



Lot: 0190316

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|                                                                                                                                  |               |                                                                                                           |                           |                          |
|----------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------|---------------------------|--------------------------|
| Ciserano, 15/09/2014                                                                                                             |               | <b>BATCH No. 117214015</b>                                                                                |                           |                          |
| <b>ANALYSIS No. F183/2014</b>                                                                                                    |               |                                                                                                           |                           |                          |
| Manufacturing date: June 2014                                                                                                    |               | Retest date: June 2019                                                                                    | Batch size: 817,00 Kg     |                          |
| <b>PRODUCT</b>                                                                                                                   |               | <b>PYRANTEL PAMOATE</b><br>CAS N. 22204-24-6                                                              |                           |                          |
| Physical State: powder                                                                                                           |               | Molecular weight: 594,69                                                                                  |                           |                          |
| Colour: yellow to tan                                                                                                            |               | Formula : C <sub>11</sub> H <sub>14</sub> N <sub>2</sub> S.C <sub>23</sub> H <sub>16</sub> O <sub>6</sub> |                           |                          |
| Odour: odourless                                                                                                                 |               | Method No. 1172/1                                                                                         |                           |                          |
| Solubility: Practically insoluble in Water and Methanol, soluble in Dimethylsulfoxide and slightly soluble in Dimethylformamide. |               |                                                                                                           |                           |                          |
| DETERMINATIONS                                                                                                                   | RESULTS       | LIMITS USP                                                                                                | LIMITS EP                 | IN-HOUSE LIMITS          |
| <b>IDENTIFICATION</b>                                                                                                            |               |                                                                                                           |                           |                          |
| I.R. spectrum                                                                                                                    | Positive      | Positive                                                                                                  | Positive                  |                          |
| Ultraviolet Absorption                                                                                                           | Positive      | Positive                                                                                                  |                           |                          |
| HPLC                                                                                                                             | Positive      | Positive                                                                                                  |                           |                          |
| Loss on drying                                                                                                                   | 0.03 %        | n.m.t. 2,0%                                                                                               | n.m.t. 1,0%               |                          |
| Residue on ignition                                                                                                              | 0.059 %       | n.m.t. 0,5%                                                                                               | n.m.t. 0,1%               |                          |
| Iron                                                                                                                             | n.m.t. 75 ppm | n.m.t. 75 ppm                                                                                             | n.m.t. 75 ppm             |                          |
| Heavy metals                                                                                                                     | n.m.t. 20 ppm | n.m.t. 50 ppm                                                                                             | n.m.t. 20 ppm             |                          |
| Chlorides                                                                                                                        | n.m.t. 0,036% |                                                                                                           | n.m.t. 0,036%             |                          |
| Sulfate                                                                                                                          | n.m.t. 0,1%   |                                                                                                           | n.m.t. 0,1%               |                          |
| <b>ASSAY</b>                                                                                                                     |               |                                                                                                           |                           |                          |
| HClO <sub>4</sub> 0,1N (Pyranтел Pamoate)                                                                                        | 101.23 %      |                                                                                                           | min. 98,0%<br>max. 102,0% |                          |
| TBAOH 0,1N (pamoic acid)                                                                                                         | 65.00 %       |                                                                                                           |                           | min. 63,4%<br>max. 67,3% |
| HPLC (USP)                                                                                                                       |               |                                                                                                           |                           |                          |
| Pyranтел Pamoate (on dried basis)                                                                                                | 99.7 %        | min. 97,0%<br>max. 103,0%                                                                                 |                           |                          |
| pamoic acid (on dried basis)                                                                                                     | 64.9 %        | min. 63,4%<br>max. 67,3%                                                                                  |                           |                          |

