines*

**8** *new guidelines*

*Recommendations on environmental aspects for the prevention of antimicrobial resistance, health-based exposure limits in cleaning validation, and GXPs for R&D facilities*

World Health Organization



# Contents of the 10th Edition of the GMP Compendium

1. **WHO good manufacturing practices: main principles for pharmaceutical products**
2. **WHO good manufacturing practices: starting materials**
   - API, excipients
3. **WHO good manufacturing practices: specific medical products**
   - Sterile products, biological products, blood establishments, medicinal gases, radiopharmaceuticals, herbal medicines, investigational products, investigational radiopharmaceuticals
4. **Related guidelines**
5. **Laboratory guidelines**
6. **Inspections**
7. **Further reading**
8. **Revision history**

# The 10th edition of WHO's Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials, Volume 1, is a key resource for safeguarding the quality, safety, and effectiveness of medicines.

*Compendium empowers countries to establish robust regulatory systems and uphold international standards in pharmaceutical quality assurance.*

*Reflects the latest guidelines adopted by the Expert Committee on Specifications for Pharmaceutical Preparations (54th, 55th, 56th, 57th meetings).*

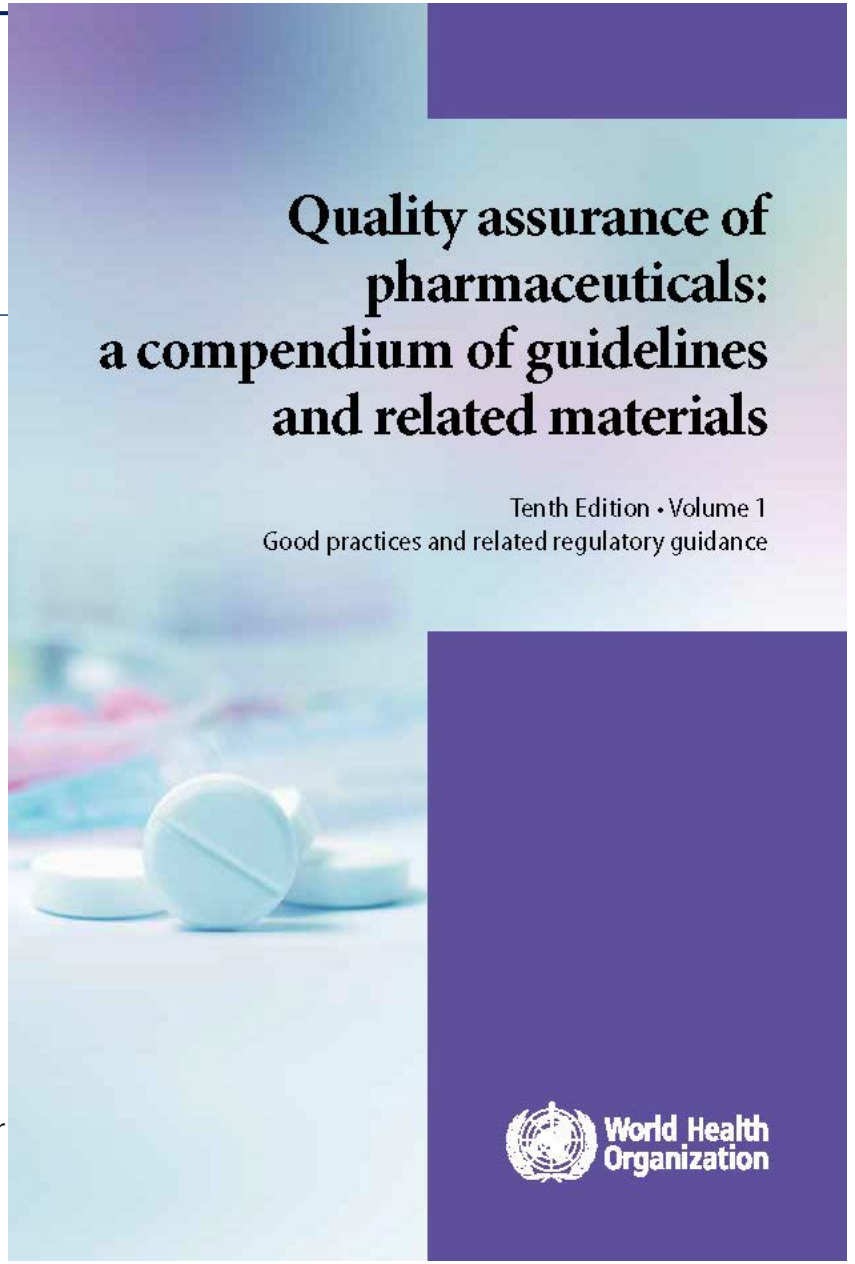
***61*** *guidelines*

8 *Revised guidelines*

8 *New guidelines*

*Recommendations on protocol to conduct equilibrium solubility experiments, good regulatory practices, good reliance practices, good practices for collaborative procedures, points to consider for setting remaining shelf life upon delivery.*

World Health Organization



# Contents of the 10th edition of the QA Compendium – Volume 1

1. Pharmaceutical development
2. Marketing authorization: quality
3. Marketing authorization: bioequivalence
4. Regulatory standards: general guidance
5. Contract research organizations
6. Prequalification
7. Regulatory standards: collaborative procedure and reliance
8. Storage, distribution and supply
9. Good pharmacy practices
10. Post-market surveillance
11. Quality control
