National Center for Vector Borne Diseases Control, Delhi

Technical Specifications of Rapid Diagnostic Test kit for Kala-Azar

10.03.2023

A. Performance:

The product (IgG - an Antibody based test) should have at least 95% and above specificity and sensitivity for wider competition under field conditions.

B. Ease of Use:

Kits should allow for use whole blood/serum for conducting the test.

C. Packaging:

Each kit should be thematically sealed in non –permeable pouch and should have moisture absorbent material . 25 such test kits or lesser quantity as required by programme should be packed in a box. Adequate literature detailing the kit components , principle, methodologies and validity criteria should be provided as the kit insert with test kit.

Storage conditions, expiry dates and limitation of test should be provided. The small box should be packed in a bigger card board carton containing 10 such small boxes. The cartoon should be sealed with sealing tape.

Ground transportation can be carried out during any stage of delivery without delay , maintaining the temperature requirement while the vehicle is moving and is parked. Avoid vehicle parking in sun having Test kits.

D. Condition of uses:

Test should have thermal stability for use in areas with very high ambient temperature as per evaluation after 60 days of incubation at room temperature 30 to 45 degree Celsius.

E. Shelf life:

Shelf life from manufacturing date to expiry date should be at least 2 years and it should not have lost more than 1/6th of their effective life from date the date at the time material is offered for inspection. In case of losses due to premature deterioration as a result of biological and other activities during the life of potency of the test, it will be made good by the supplying firm at their own cost.

F. Quality Assurance:

The product should be complied with BIS/ ISO 13485:2016 standards or latest.

G. Registration of Product:

The product should be licensed for import/ manufacture by DCG (I) / State drug controller under drugs and cosmetics Act 1940 and rules framed therein.

H. Field tested:

Satisfactory field tested report should have been generated through any reputed institute(s) designated by the programme such as ICMR-RMRIMS, Patna.

I. labeling:

a). Each test kit should have space for recording particular of the patients, time and date of the test.
b). The large carton (containing 10 small boxes) and small boxes (containing 25 test kits) should have the following marking; Name of the test, Lot/Batch number, Manufacturing and expiry date, Name of manufacturer and address, Details of content, storage conditions, Handling procedures, Disposal instruction for the box and its content.
c). NVBDCP-Dte. GHS, Govt. of INDIA supply – NOT FOR SALE.

Above Technical Specification of Rapid Diagnostic Test kit under NVBDCP approved by Technical Specification Committee in the meeting held on 20.02.2023.

Dr. M.N. Reddy,
Asst. Director (Ento.), CIB&RC

Dr. Kuldeep Singh
Scientist – B, NIMR

Dr. Ravi Kant Sharma,
DDC(I), CDSCO

Sh. Manoj Kumar Sinha,
Deputy Secretary (Proc.)

Dr. Rinku Sharma,
Joint Director, NCVBDC

Dr. Dhruv Pandey,
NPO-NTD, WHO

Dr. Krishna Pandey,
Director, RMRIMS(ICMR)
DIRECTOR
ICMR-Rajendra Memorial Research Institute of Medical Sciences, Agamkuan, Patna-800007

Dr. Rupak Chatterjee
Advisor (Stores)

Dr. Ashwani Kumar,
Director, VCRC(ICMR)

Dr. Amita Bali
DDG (Store), Dte.GHS

Sh. D.K.Singh
DDG & Director (Proc.)

Dr. Nupur Roy,
Sr. CMO (SAG)

Dr. Tanu Jain
Director, NCVBDC

Dr. Anil Kumar,
Addl. DG, Dte. GHS & Chairperson

National Center for Vector Borne Diseases Control, Delhi

Technical Specification of Synthetic Pyrethroids (wdp) under Kala-Azar

10.03.2023

A. WHO Specification for Public Health Insecticide/Pesticide

1. Deltamethrin -333/WP
2. Cyfluthrin - 385/WP
3. Lambdacyhalothrin - 463/WP
4. Alphacypermethrin - 454/WP
5. Bifenthrin – 415/WP (interim)

B. The Central Insecticide Board (CIB) has approved the following Insecticides for Public Health use.

1. Deltamethrin 2.5% (wdp)
2. Cyfluthrin 10% (wdp)
3. Lambdacyhalothrin 10% (wdp)
4. Alphacypermethrin 5% (wdp)
5. Bifenthrin 10% WP

The details of the description, active ingredient, physical properties, wet sieve test,wettability, persistent foam, storage stability as per WHO specification is enclosed at **Annexure - 2** for each insecticide(s) mentioned at B above.

Above Technical Specification of Synthetic Pyrethroid (wdp) – KA under NVBDCP approved by Technical Specification Committee in the meeting held on 20.02.2023

Dr. M.N. Reddy,
Asst. Director (Ento.), CIB&RC

Dr. Kuldeep Singh
Scientist – B, NIMR

Dr. Ravi Kant Sharma,
DDC(I), CDSCO

Sh. Manoj Kumar Sinha,
Deputy Secretary (Proc.)

Dr. Rinku Sharma,
Joint Director, NCVBDC

Dr. Dhruv Pandey,
NPO-NTD, WHO

Dr. [illegible]
Director, RMRIMS(ICMR)

DIRECTOR
ICMR-Rajendra Memorial Research
Institute of Medical Sciences
[illegible]-800007

Dr Rupak Chatterjee
Advisor (Stores)

Dr. Ashwani Kumar,
Director, VCRC(ICMR)

Dr Amita Bali
DDG (Store),Dte GHS

Sh. D.K.Singh
DDG & Director (Proc.)

Dr. Nupur Roy,
Sr CMO (SAG)

Dr. Tanu Jain
Director, NCVBDC

Dr. Anil Kumar,
Addl. DG, Dte. GHS
& Chairperson

ANNEXURE 2

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN WETTABLE POWDER

WHO specification 333/WP (September 2005)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005, 333/2006.2). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TCfrom the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation reports (333/2004, 333/2005, 333/2006.2), as PART TWO, form an integral part of this publication.