Qualified Person

Quality Control Manager

| Ciserano, 15/09/2014                                                                                                             |                  | <b>BATCH No.</b> 117214015            |              |                                  |
|----------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------|--------------|----------------------------------|
| <b>ANALYSIS No.</b> F183/2014                                                                                                    |                  |                                       |              |                                  |
| Manufacturing date: June 2014                                                                                                    |                  | Retest date: June 2019                |              | Batch size: 817,00 Kg            |
| <b>PRODUCT</b>                                                                                                                   |                  | PYRANTEL PAMOATE<br>CAS N. 22204-24-6 |              |                                  |
| Physical State: powder                                                                                                           |                  | Molecular weight: 594.69              |              |                                  |
| Colour: yellow to tan                                                                                                            |                  | Formula : C11H14N2S.C23H16O6          |              |                                  |
| Odour: odourless                                                                                                                 |                  | Method No. 1172/1                     |              |                                  |
| Solubility: Practically insoluble in Water and Methanol, soluble in Dimethylsulfoxide and slightly soluble in Dimethylformamide. |                  |                                       |              |                                  |
| DETERMINATIONS                                                                                                                   | RESULTS          | LIMITS USP                            | LIMITS EP    | IN-HOUSE LIMITS                  |
| <b>Related Compounds (TLC)</b>                                                                                                   |                  |                                       |              |                                  |
| Single impurity max                                                                                                              | Not detectable   | n.m.t. 1,0%                           |              |                                  |
| <b>Related substances (HPLC)</b>                                                                                                 |                  |                                       |              |                                  |
| <b>Impurities List</b>                                                                                                           |                  |                                       |              |                                  |
| Cis-isomer                                                                                                                       | Not detectable   |                                       | n.m.t. 0,25% |                                  |
| Thiopheneacrylamide                                                                                                              | Not detectable   |                                       | n.m.t. 0,20% |                                  |
| Total known impurities                                                                                                           | Not detectable   |                                       | n.m.t. 0,3%  |                                  |
| Unknown Impurity Max                                                                                                             | 0.03 %           |                                       | n.m.t. 0,10% | n.m.t. 0,3%                      |
| Total unknown impurities                                                                                                         | 0.10 %           |                                       |              | n.m.t. 0,5%                      |
| Total Impurities                                                                                                                 | 0.10 %           |                                       |              |                                  |
| <b>RESIDUAL SOLVENTS</b>                                                                                                         |                  |                                       |              |                                  |
| Methanol                                                                                                                         | Not quantifiable |                                       |              | n.m.t. 150 ppm                   |
| Acetone                                                                                                                          | 11.6 ppm         |                                       |              | n.m.t. 50 ppm                    |
| <b>Particle size</b>                                                                                                             | 98.2 %           |                                       |              | n.l.t. 60% passes 75 mcm         |
| <b>Bulk density</b>                                                                                                              | 0.32 g/ml        |                                       |              | min. 0,20 g/ml<br>max. 0,45 g/ml |
| <b>Tapped density</b>                                                                                                            | 0.56 g/ml        |                                       |              | min. 0,40 g/ml<br>max. 0,70 g/ml |

Qualified Person

Quality Control Manager

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| Ciserano, 15/09/2014                                                                                                             |                | <b>BATCH No. 117214015</b>                                                                                |           |                                           |
| <b>ANALYSIS No. F183/2014</b>                                                                                                    |                |                                                                                                           |           |                                           |
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| <b>PRODUCT</b>                                                                                                                   |                | PYRANTEL PAMOATE<br>CAS N. 22204-24-6                                                                     |           |                                           |
| Physical State: powder                                                                                                           |                | Molecular weight: 594.69                                                                                  |           |                                           |
| Colour: yellow to tan                                                                                                            |                | Formula : C <sub>11</sub> H <sub>14</sub> N <sub>2</sub> S.C <sub>23</sub> H <sub>16</sub> O <sub>6</sub> |           |                                           |
| Odour: odourless                                                                                                                 |                | Method No. 1172/1                                                                                         |           |                                           |
| Solubility: Practically insoluble in Water and Methanol, soluble in Dimethylsulfoxide and slightly soluble in Dimethylformamide. |                |                                                                                                           |           |                                           |
| DETERMINATIONS                                                                                                                   | RESULTS        | LIMITS USP                                                                                                | LIMITS EP | IN-HOUSE LIMITS                           |
| <b>FOREIGN SUBSTANCES</b><br>Extraneous materials                                                                                | Not detectable |                                                                                                           |           | max 5 particles/20 g<br>smaller than 1 mm |
| Powders                                                                                                                          | n.m.t. 20 ppm  |                                                                                                           |           | n.m.t. 20 ppm                             |

We hereby certify that the material identified above has been analysed and found in accordance with the specifications of USP and Ph. Eur..

Qualified Person

Quality Control Manager

Release date: 24/07/2014