12. Further reading
13. Revision history


# Guidelines adopted at the 58th ECSPP meeting – 07 t0 11 October 2024 *(to be published in TRS 1060, 2025)*

- **GMP-related**
  - WHO GxP considerations for the prevention and control of nitrosamines in Pharmaceutical Products **(Annex 2)** ***(new)***
  - WHO GMP for excipients used in pharmaceutical products – Appendices 1 and 2 (**Annex 3)** ***(new)***
  - Good practices for blood establishments, (jointly with the Expert Committee on Biological Standardization) **(Annex 4)** ***(revised)***
- **Regulatory topics**
  - WHO Biowaiver List (**Annex 5)** ***(updated)***
  - Guideline on bioanalytical method validation and study sample analysis **(Annex 6)** ***(new)***
  - Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products **(Annex 7)** ***(revised)***
  - Collaborative procedure between WHO and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified vector control products **(Annex 8)** ***(new)***
  - Guidance for the graphic representation of pharmaceutical substances in the publications of International Nonproprietary Names and The International Pharmacopoeia (**Annex 9)** ***(new)***

# Standards for generic product development & regulatory approval

World Health Organization

# WHO guidelines for multisource (generic) products

- **Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 8, WHO Technical Report Series, No. 1052, 2024) (republished)**
- WHO guideline on Biopharmaceutics Classification System-based biowaivers, Annex 7, TRS 1052, 2024
- WHO guideline on bioanalytical method validation and study sample analysis *(Annex 6, TRS 1060, 2025)*
- Guidance for organizations performing in vivo bioequivalence studies (revision) (2016)
- Guidelines for registration of fixed-dose combination medicinal products (2005)
- Guidance on selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products (2015)
- General background notes on the list of international comparator pharmaceutical products (2017)

# The WHO International Comparator Product List: A key resource to manufacturers and regulators for demonstrating interchangeability of generic medicines

