6.13 **WATER DISPERSIBLE TABLETS**

Note for preparation of draft specifications. Do not omit clauses or insert additional clauses, nor insert limits that are more lax than those than given in the guidelines, without referring to Section 4.. From the “Notes” provided at the end of this guideline, incorporate only those which are applicable to the particular specification.

**…… [*Taxon*] WATER-DISPERSIBLE TABLETS**

[CIPAC number]/WT (month & year of publication)

6.13.1 **Description** (Note 1)

The material shall consist of an homogenous mixture of technical…… [taxon] complying with the requirements of FAO / WHO specification [……], in the form of ...... (see Section 4.2), together with carriersand any other necessary formulants. It shall be in the form of tablets for application after disintegration and dispersion in water. The formulation shall be dry, unbroken, free-flowing tablets and shall be free from visible extraneous matter.

In case there is no TK, the material shall contain ...... [taxon], in the form of ...... (see Section 4.2), together with carriers and any other necessary formulants. It shall be in the form of tablets for application after disintegration and dispersion in water. The formulation shall be dry, unbroken and free-flowing tablets, and shall be free from visible extraneous matter.

6.13.2 **Active Ingredient** (Note 1)

6.13.2.1 **Identity (Note 2)**

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

6.13.2.2 **….[Taxon] content (**Note 2**)**

The …… [taxon] content shall be declared (g/kg, or for liquids only, g/l at 20 ± 2 °C, or CFU/g, CFU/ml or biopotency units or another appropriate microbial unit),, and when determined, the average content measured shall be within the following declared tolerance range:

|  |  |
| --- | --- |
| Declared content | Tolerance |
|  | Minimum declared | Maximum declared |
| In g/kg or g/L or CFU/g or CFU/mL or UI/g or UI/mL, etc. |
|  |  |  |

6.13.2.2 **Tablet dose uniformity, if required**

The ...... [taxon] content, measured separately in ...... tablets, shall have a relative standard deviation (RSD) of not more than ...... %.

###### 6.13.3 **Relevant impurities (Note 1)**

6.13.3.1 **Microbial contaminants** (Note 3), if required

 [Taxon] content: Absence in ...... g or ...... ml or a maximum value (with appropriate unit).

6.13.3.2 **Secondary compounds** (Note 3), if required

Insert name (any identification code, if exists).

Maximum: ...... (insert appropriate unit).

6.13.3.3 **Chemical impurities from the manufacturing process)** (Note 3), if required

Maximum: ...... (insert chemical name) g/kg.

6.13.3.4 **Water** (MT 30.6), if required

Maximum …… g/kg

6.13.4. **Physical properties**

6.13.4.1  **Acidity and/or alkalinity** (MT 191) **or pH range** (CIPAC MT 75.3), Notes 4, 5 & 6), if required (Note 7)

Maximum acidity: ...... g/kg calculated as H2SO4.

Maximum alkalinity: ...... g/kg calculated as NaOH.

pH range: ...... to ......

6.13.4.2 **Disintegration of tablets** (MT 197) (Note 8)

For effervescent tablets (Note 7) or if required for non-effervescent.

Maximum: ...... % of residue after specified disintegration time.

6.13.4.3 **Wet sieve test** (MT 185.1) (Notes 5 & 9)

After complete disintegration of the tablet or a fragment of a tablet follows procedure (b) wet sieving of CIPAC MT 185.1.

Maximum: ...... % retained on a 75 μm test sieve.

6.13.4.4 **Suspensibility** (MT 184.1) (Notes 5, 10, 11 & 12)

Minimum ......% after 30 min in CIPAC standard water D at 25 ± 5 °C.

6.13.4.5 **Persistent foam** (MT 47.3) (Notes 5 & 13)

Maximum: ...... ml after 1 minute.

6.13.4.6 **Tablet integrity** (Note 14)

No broken, soft or sticky tablets should be present.

Fragments: yes/no

Soft/sticky: yes/no

6.13.4.7 **Attrition resistance of tablets** (MT 178.3) (Notes 15 & 16), if required

Minimum attrition resistance: ...... %.

# 6.13.5 Storage stability

# 6.13.5.1 Low temperature stability (MT 39.3) (Note 17), if required

# After storage at 0 ± 2 °C for 7 days, the determined average active ingredient content must not be lower than the specified minimum active ingredient content. After storage at 0 ± 2 °C for 7 days, the determined average active ingredient content must not be lower than ...... % relative to the determined average content found before storage (Note 18).

# 6.13.5.1 Stability at elevated temperature (MT 46.4)

# After storage at 54 ± 2 °C for 14 days (Note 19) without pressure (Note 20), the determined average active ingredient content must not be lower than ...... % relative to the determined average content found before storage (Note 18) and the formulation shall continue to comply with the clauses for:

# – acidity/alkalinity/pH range (6.13.4.1),

# – disintegration of tablets (6.13.4.2)

# – wet sieve test (6.13.4.3),

# – suspensibility (6.13.4.4),

# – tablet integrity (6.13.4.6),

# – attrition resistance of tablets (6.13.4.7),

as required.

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Note 1 Measuring the active ingredient content or relevant impurities requires a representative sample of the tablet. A representative sample is obtained by grinding one or several tablets and then sampling the homogeneous powder.

Note 2 Method(s) of identification and quantitation must be peer validated/ILV. If the methods have not yet been published, then full details with appropriate method validation data must be submitted to FAO/WHO by the proposer.

Note 3 This clause should include only relevant impurities and the title should be changed to reflect the name of the relevant impurity. Method(s) of analysis must be peer validated/ILV.

Note 4 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 5 If tests need to be conducted at use-rate, a tablet may be broken and fragments be used. The following tests may require breaking tablets:

|  |  |  |  |
| --- | --- | --- | --- |
| Point | Property | CIPAC | Rate |
| 6.13.4.1 | Acidity or alkalinity pH range | MT 191MT 75.3 | 10 g add 100 mL1g make up 100 mL |
| 6.13.4.3 | Wet sieve | MT 185.1 | Maximum recommended use rate |
| 6.13.4.4 | Suspensibility | MT 184.1 |
| 6.13.4.5 | Persistent foam | MT 47.3 |

 Tablets or fragments of tablets must be completely disintegrated for the purposes of CIPAC methods MT 191, MT 75.3, MT 185.1, MT 184.1, and MT 47.3.

Note 6 Before performing the CIPAC test, it is necessary to let the tablet(s) or fragments of a tablet disintegrate completely in a 250 ml beaker containing 50 ml of the water required by the method. A gentle stirring may be needed.

Note 7 This clause is not applicable to effervescent tablets, as they incorporate an effervescent system.