1 **Description**

The material shall consist of a homogeneous mixture of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), together with filler(s) and any other necessary formulants It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

2 **Active ingredient**

2.1 **Identity tests** (333/WP/M/2, CIPAC Handbook L, p.45, 2006)

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

2.2 **Deltamethrin content** (333/WP/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg Tolerance
up to 25
above 25 up to 100
Note. the upper limit is included in each range
± 25% of the declared content
± 10% of the declared content

3 **Relevant impurities** (Note 1)

4 **Physical properties**

4.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of
current versions by checking at: http://www.who.int/quality/en/.

4.2 **Wet sieve test** (MT 59.3, CIPAC Handbook F, p.179, 1995)

Maximum: 2% retained on a 75 µm test sieve.

4.3 **Suspensibility** (MT 15.1, CIPAC Handbook F, p.145, 1995) (Notes 2 & 3)

A minimum of 60% of the deltamethrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C (Note 4).

4.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 5)

Maximum: 60 ml after 1 min.

4.5 **Wettability** (MT 53.3, CIPAC Handbook F, p.164, 1995)

The formulation shall be completely wetted in 2 min without swirling.

5 **Storage stability**

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined mean content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

– pH range (4.1);
– wet sieve test (4.2);
– suspensibility (4.3);
– wettability (4.5).

Note 1 There are no relevant impurities to be controlled in products of the manufacturers identified in
evaluation reports 333/2004, 333/2005 and 333/2006.2. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at ≥1 g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.
Note 2 The formulation should be tested at the highest and lowest rates of use recommended by the
supplier, provided this does not exceed the conditions given in method MT 15.1.
Note 3 This test will normally only be carried out after the heat stability test, 5.1.
Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still
in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".
Note 5 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

CYFLUTHRIN WETTABLE POWDER (WP)

WHO Specification 385/WP (November 2004)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (385/2003). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (385/2003) as PART TWO forms an integral part of this publication.

1 **Description**

The material shall consist of an homogeneous mixture of technical cyfluthrin, complying with the requirements of FAO/WHO specification 385/TC (2003), together with filler(s) and any other necessary formulants. It shall be in the form of a fine beige powder, free from visible extraneous matter and hard lumps.

Where the material is packaged in sealed water-soluble bags (Note 1), the material shall consist of a defined quantity of cyfluthrin wettable powder, complying with the requirements of WHO specification 385/WP contained in a sealed water-soluble bag.

2 **Active ingredient**

2.1 **Identity tests** (CIPAC 385/TC/M/2, CIPAC Handbook H, p 107, 1998, 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.

2.2 **Cyfluthrin content** (CIPAC 385/WP/M/3, CIPAC Handbook H, p 113, 1998)

The cyfluthrin content shall be declared (100 g/kg) and, when determined, the average content measured shall not differ from that declared by more than the tolerance given below

Declared content in g/kg Tolerance
100 ± 10% of the declared content

3 **Relevant impurities**

3.1 **Water** (MT 30.5, CIPAC Handbook J, p 120, 2000)

Maximum: 35 g/kg.

4 **Physical properties**

4.1 **pH range** (1% dispersion) (MT 75.3, CIPAC Handbook J, p 131, 2000)
pH range: 6.0 to 7.5.
Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of
current versions by checking at: http://www.who.int/whopes/quality/en/.

4.2 **Wet sieve test** (MT 59.3, CIPAC Handbook F, p 179, 1995)

Maximum: 5% retained on a 40 µm test sieve.
Maximum: 4% retained on a 75 µm test sieve.
Maximum: 2% retained on a 100 µm test sieve.

4.3 **Suspensibility** (MT 15.1, CIPAC Handbook F, p 45, 1995; or MT 177, CIPAC Handbook F, p 445, 1995) (Notes 3, 4 and 5)

A minimum of 70% of the cyfluthrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C. In the case of water-soluble bag packaging, the provisions of clause 6.2 should be applied.

4.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p 152, 1995) (Note 6)

Maximum: 10 ml after 1 min.
In the case of water-soluble bag packaging, the provisions of clause 6.3 should be applied.

4.5 **Wettability** (MT 53.3, CIPAC Handbook F, p 164, 1995)

The formulation shall be completely wetted in 2 min without swirling.

5 **Storage stability**

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p 128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 7) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- wet sieve test (4.2);
- suspensibility (4.3).

In the case of water-soluble bag packaging, the package should be enclosed in a watertight sachet, box or any other container at 54°C for 14 days. The determined average active ingredient content must not be lower than 95 %relative to the determined average content found before storage, and theformulation shall continue to comply with the clauses for:

- pH range (4.1);
- wet sieve test (4.2);
- dissolution of the bag (6.1);
- suspensibility (6.2);
- persistent foam (6.3).

None of the bags tested should show signs of leakage or rupture during normal handling, before and after storage

6 **Material packaged in a sealed water-soluble bag** (see Notes 8, 9 and 10)

6.1 **Dissolution of the bag** (MT 176, CIPAC Handbook F, p 440, 1995)

The dissolution of the bag shall be tested on a sample of the emptied and

cleaned bag, taken according to the procedure described in Note 9, together with an appropriate proportion of the WP.
Flow time of the suspension: maximum 160 seconds.

6.2 **Suspensibility** (MT 15.1, CIPAC Handbook F, p 45, 1995; or MT 177, CIPAC Handbook F, p 445, 1995) (Notes 3, 4 and 5)

The suspensibility shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 10.

A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

6.3 **Persistent foam** (MT 47.2, CIPAC Handbook F, p 152, 1995) (Note 6)

The persistent foam shall be tested on a suspension containing the WP and the bag in the actual ratio of application, prepared according to the procedure described in Note 10.
Maximum: 10 ml after 1 min.

6.4 **Wettability** (MT 53.3, CIPAC Handbook F, p 164, 1995)

The formulation shall be completely wetted in 2 min without swirling.

Note 1 For record keeping purposes, the suffix "SB" should be added to the formulation code (WPSB).

Note 2 Complete identification of cyfluthrin requires confirmation that the diastereoisomers are present in the appropriate ratio (refer to specification 385/TC, 2003, clause 2.3).