| Essential Medicine name | Essential Medicine List dosage form/ dose strengths | International comparator product | Marketing Authorisation Holder | Markets | PQ comparator product |
|---|---|---|---|---|---|
| abacavir (ABC) | Tablet: 300 mg (as sulfate). | Ziagen | ViiV Healthcare | SRA | Ziagen (300 mg tablet, GlaxoSmithKline) |
| abacavir (ABC) | Oral liquid: 100 mg (as sulfate)/5 ml. | Ziagen | ViiV Healthcare | SRA | Ziagen (20 mg/ml oral solution, GlaxoSmithKline) |
| acetazolamide | Tablet: 250 mg. | Diamox | Mercury Pharmaceuticals Ltd | EU | N/I |
| acetic acid | Topical: 2%, in alcohol. | Acetic acid (Solution, Otic drops) | Wockhardt | USA | N/I |
| acetylcysteine | Injection: 200 mg/ml in 10-ml ampoule. | Hidonac Antidoto 5 g/25 mL<br>Fluimucil 200 mg/ml, solution for infusion<br>Acetadote 6 g/30 mL | Zambon<br>Zambon<br>Cumberland Pharmaceuticals | EU<br>EU<br>USA | N/I |
| acetylcysteine | Oral liquid: 10%; 20% | Fluimucil or Flumil 20mg/mL | Zambon | EU | N/I |
| acetylsalicylic acid | Tablet: 100 mg to 500 mg. | Aspirin | Bayer | EU | N/I |
| acetylsalicylic acid | Suppository: 50 mg to 150 mg. | Resprin Suppositories 300 mg | Ricesteele Manufacturing Ltd. | United Kingdom | N/I |
| acetylsalicylic acid | Tablet: 300 mg to 500 mg. | Aspirin | Bayer | EU | N/I |
| acetylsalicylic acid | Tablet: 100 mg. | Aspirin | Bayer | EU | N/I |
| aciclovir | Ointment: 3% W/W. | Zovirax | GlaxoSmithKline / Wellcome | EU | N/I |
| aciclovir | Oral liquid: 200 mg/5 ml. | Zovirax | GlaxoSmithKline / Wellcome | EU | N/I |
| aciclovir | Powder for injection: 250 mg (as sodium salt) in vial. | Zovirax | GlaxoSmithKline / Wellcome | EU | Zovirax (GlaxoSmithKline) |
| aciclovir | Tablet: 200 mg. | Zovirax | GlaxoSmithKline / Wellcome | EU | Zovirax (GlaxoSmithKline) |
| albendazole | Tablet (chewable): 400 mg. | Eskazole | GlaxoSmithKline | EU | Eskazole 400 mg (chewable) tablet (GlaxoSmithKline)<br>Albenza 200 mg (chewable) tablet (Amedra Pharms, USA) |
| allopurinol | Tablet: 100 mg. | Zyloric<br>Zyloprim | Aspen or Faes<br>Sebela Ireland LTD | EU<br>USA | N/I |
| allopurinol | Tablet: 100 mg to 300 mg. | Zyloric<br>Zyloprim | Aspen or Faes<br>Sebela Ireland LTD | EU<br>USA | N/I |
| amidotrizoate | Injection: 140 mg to 420 mg iodine (as sodium or meglumine salt)/ml in 20-ml ampoule. | Urografin | Bayer | EU | N/I |

# **The WHO Biowaiver List:** the numbers

**16**
Laboratories

**50** APIs prioritized from EML

**38**
Manufacturers

**+300** Samples received

**+1500**
Experiments

**6**
cycles

# What's on the horizon?

**Incorporating climate and environmental sustainability**

**Reducing the gap in access to innovations between high- and low-income settings.**

**Increasing transparency and stakeholder engagement.**

More opportunities for input and feedback in development/revision of the standards

Transparency through the digital platform for stakeholder consultations on draft guidelines

Publish the pipeline/workplan of guidelines under consideration




# GMP Guidelines work plan 2024 - 2027

| Full title of guideline | Type of guideline | Proposal | Status of Development | Expected Timeline for adoption |
|---|---|---|---|---|
| Points-to-consider/Reflection paper on Artificial Intelligence in Pharmaceutical Manufacturing | Production | New | 1. Concept Note | 59th ECSPP |
| Points-to-consider/Reflection paper on continuous manufacturing | Production | New | 3. Expert Group review | 59th ECSPP |
| TRS 1003 - Annex 3: Prequalification of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies, Annex 3, WHO Technical Report Series, No. 1003, 2017 | Quality Control | Revision | 5. Exploratory | 59th ECSPP |
| WHO good manufacturing practices for pharmaceutical products: Main principles | Production | Revision | 1. Concept Note | 59th ECSPP |
| Guideline on design of QCL | Quality Control | New | 3. Expert Group review | 59th ECSPP |
| WHO guidelines for sampling of pharmaceutical products and related materials (Annex 4, TRS 929, 2005) | Quality Control | Revision | 1. Concept Note | 60th ECSPP |
| TRS 961 - Annex 13: WHO guidelines for preparing a laboratory information file, Annex 13, WHO Technical Report Series 961, 2011 | Quality Control | Revision | 1. Concept Note | 60th ECSPP |

