Technical Requirements for Pharmaceuticals. Experience with submissions of dossiers

Henrik K.Nielsen

Technical Specialist

Essential Medicines Unit - Medicines and Nutrition Centre

UNICEF SUPPLIER MEETING 24-26 SEPTEMBER 2012

UNICEF SUPPLY DIVISION - COPENHAGEN, DENMARK

UNICEF SD

- Product evaluation is a key tool to ensure product quality
- UNICEF SD Technical Requirements for Pharmaceutical Products
- Specification of the Finished Pharmaceutical Product
- The Interagency Pharmaceutical Product Questionnaire

Technical Requirements for Pharmaceutical Products

- UNICEF SD Technical Requirements for Pharmaceutical Products
- Follows every tender related to pharmaceutical products

- http://www.unicef.org/supply/files/Final_Technical_Requirements_pharma_4th_edition_06.01.2012_AO.pdf

Wanted - Glad You Ca... http://www.unicef.org/... 66.7% Find

unicef

TECHNICAL REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS

4th Edition January 2012



Specifications

- Specifications are reviewed and updated if required in connection with every Tender
- Amoxicillin 250mg scored dispersible tablets, blister of 10 dispersible tablets, pack of 10x10 dispersible tablets.
- **Technical Specifications:**
- The dispersible tablets should contain Amoxicillin Trihydrate equivalent to 250mg Amoxicillin complying with one of the pharmacopoeias:
- BP
- Ph.Eur.
- Ph.Int.
- USP (Amoxicillin)

Specifications

- **The dispersible tablets should comply with one of the pharmacopoeias:**
- BP general monograph for tablets and general notices
- Ph.Eur. general monograph for tablets and general notices
- Amoxicillin Tablets for Oral Suspension USP, general notices and requirements

- Preference would be given to colorants free formulations
- and to formulations with long term stability studies conducted under Zone IV a or Zone IV b conditions (30C/65RH/75RH)

Specifications

- **Packaging and labelling:**
- As per UNICEF Technical Requirements for Pharm. Products
- A Patient Information Leaflet should be included in each pack.

The Interagency Pharmaceutical Product Questionnaire

IPPQ

- Complete Interagency Pharmaceutical Product Questionnaire for manufacturers:
- Full International Non-proprietary Name (INN name)
- No brand or trade name
- GMP certificate of FPP Manufacturing site
- Marketing Authorisation in country of origin, and exporting countries if applicable
- Certificate of Pharmaceutical product (CPP)
- API, Reference to Pharmacopeias and CEP/DMF
- GMP certificate of the API Manufacturing site/CoA of the API
- Specifications for the Finished Pharmaceutical Product
- (reference to Ph.Int, Ph.Eur, BP or USP where applicable)
- Stability reports of the Finished Pharmaceutical Product
- Language requirements: English and French unless other specified

The Interagency Pharmaceutical Product Questionnaire

- Complete Interagency Pharmaceutical Product Questionnaire
- Reduced workload for both the bidder and agencies
- Considered as the basic minimum

Challenges

- Incomplete filled in questionnaire
- Inadequate information/missing data

- Usually follow up via e-mails to obtain missing information

Challenges

Notification about changes:

- Finished product specifications (excipients, API)
- Changes in manufacturing site
- Packaging materials

Challenges

Some companies include the Essential Medicines logo on the label of the pharmaceutical product.

Please note the logo is a property of the WHO

Stability testing

- Stability studies should be conducted in the presentation supplied reflecting real time and accelerated stability conditions as per WHO/ICH Guidelines.
- The proposed shelf-life and storage conditions must be supported by the stability studies report submitted
- Please indicate the pack size/presentation in the stability report instead of ”Bulk”
- In-use stability reports are often missing (e.g. reconstituted Powder for oral suspension)
- Terms such as storage at ambient conditions or room temperature should be avoided.

Storage conditions

- Recommended storage conditions as indicated in WHO TRS 953 Annex 3

Table 2

Recommended labelling statements for finished pharmaceutical products (FPPs)

Testing condition under which the stability of the FPP has been demonstrated	Recommended labelling statement[a]
25 °C/60% RH (long-term) 40 °C/75% RH (accelerated)	"Do not store above 25 °C"
25 °C/60% RH (long-term) 30 °C/65% RH (intermediate, failure of accelerated)	"Do not store above 25 °C"[b]
30 °C/65% RH (long-term) 40 °C/75% RH (accelerated)	"Do not store above 30 °C"[b]
30 °C/75% RH (long-term) 40 °C/75% RH (accelerated)	"Do not store above 30 °C"
5 °C ± 3 °C	"Store in a refrigerator (2 °C to 8 °C)"
-20 °C ± 5 °C	"Store in freezer"

[a] During storage, shipment and distribution of the FPP, the current *good distribution practices (GDP) for pharmaceutical products* are to be observed (*3*). Details on storage and labelling requirements can be found in *WHO guide to* good storage practices *for pharmaceuticals* (*2*).

[b] "Protect from moisture" should be added as applicable.

Sample for technical evaluation

- Samples should be labeled and packed in the format as they will appear at the time of supply. Please remember to include leaflet.

- A few tablets in a plastic bag makes the evaluation of the sample difficult as an example

Commitments

- Manufacturers are sometimes asked to give a commitment

- Typical to initiate/continue stability studies

  or

- Establish new shelf life based on extrapolation of stability data in accordance with ICH (Q1A/Q1E)/WHO Stability guidelines

Challenges

- We receive huge amounts of paper (i.e. IPPQ including attachments) in connection with every tender.

- Please note we do accept to receive the documentation on CD (specified in the tender documents).


Thank You
unicef