Note 3 The formulation should be tested at the highest and lowest rates of use recommended by the
supplier, provided this does not exceed the conditions given in methods MT 15.1 or MT 177.

Note 4 This test will normally only be carried out after the heat stability test 5.1.

Note 5 Chemical assay is the only fully reliable method to measure the mass of active ingredient still
in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 6 The mass of sample to be used in the test should be at the highest rate of use recommended
by the supplier.

Note 7 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

Note 8 Sub-sampling

Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals.
Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for.

- active ingredient identity (2 1);
- active ingredient content (2.2),
- water content (3.2);
- pH range (4.1);
- wet sieve test (4.2);
- wettability (4.5);
- dissolution of the bag (6.1);
- suspensibility (6.2);
- persistent foam (6.3).

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test (6.1). Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (6.2) and persistent foam (6.3) tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Note 9 The sampling of the bag for the dissolution test should be as follows:

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag .Carry out the dissolution test immediately to avoid any modification of the sample.

Note 10 The procedure for adding the bag material to the solution for the suspensibility and the persistent foam tests should be as follows:

Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a 100 mg sample (n mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by

stirring in the standard water used for the tests to give a final volume of n ml. Store the stock solution in a stoppered bottle before use.

Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the wettable powder, according to the following equation.
V(ml) = X x 1000B
W
where: B (g) = weight of the emptied and cleaned bag;
W (g) = nominal weight of the WP contained in the bag;
X (g) = weight of the WP sample used in the test.

LAMBDA-CYHALOTHRIN WETTABLE POWDER

WHO Specification 463/WP (2003 I)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (463/2003, 463/2006). It should be applicable to relevant products of these manufacturers, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a
guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation reports (463/2003 , 463/2006), as PART TWO, form an integral part of this publication.

1 **Description**

The material shall consist of an homogeneous mixture of technical lambdacyhalothrin, complying with the requirements of WHO specification 463/TC
(2003), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps. Where the material is packaged in sealed water soluble bags (Note 1), the material shall consist of a defined quantity of a lambda-cyhalothrin wettable powder, complying with the requirements of WHO specification 463/WP, contained in a sealed water soluble bag.

2 **Active ingredient**

2.1 **Identity tests** (CIPAC 463/WP/M-, CIPAC Handbook E, 1992)

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

2.2 **Lambda-cyhalothrin content** (CIPAC 463/WP/M-, CIPAC Handbook E, 1992)

The lambda-cyhalothrin content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the following amounts:

Declared content in g/kg Permitted tolerance

up to 25 ± 15% of the declared content

above 25 up to 100 ± 10% of the declared content

Note: in each range the upper limit is included.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of
current versions by checking at: http://www.who.int/whopes/quality/en/.

3 **Physical properties**

3.1 **pH range** (MT 75.2)

pH range: 5.5 to 9.0.

3.2 **Wet sieve test** (MT 59.3)

Maximum: 2 % retained on a 75 µm test sieve.

3.3 **Suspensibility** (MT 184) (Notes 2 and 3)

A minimum of 50 % of the lambda-cyhalothrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C (Note 4). In the case of water soluble bag packaging, the provisions of clause 5.2 should be applied.

3.4 **Persistent foam** (MT 47.2) (Note 5)

Maximum: 60ml after 1 min.

In the case of water soluble bag packaging, the provisions of clause 5.3 should be applied.

3.5 **Wettability** (MT 53.3)

The formulation shall be completely wetted in 1 min, without swirling.

4 **Storage stability**

4.1 **Stability at elevated temperature** (MT 46.3)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- pH range (3.1);
- wet sieve test (3.2);
- suspensibility (3.3);
- wettability (3.5).

In the case of water soluble bag packaging, the package should be enclosed in a watertight sachet, box or any other container, at 30°C for 18 weeks. The determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- pH range (3.1);
- wet sieve test (3.2);
- dissolution of the bag (5.1);
- suspensibility (5.2);
- persistent foam (5.3).

None of the bags tested should show signs of leakage or rupture during normal handling, before and after storage.

5 **Material packaged in a sealed water soluble bag** (Note 7)

5.1 **Dissolution of the bag** (MT 176) (Note 8)

The dissolution of the bag shall be tested on a sample of the emptied and cleaned bag taken according to the procedure described in Note 8, together with an appropriate proportion of the WP. Flow time of the suspension: maximum 30 sec.

5.2 **Suspensibility** (MT 184) (Notes 2 and 3)

The suspensibility shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 9.

A minimum of 50% shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C (Note 4).

5.3 **Persistent foam** (MT 47.2) (Note 5)

The persistent foam shall be tested on a suspension containing the WP and the bag in the actual ratio of application, prepared according to the procedure described in Note 9.
Maximum: 60ml after 1 min.

Note 1 For record keeping purposes, the suffix "SB" should be added to the formulation code (WPSB).
Note 2 The formulation should be tested at the highest and lowest rates of use recommended by
the supplier, provided this does not exceed the conditions given in method MT 184.
Note 3 This test will normally only be carried out after the heat stability test 4.1.
Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".
Note 5 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.
Note 6 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.
Note 7 Sub-sampling
Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:
- active ingredient identity (2.1),
- active ingredient content (2.2);
- pH range (3.1);
- wet sieve test (3.2);
- wettability (3.5);
- dissolution of the bag (5.1);
- suspensibility (5.2);
- persistent foam (5.3).

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test (5.1). Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (5.2) and persistent foam (5.3) tests. In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Note 8 The sampling of the bag for the dissolution test should be as follows:

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag. Carry out the dissolution test immediately to avoid any modification of the sample. Note 9 The procedure for adding the bag material to the solution for the suspensibility and the persistent foam tests should be as follows: Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a 100 mg sample (n mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by stirring in the standard water used for the tests to give a

BIFENTHRIN
WETTABLE POWDER

Interim specification WHO/IS/WP/415/2001

CAUTION: The use of hard water may create suspensibility problems.