# Guidelines work plan – pipeline – Regulatory topics

| Full title of guideline | Type of guideline | Proposal | Status of Development | Expected Timeline for adoption |
|---|---|---|---|---|
| Good practices for implementing WHO regulatory guidelines | Regulatory Standards | New | 2. Drafting | 59th ECSPP |
| Guideline on bioequivalence for immediate-release solid oral dosage forms | Regulatory Standards | Revision | 1. Concept Note | 60th ECSPP |
| Guideline on biowaivers for additional strength | Regulatory Standards | Revision | 5. Exploratory | 60th ECSPP |
| Guideline on Regulatory Consideration Document for Medical Oxygen | Regulatory Standards | New | 1. Concept Note | 59th ECSPP |
| Good practices on market surveillance and control | Regulatory Standards | New | 2. Drafting | 59th ECSPP |
| Development of paediatric medicines: points to consider in formulation (Annex 5, TRS 970, 2012) | Development | Revision | 3. Expert Group review | 59th ECSPP |
| **Guidelines on the evaluation of combination products (drug-device)** | **Regulatory Standards** | **New** | **5. Exploratory** | **60th ECSPP** |
| **Points to consider or reflection document on pre-registration testing** | **Regulatory Standards** | **New** | **5. Exploratory** | **60th ECSPP** |
| **Guidelines on packaging for pharmaceutical products (Annex 9, TRS 2012, 2002)** | **Regulatory Standards** | **Revision** | **5. Exploratory** | **60th ECSPP** |
| **Model Quality Assurance System for Procurement Agencies** | **Distribution** | **Revision** | **1. Concept Note** | **61st ECSPP** |
| **WHO general guidance on variations to multisource pharmaceutical products (Annex 10, TRS 996, 2016)** | **Regulatory Standards** | **Revision** | **5. Exploratory** | **61st ECSPP** |
| Guidelines for safe disposal of unwanted pharmaceuticals | Distribution | New | 5. Exploratory | TBC |
| Guidelines on benefit-risk assessment to support regulatory decisions | Regulatory Standards | New | 5. Exploratory | TBC |
| Points to consider on the implementation of e-labelling ( e-leaflet or e-PIL) | Regulatory Standards | New | 5. Exploratory | TBC |
| Good review practices: guidelines for national and regional regulatory authorities (Annex 9, TRS 992, 2015) | Development | Revision | 5. Exploratory | TBC |
| Guidelines for registration of fixed-dose combination medicinal products (Annex 5, TRS 929, 2005) | Regulatory Standards | Revision | 5. Exploratory | TBC |
| WHO good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions | Quality Assurance | Revision | 5. Exploratory | TBC |
| WHO guidelines on quality risk management | Regulatory Standards | Revision | 5. Exploratory | TBC |

Working documents in public consultation

https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/working-documents-public-consultation

# Working documents in public consultation

Please send any comments you may have to the responsible person indicated in the box on the first page of each working document. You will need to use the table for comments for such purpose.

- WHO regulatory guidance and related texts: revisions/new texts for discussion (QAS23.940)
  Table for comments
- WHO Biowaiver Project - Prioritization exercise of active pharmaceutical ingredients for cycle VI (2024) and preliminary results from cycle V (2023) (QAS/23.936)
- IAEA/WHO good manufacturing practices for in-house cold kits for radiopharmaceutical preparations (QAS/23.932)
- WHO good manufacturing practices and inspection guidelines compendium gap analysis for revisions/new text (QAS/23.931)
  Table for comments
- WHO guideline on biopharmaceutics Classification System -based Biowaivers (QAS/23.929)
- WHO good practices for pharmaceutical quality control laboratories (QAS/21.882)