1. Specification

1.1 Description

The material shall consist of an homogeneous mixture of technical bifenthrin, complying with the requirements of WHO specification WHO/IS/TC/415/2001, in a form of a fine, free flowing powder that wets out readily on stirring into water, together with filler(s) and any other necessary formulants. It shall be in form of a fine off-white to tan powder free from visible extraneous matter and hard lumps.

1.2 Chemical and physical requirements

The material, sampled from any part of the consignment (see method WHO/M/1.R1) shall comply with the requirements of section 1.1 and with the following requirements.

1.2.1 Bifenthrin *content (g/kg basis)*

The content of bifenthrin (g/kg basis), determined by the method described in section 2.1, shall not differ from the declared content by more than the following amount:

Declared content	*Permitted Tolerance*
Above 25 up to 100 g/kg	± 10% of the declared content
Above 100 up to 250 g/kg	± 6% of the declared content

Higher declared contents are not currently available

The average content of all samples taken shall not be lower than the declared content.

1.2.2 Water

The water content determined by the method described in WHO/M/7.R.1 (equivalent to CIPAC method MT 30.5, CIPAC Handbook J, p. 120), shall not be higher than 30.0 g/kg.

1.2.3. *Wet sieving*

Not less than 98% of the powder shall pass through a 75 ∝m sieve and not less than 95% of the powder shall pass through a 60 ∝m sieve, when tested by the CIPAC method MT 59.3 (CIPAC Handbook F, p.179).

1.2.4 *Suspensibility*

In WHO hard standard water. When tested by the CIPAC method MT 15.1 (CIPAC Handbook F, p.45), a minimum of 60 % of the bifenthrin content found under 1.2.1 shall be in suspense on after 30 minutes in WHO standard hard water (WHO method WHO/M/29) at 30 + 2^{0}C. Alternatively, if the buyer requires other standard waters to be used, then this shall be specified when ordering.

1.2.5 *pH range & Acidity*

The pH of the material, when determined by the CIPAC method MT 75 (CIPAC Handbook F, p.205), shall be in the range 8.00 to 10.0.

The acidity of the material, when determined by the CIPAC method MT 31 (CIPAC Handbook F, p.96), shall not be higher than 0.5 g/kg calculated as H2SO4.

1.2.6 *Persistent foam*

The persistent foam of the material at the top of a 250 mL of suspension prepared in standard hard water, shall not exceed 15 mL when tested by the CIPAC method MT 47.2 (CIPAC Handbook F, p.152) after 1 minute.

1.2.7 *Wettability*

In WHO standard hard water (WHO/M/29).The wettability of the material, when determined by the CIPAC method MT 53.3 (CIPAC Handbook F, p.164), shall not be higher than 3 minutes.

1.2.8 *Heat stability*

The powder after treatment as described in section 2.2 must comply with the requirements of sections 1.2.1, 1.2.3, 1.2.4 and 1.2.7 of this specification.

1.3 Packing and marking of packages

The bifenthrin wettable powder shall be packed in suitable clean bulk packs, as specified in the order.

All packages shall bear, durably and legibly marked on the containers, the following:

2 The product should be tested at the highest and lowest rates of use recommended by the supplier, provided this is consistent with the conditions given in the method.

Manufacturer's name
Bifenthrin wettable powder
Bifenthrin... ...g/kg
Batch number or reference number, and date of test
Net weight of contents
Date of formulation
Instruction for use

and the following minimum cautionary notice:

Bifenthrin is a pyrethroid that acts predominantly on the central nervous system: high dosages have been found to cause tremor and clonic convulsions in experimental animals. A high concentration in air may be irritant to the eyes and contact with the concentrated product may induce a temporary tingling sensation, particularly on the face. It may be hazardous if swallowed. Do not inhale spray mist. Avoid skin contact: wear protective gloves, clean protective clothing, and a face mask (surgical type) when handling the product. Wash hands and exposed skin thoroughly after using.

Keep containers out of reach of children and well away from foodstuffs and animal feed and their containers. If poisoning occurs, call a physician. Treatment is symptomatic.

Bifenthrin is toxic to aquatic wildlife. Avoid accidental contamination of water.

Methods of determining chemical and physical properties

2.1 Bifenthrin content

2.1.1 Outline of method

This test method describes the analysis of wettable powder formulations.

Improved column technology and method optimization have yielded a method which give results equivalent or superior to previous methods.

Bifenthrin is determined by comparison to an internal standard, octacosane. A test solution containing a known concentration of octacosane is utilized by comparing instrument response (peak area) of the internal standard to the relative response of bifenthrin, taking into account the amount of sample being analyzed.

2.1.2 Apparatus

Analytical Balance. Capable of accurately weighing to 0.1 mg or equivalent.

Centrifuge.
Gas Chromatograph. Capable of operating over the range 100 to 300°C, fittedwith a flame ionization detector and data collection system and if possible an autosampler.

Graduated Cylinder, 500 mL.
Reciprocating Shaker.
Vials, Minimum 40 mL capacity, with poly-lined cap.
Volumetric Pipette.
Magnetic Stirrer and stir bar.

Column. Megabore DB-210, 30 meter length, 0.53 mm internal diameter, film thickness 1 m; maximum temperature (isothermal) 200 C. Available from J&W Scientific, or equivalent.

2.1.3 Reagents

Octacosane. Eastman Kodak Chemical Co or equivalent.
Heptane.
Acetone.
Bifenthrin, Analytical Standard Grade, available from FMC Corporation, Agricultural Chemical Group, Princeton, NJ, USA.

2.1.4 Analytical instrument parameters

Gas Chromatograph parameters (all conditions may be adjusted to optimize results):

Oven Temperature:	205 C
Injection Port Temperature:	240 C
Detector Temperature:	300 C

Data Station Parameters (all parameters may be modified to optimize results):

Run Time:	8 minutes
Chart Speed:	0.5 cm/min
Zero:	5% full scale

2.1.5 Determination of response factor "RF"

Weigh 0.1 g of the analytical standard, to the nearest 0.001g, and place into a vial.

Prepare an internal standard stock solution by weighting 2.5 g octacosane, to the nearest 0.01 g, and placing it into a bottle with a capacity of at least 1000 mL. To this add 700 mL of heptane and 175 mL of acetone, which have been measured bya graduated cylinder. Mix well using a magnetic stirrer.

Pipette 40 mL of the internal standard stock solution to the vial containing the analytical standard; mix on reciprocating shaker until dissolved.

Inject 1 L of the standard solution into the gas chromatograph.

Obtain several chromatograms and measure the peak areas of the internal standard and bifenthrin.

Calculate response factor by the following formula:

$$Rf = \frac{A_{is} \times WT_{std} \times P_{std}}{A_{std} \times WT_{is} \times P_{is}}$$

Where: A_{is} = Area internal standard

A_{std} = Area bifenthrin
WT_{std} = Weight of standard
WT_{is} = Weight of internal standard
P_{std} = Purity of bifenthrin standard
Pis = Purity of internal standard

2.1.6 *Sample preparation*

Bifenthrin wettable formulations: weight a sufficient amount of sample to obtain 0.1 g bifenthrin into a vial; add 40 mL of internal standard stock solution and mix on reciprocating shaker for 30 minutes.

Inject 1 µL portions of the sample solutions, obtaining three replicate injections for each. Run a standard injection series after every three or four samples.

Calculate percent (%) active ingredient bifenthrin by the following formula:

$$\% = \frac{A_{spl} \times WT_{is} \times RF \times 100}{A_{is} \times WTspl}$$

Where: A_{spl} = Area of bifenthrin in sample
WT_{is} = Internal standard weight
RF = Response Factor
A_{is} = Area of internal standard peak
WT_{spl} = Sample weight

2.2 Heat stability treatment

54 + 2°C for 14 days (CIPAC method MT 46.1, CIPAC Handbook F, p.149), unless other temperatures and times are requested (FAO Manual on the development and use of FAO specifications for plant protection products, no.149, p.33).

After completion of the heat stability treatment, the samples should not be exposed to heat, bright sunshine, or atmospheric humidity.

If required the test should be conducted in the commercial type pack.

ALPHA-CYPERMETHRIN WETTABLE POWDER

WHO specification 454/WP (February 2015*)

This specification, which is PART ONE of this publication, is based on evaluations of data submitted by the manufacturers whose names are listed in the evaluation reports (454/2005, 454/2007, 454/2009, 454/2011). It should be applicable to relevant products of these manufacturers, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation reports (454/2005, 454/2007, 454/2009, 454/2011), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical alpha-cypermethrin, complying with the requirements of WHO specification 454/TC (January 2013), together with filler(s) and any other necessary formulants. It shall be in the form of a freely flowing fine powder, free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 Identity tests (454/WP/(M)/2, CIPAC Handbook H, p.18, 1998)

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

2.2 Alpha-cypermethrin content (454/WP/(M)/3, CIPAC Handbook H, p.18, 1998)

The alpha-cypermethrin content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the following tolerance.

Declared content in g/kg	Tolerance
above 25 up to 100 Note: the upper limit is included in the range.	± 10% of the declared content

3 Physical properties

3.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 4.0 to 8.0.

3.2 Wet sieve test (MT 185, CIPAC Handbook K, p.149, 2003)

Maximum: 2% of the formulation shall be retained on a 75 µm test sieve.

---

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/

3.3 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Note 1)
A minimum of 70% of the alpha-cypermethrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C (Note 2).

3.4 **Wettability** (MT 53.3.2, CIPAC Handbook F, p.164, 1995)

The formulation shall be completely wetted in 1 min with swirling.

3.5 **Persistent foam** (MT 47.3) (Notes 3 & 4)

Maximum: 60 ml after 1min.

4 Storage stability

4.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 5), and the formulation shall continue to comply with the clauses for:

- pH range (3.1),
- wet sieve test (3.2),
- suspensibility (3.3),
- wettability (3.4).

Note 1 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided it does not exceed the conditions given in method MT 184.

Note 2 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 3 The CIPAC method MT 47.2 published in Handbook F for determination of persistent foam created when formulations are added to water before use was updated to MT 47.3. This new method was accepted as a full CIPAC method in 2013. Prior to its publication in the next Handbook, copies of the method can be obtained through the CIPAC website, http://www.cipac.org/cipacpub.htm

Note 4 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 5 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

Minutes of the Technical Specification Committee meeting on Rapid Diagnostic test kit for kala-azar and Synthetic Pyrethroid (wdp) for Kala-azar.
Date: 20th February, 2023, Dte. GHS, Nirman Bhawan, New Delhi

A meeting in hybrid mode was held on 20/02/2023 (2.00 pm to 4.00 pm) at Resource Centre (445-A), Dte. GHS, Nirman Bhawan under the Chairmanship of Addl. DGHS with members of the Technical Specification Committee for review and finalizing technical specification of Kala-azar {RDK-KA & SP(wdp)-KA}. **The list of participants is annexed.**

The main discussion points are given below:

- NCVBDC briefed the committee that the Indoor Residual Spray in kala-azar endemic areas were switched over from DDT 50% wdp to Synthetic Pyrethroid (wdp) as some of the areas were showing resistance to the sand fly vector.
- As per trial permission granted by CIB&RC, IRS activities are being undertaken in the kala-azar endemic areas with Synthetic pyrethroid. As of now, NCVBDC have got supplies of Alphacypermethrin 5% wdp only, as found L1 bidder in the tender is invited by procurement agency. Representative of CIB&RC conveyed that the permission to use SP(wdp) has been extended for the first round of this year. Representative of CIB informed that data generated by international agency eg. LSTM is not accepted by CIB.
- NCVBDC presented the current Technical Specification of SP(wdp) and RDK-KAto the Technical Specification Committee experts. The experts provided inputs on the technical specifications of SP(wdp) and RDK-KA and suggested the incorporation of the same.