**Table for comments template** >

**All final texts/guidelines** >

## New working documents under review for norms and standards for pharmaceuticals

### for medicines quality assurance

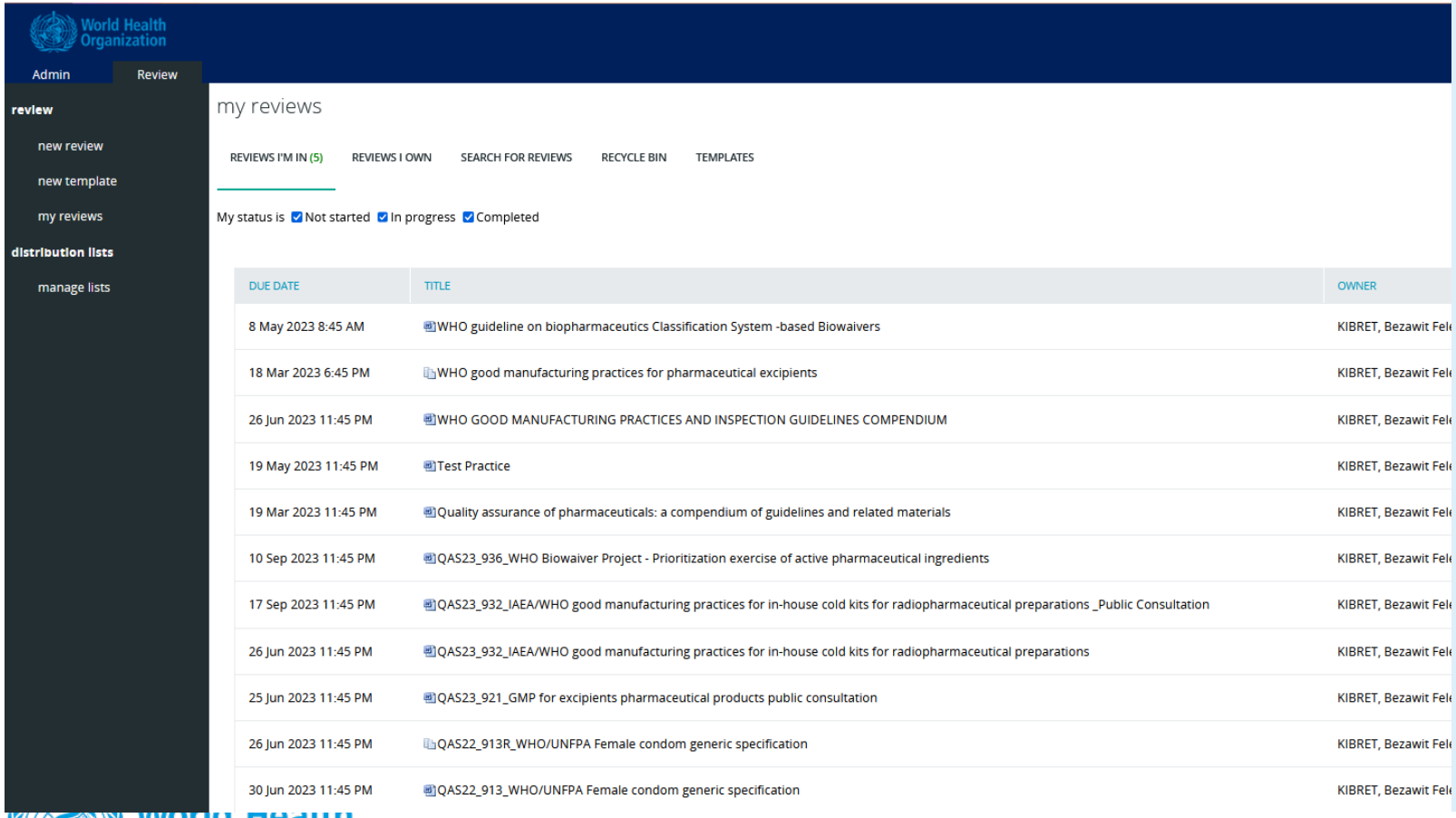
- WHO good manufacturing practices for excipients used in pharmaceutical products (QAS/23.921)
- WHO/UNFPA Female condom generic specification (QAS/22.913/Rev1)
- WHO/UNFPA condom quality assurance (QAS/19.807)

## Monographs and general texts under review/revision for inclusion in The International Pharmacopoeia

### for inclusion in the International Pharmacopoeia

- Estradiol Valerate and Norethisterone Enantate injection (QAS23.941)
- Tenofovir Disoproxil Fumarate (QAS/23.939)
- Ethambutol dihydrochloride disperible tablets (QAS/23.935)
- Albendazole chewable tablets (QAS/23-934)
- Efavirenz (QAS/23.928)
- Micro determination of water (QAS/23.926)
- Test for diethylene glycol and ethylene glycol in liquid preparations for oral use (QAS/23.922/Rev.1)
- Zidovudine (QAS/22.918)

# Use an electronic platform, PleaseReview for collecting comments, reviewing comments, feedback to commentators and reporting to the Expert Committee.




- **Reduce time and effort** required to provide comments to draft WHO guidelines/monographs
- **Automated processes** e.g., generating reports, saving information.
- Transparency and accountability on how comments are handled after public consultations.

World Health Organization

Go to https://who.pleasereview.net/

If you wish to receive all our draft guidelines, please send your email address to nsp@who.int and your name will be added to our electronic mailing list.

World Health Organization

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