SP(wdp)-KA

- As the disease is in elimination mode, it is agreed that at present, committee will go only for some minor changes in the current specification.
- It was opined to remove EtofenpProx - 471/WP from the specification as it is not registered / approved by CIB&RC from the list of public health insecticides/pesticides of SP(wdp).
- Committee decided to remove the conversion / calculation and comparison formula along with dosages per square metre from the specification and to retain requirement/ million population, and asked the programme division to submit it separately to Procurement agency. It is also decided that entire paras D & E to be removed.
- It was agreed that only one synthetic pyrethroid may be procured with revision of its name in indent as SP with no mention of percentage or specify the single SP Alphacypermethrin 5% wdp.
- Director, NCVBDC requested RMRIMS if they could generate susceptibility / resistance data on all SPs within a year, so as to procure all SPs futuristically in the sustenance period, to which RMRIMS representative had said that they may conduct a field study.
- Dr. Ashwani Kumar, informed that WHO released diagnostic concentrations for sandflies may be used for resistance monitoring studies including against different SP compounds.
- Dr. Kalpana Baruah recommended that longitudinal data over 2-3 seasons should be beneficial.

RDK-KA

- It was agreed by the members that the details of packaging, storage and shelf life description as similar to the Bivalent RDT – Malaria may be used for RDK also as this has been discussed after detail deliberation and agreed to include the same in RDK.
- RMRIMS, Patna informed that in the description of product, it should be written as the product, IgG / Antibody based test kit.
- Dr. Rinku Sharma opined that the information relating to RDT kits' storage temperature may be revised and obtained from RMRIMS.
- DDC(I) informed that the quality parameter for the product should be written as: the product should comply with BIS / ISO 13485 or latest.
- ICMR-RMRIMS to be identified as the reputed institute under the column of "Field tested" in para H.
- It was agreed that the Draft Technical Specifications of SP(wdp) and RDK-KA will be updated post incorporation of suggestions of the experts and the same will be circulated to experts for their final inputs (if any) and signature.

The meeting ended with a vote of Thanks to the Chair.

Dr. M.N. Reddy,
Asst. Director (Ento.), CIB&RC

Dr. Kuldeep Singh
Scientist – B, NIMR(ICMR)

Dr. Ravi Kant Sharma,
DDC(I), CDSCO

Sh. Manoj Kumar Sinha,
Deputy Secretary (Proc.),MoH&FW

Dr. Rinku Sharma,
Joint Director, NCVBDC

Dr. Dhruv Pandey,
NPO-NTD, WHO

Dr. [illegible] Pandey,
Director, RMRIMS(ICMR)
DIRECTOR
ICMR-Rajendra Memorial Research Institute of Medical Science

Dr. Rupak Chatterjee
Advisor (Stores)

Dr. Ashwani Kumar,
Director, VCRC(ICMR)

Dr. Amita Bali
DDG (Stores),Dte.GHS

Sh. D.K.Singh
DDG & Director (Proc.)

Dr. Nupur Roy,
Sr. CMO (SAG)

Dr. Tanu Jain
Director, NCVBDC

Dr. Anil Kumar,
Addl. DG, Dte. GHS
& Chairperson

Annexure

In Person Participation

1. Dr. Anil Kumar, Additional DG, Dte. GHS– Chair
2. Dr. Tanu Jain, Director, NCVBDC, Delhi.
3. Dr. Nupur Roy, Sr. CMO(SAG), NCVBDC, Delhi
4. Dr. Amita Bali, DDG(Store), Dte. GHS
5. Dr. Rupak Chatterjee, Advisor (Store), Dte. GHS
6. Sh. D.K. Singh, DDG(Proc.), Dte. GHS
7. Dr. Rinku Sharma, Joint Director, NCVBDC, Delhi.
8. Dr. Kuldeep Singh, Scientist B, NIMR(ICMR), Delhi
9. Dr. M. Narsi Reddy, Asst. Director (Ento.), CIB&RC, Faridabad.
10. Dr. Jagadeep Adhikam, Medical Officer, NCVBDC, Delhi

Virtual Participation

1. Dr. Krishna Pandey, Director, RMRIMS (ICMR), Patna.
2. Dr. Ashwani Kumar, Director, VCRC (ICMR), Puducherry.
3. Dr. Manju Rahi, DDG & Director in charge (NIMR), ICMR, Delhi.
4. Dr. Kalpana Baruah, Consultant (Entomology), NCVBDC
5. Dr. Ravi Kant Sharma, DDC(I), CDSCO, Dte. GHS, Delhi.
6. Dr. Dhruv Pandey, NPO-NTD, WHO country office
7. Sh. Manoj Kumar Sinha, Deputy Secretary (Proc.), MoH&FW
8. Ms. Anjana, GM(Proc.), CMSS
9. Ms. Akansha Jain, AGM(QA), CMSS

Para	Present Specification (SP-wdp for KA-1)	Proposed changes as per TSC Meeting 20.02.23
A	WHO Specification for Public Health Insecticide/Pesticide 1. Deltamethrin -333/WP 2. Cyfluthrin - 385/WP 3. Lambdacyhalothrin - 463/WP 4. EtofenpProx - 471/WP 5. Alphacypermethrin - 454/WP 6. Bifenthrin - 415/WP (interim)	1 EtofenpProx - 471/WP to be removed. 2. details of annexure for Alphacypermethrin - 454/WP to be changed as per WHO Feb. 2015 update
B	The Central Insecticide Board (CIB) has approved the following Insecticides for Public Health use. 1. Deltamethrin 2.5% (wdp) 2. Cyfluthrin 10% (wdp) 3. Lambdacyhalothrin 10% (wdp) 4. Alphacypermethrin 5% (wdp) 5. Bifenthrin 10% WP EtofenpProx is not registered under CIB	1. EtofenpProx - 471/WP to be removed.
The details of the description, active ingredient, physical properties, wet sieve test, wettability, persistent foam, storage stability as per WHO specification is enclosed at Annexure for each insecticide(s) mentioned at B above.		

Para	Present Specification (SP-wdp for KA-2)			Proposed changes as per TSC Meeting 20.02.23
C	The committee also looks into the conversion formula i.e calculations for comparison of requirement vis-a-vis cost due to variation in their active ingredient			To be removed.
Sr No	Insecticide (wdp)	Requirement/million population (MT)	Dosages /m^2 of active ingredient	
1	Deltamethrin 2.5%	60.00 MT	20mg/m^2	
2	Cyfluthrin 10%	18.75 MT	20mg/m^2	
3	Lambdacyhalothrin	18.75 MT	25mg/m^2	
4	Alphacypermethrin	37.5 MT	25mg/m^2	
5	Bifenthrin	18.75 MT	25mg/m^2	

Para	Present Specification(SP-wdp for KA-3)	Proposed review
D	The dose spray remains un-altered in NVBDCP considering the respective dose of Cyfluthrin, Lambdacyhalothrin and Bifenthrin which are available in high concentration i.e. 10% WDP. The quantity would be 3.2 times more if the strength is reduced to 2.5%. 60 MT: 18.75 MT (for 1 million Population) 3.2 : 1 Similarly, Alphacypermthrin which is available in high concentration i.e. 5% WDP. The quantity would be 1.6 times more if the strength is reduced to 2.5%. 60 MT: 37.50. MT (for 1 million Population) 1.6 : 1	To be removed.

E	Similarly the cost of different insecticides may be calculated based on same mathematical formula as mentioned above. For example Deltamethrin 2.5% - Rs. 7,80,000 = Rs. 7,80,000 Cyfluthrin 10% - Rs. 24,96,000 = Rs. 7,80,000 Divided by 3.2 Lambdacyhalothrin 10% -Rs. 24,96,000 = Rs. 7,80,000 Divided by 3.2 Bifenthrin 10% -Rs. 24,96,000 = Rs. 7,80,000 Divided by 3.2 Alphacypermethrin 5% -Rs.4,87,500 = Rs. 7,80,000 Divided by 1.6 (the price is indicative one & here its use is only for calculation purposes/comparison of rates).	To be removed.

Para	Present Specification (RDK-KA-1)	Proposed changes as per TSC Meeting 20.02.23
A. Performance	The product should have at least 95% and above specificity and sensitivity for wider competition under field conditions.	The product (IgG - an Antibody based test) should have at least 95% and above specificity and sensitivity for wider competition under field conditions.
B. Ease of Use	Kits should allow for use whole blood/serum for conducting the test.	No Change
C. Packaging	o Each rapid test strip should be individually packed in moisture proof pouch. o Not only the Goods, but also the packaging component should also conform to specifications suitable for use in a climate similar to that prevailing in the country of the purchaser. o All packaging must be properly sealed and tamper-proof. o Goods requiring refrigeration for stability must specifically indicate storage requirements on labels and containers and be shipped in the special containers to ensure stability in transit from point of shipment to the port of entry.	Each kit should be thematically sealed in non –permeable pouch and should have moisture absorbent material . 25 such test kits or lesser quantity as required by programme should be packed in a box. Adequate literature detailing the kit components , principle, methodologies and validity criteria should be provided as the kit insert with test kit. Storage conditions, expiry dates and limitation of test should be provided. The small box should be packed in a bigger card board carton containing 10 such small boxes. The cartoon should be sealed with sealing tape. Ground transportation can be carried out during any stage of delivery without delay , maintaining the temperature requirement while the vehicle is moving and is parked. Avoid vehicle parking in sun having Test kits.

Para	Present Specification (RDK-KA-2)	Proposed changes as per TSC Meeting 20.02.23
D. Condition of storage	The Kit should be stable through its Shelf life, when stored at a maximum of 30 degree Celsius.	Test should have thermal stability for use in areas with very high ambient temperature as per evaluation after 60 days of incubation at room temperature 30 to 45 degree Celsius.

E. Shelf life	Minimum two years. Shelf life from manufacturing day to expiry date should be at least 2 years and it should not pass more than 1/4th (for imported) and 1/6th of their effective life from the date at the time material offered for inspection. Losses due to premature deterioration as a result of biological and other activities during the life of potency of the Rapid Diagnostic Test kits will be made good by the firm at their cost	Shelf life from manufacturing date to expiry date should be at least 2 years and it should not have lost more than 1/6th of their effective life from date the date at the time material is offered for inspection. In case of losses due to premature deterioration as a result of biological and other activities during the life of potency of the test , it will be made good by the supplying firm at their own cost.
F. Quality Assurance	The product should be complied with ISO 13485/BIS standards.	The product should be complied with BIS/ ISO 13485:2016 standards or latest.

Para	Present Specification (RDK-KA-3)	Proposed changes as per TSC Meeting 20.02.23
G. Registration of Product	The product should be licensed for import/ manufacture by DCG (I) / State drug controller under drugs and cosmetics Act 1940 and rules framed therein.	No Change
H. Field tested	Satisfactory field tested report should have been generated through any reputed institute(s) designated by the programme.	Satisfactory field tested report should have been generated through any reputed institute(s) designated by the programme such as ICMR-RMRIMS, Patna
I. labeling	Each strip of the test should be labeled as NVBDCP SUPPLY - NOT FOR SALE.	a). Each test kit should have space for recording particular of the patients, time and date of the test. b) The large carton (containing 10 small boxes) and small boxes (containing 25 test kits) should have the following marking; Name of the test, Lot/Batch number, Manufacturing and expiry date, Name of manufacturer and address, Details of content, storage conditions, Handling procedures, Disposal instruction for the box and its content. c). NVBDCP-Dte. GHS, Govt. of INDIA supply – NOT FOR SALE.

-End-

Nupur Roy

Krishna Pandey

Anil Kumar

Gmail NVBDCP KA <kadiv.nvbdcp@gmail.com>

Draft Minutes of the Technical Specification Committee (TSC) to review/finalize technical specifications of Kala-azar diagnostic kit / Synthetic Pyrethroid (wdp)- Insecticide reg.

Devendra Kumar Singh <dk.singh63@gov.in> 23 February 2023 at 13:54
To: Rupak Chatterjee <rupak.1960@gov.in>
Cc: kadiv nvbdcp <kadiv.nvbdcp@gmail.com>, "Dr.AnilKumar" <Anil.kumar07@gov.in>, dir ncvbdc <dir.ncvbdc@gmail.com>, Amita Bali <bali.amita@gov.in>, drmanjurahi@gmail.com, mso-mohfw <mso-mohfw@nic.in>, Krishna Pandey <pandey.krishna@icmr.gov.in>, ashwani07@gmail.com, Ashwani Kumar <director.vcrc@icmr.gov.in>, directorvcrc@gmail.com, rinkusharma2005@gmail.com, Manoj Kumar Sinha <Mk.sinha26@nic.in>, pandeyd@who.int, "DR.RAVIKANT SHARMA" <rk.sharma66@nic.in>, SONAI RAJAN <sonai.rajan@gov.in>, NarsiReddy mandadi <narsi.mandadi@gov.in>, kuldeepgju17@gmail.com, nimrguwahati@gmail.com, drkalpanabaruah@gmail.com, gmproc cmss <gmproc.cmss@gmail.com>, cmss agmqa1 <cmss.agmqa1@gmail.com>, nupur nvbdcp <nupur.nvbdcp@gmail.com>, jagadeep adhikam nvbdcp <jagadeep.adhikam.nvbdcp@gmail.com>, mobassir novel <mobassir.novel@gmail.com>

Minutes seem to be OK.
D. K Singh

From: "Rupak Chatterjee" <rupak.1960@gov.in>
To: "kadiv nvbdcp" <kadiv.nvbdcp@gmail.com>
Cc: "Dr.AnilKumar" <Anil.kumar07@gov.in>, "dir ncvbdc" <dir.ncvbdc@gmail.com>, "Amita Bali" <bali.amita@gov.in>, drmanjurahi@gmail.com, "mso-mohfw" <mso-mohfw@nic.in>, "Devendra Kumar Singh" <dk.singh63@gov.in>, "Krishna Pandey" <pandey.krishna@icmr.gov.in>, ashwani07@gmail.com, "Ashwani Kumar" <director.vcrc@icmr.gov.in>, directorvcrc@gmail.com, rinkusharma2005@gmail.com, "Manoj Kumar Sinha" <Mk.sinha26@nic.in>, pandeyd@who.int, "DR.RAVIKANT SHARMA" <rk.sharma66@nic.in>, "SONAI RAJAN" <sonai.rajan@gov.in>, "NarsiReddy mandadi" <narsi.mandadi@gov.in>, kuldeepgju17@gmail.com, nimrguwahati@gmail.com, drkalpanabaruah@gmail.com, "gmproc cmss" <gmproc.cmss@gmail.com>, "cmss agmqa1" <cmss.agmqa1@gmail.com>, "nupur nvbdcp" <nupur.nvbdcp@gmail.com>, "jagadeep adhikam nvbdcp" <jagadeep.adhikam.nvbdcp@gmail.com>, "mobassir novel" <mobassir.novel@gmail.com>
Sent: Thursday, February 23, 2023 12:22:58 PM
Subject: Re: Draft Minutes of the Technical Specification Committee (TSC) to review/finalize technical specifications of Kala-azar diagnostic kit / Synthetic Pyrethroid (wdp)- Insecticide reg.

Dear Sir,

I have gone through the minutes and amendments suggested and they seem to be OK.

Regards,

Dr Rupak Chatterjee.

From: "kadiv nvbdcp" <kadiv.nvbdcp@gmail.com>
To: "Dr.AnilKumar" <Anil.kumar07@gov.in>, "dir ncvbdc" <dir.ncvbdc@gmail.com>, "Amita Bali" <bali.amita@gov.in>, drmanjurahi@gmail.com, "Rupak Chatterjee" <rupak.1960@gov.in>, "mso-mohfw" <mso-mohfw@nic.in>, "Devendra Kumar Singh" <dk.singh63@gov.in>, "Krishna Pandey" <pandey.krishna@icmr.gov.in>, ashwani07@gmail.com, "Ashwani Kumar" <director.vcrc@icmr.gov.in>, directorvcrc@gmail.com, rinkusharma2005@gmail.com, "Manoj Kumar Sinha" <Mk.sinha26@nic.in>, pandeyd@who.int, "DR.RAVIKANT SHARMA" <rk.sharma66@nic.in>, "SONAI RAJAN" <sonai.rajan@gov.in>, "NarsiReddy mandadi" <narsi.mandadi@gov.in>, kuldeepgju17@gmail.com, nimrguwahati@gmail.com, drkalpanabaruah@gmail.com, "gmproc cmss" <gmproc.cmss@gmail.com>, "cmss agmqa1" <cmss.agmqa1@gmail.com>
Cc: "nupur nvbdcp" <nupur.nvbdcp@gmail.com>, "jagadeep adhikam nvbdcp" <jagadeep.adhikam.nvbdcp@gmail.com>, "mobassir novel" <mobassir.novel@gmail.com>
Sent: Wednesday, February 22, 2023 2:30:13 PM
Subject: Draft Minutes of the Technical Specification Committee (TSC) to review/finalize technical specifications of Kala-azar diagnostic kit / Synthetic Pyrethroid (wdp)- Insecticide reg.

Respected Sir/Madam,

Draft Minutes of the Technical Specification Committee (TSC) to review/finalize technical specifications of Kala-azar diagnostic kit / Synthetic Pyrethroid (wdp) - Insecticide for kala-azar held (virtual mode) under the chairmanship of Additional DG, Dte. GHS on 20.02.2023 at 02:00 PM is attached herewith for your kind comments/approval.

Current technical specification of Synthetic Pyrethroid (wdp), Rapid Diagnostic Test Kit for kala-azar, Bivalent RDT for Malaria and update on Alphacypermethrin 5% wdp (of February 2015 received from WHO) is also attached herewith for kind perusal.

It is requested to give your input/comments in track change mode for consideration by 26.02.2023.

--
Kala Azar Division
National Center Vector Borne Diseases Control
[Ministry of Health & Family Welfare]
Govt. of India
Dte. of NVBDCP
22-Sham Nath Marg, Delhi-110054