BATCH ANALYSESBATCHBATCH ANALYSESANALYSES ANALYSES ANALYSES ANALYSES

INTRODUCTIONINTRODUCTIONINTRODUCTION

BATCHES STUDIEDBATCHESBATCHES STUDIEDSTUDIED Information and results on industrial batches manufactured according to the process are presented in the following tables and compared to the release specifications of the drug product.Information and results on industrial batches manufactured according to the process are presented in the following tables and compared to the release specifications of the drug product.Information and results on industrial batches manufactured according to the process are presented in the following tables and compared to the release specifications of the drug product.

|  |  |  |  |
| --- | --- | --- | --- |
| Information | Batch No. | | |
| 2051416 | 2051102 | 2051417 |
| Date of manufacture | April 2021 | April 2021 | April 2021 |
| Batch size (tablets) | 2.000.000 | 2.000.000 | 2.000.000 |
| Batch use | Industrial batches | | |
| Manufacturing sites | Laboratoires | | |

BATCHES STUDIEDBATCHESBATCHES STUDIEDSTUDIED

RESULTSRESULTSRESULTS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tests** | **Specifications** | **Results** | | |
| 2051416 | 2051102 | 2051417 |
| **Appearance** | White, rod-shaped, film-coated tablet | Complies | Complies | Complies |
| **Average mass (mg)** | 88.4 to 97.6 (95 % to 105 % of theoretical mass) | 183.7 mg | 184.1 mg | 184.4 mg |
| **Uniformity of content** Ph. Eur. (2.9.40)   * S949 * S152 | Complies to Ph. Eur.  Acceptance Value (AV) ≤ 15.0%  Acceptance Value (AV) ≤ 15.0% | Complies  8 | Complies  8 | Complies  8 |
| **Microbiological quality** (Ph. Eur 5.1.4) | . Total aerobic microbial count (TAMC): ≤ 103 CFU/g  . Total combined yeasts/moulds count (TYMC): ≤ 102 CFU/g  . Escherichia coli: absence/1 g | Skip Test - Not Applicable | Skip Test - Not Applicable | Skip Test - Not Applicable |
| **Identification of drug** |  |  |  |  |
| **substance** |  |  |  |  |
| Liquid chromatography |  |  |  |  |
| - S 949  - S 152 | 0.95 ≤ *RTES*1520 ≤ 1.05  *RTTS*1520 | Positive | Positive | Positive |
|  | 0.95 ≤ *RTES* 9490  6 ≤ 1.05  *RTTS* 9490  6 | Positive | Positive | Positive |
| Thin-layer chromatography |  |  |  |  |
| - S 949  - S 152 | Must be identical to standard | Positive Positive | Positive Positive | Positive Positive |
| **Drug substance content (mg/tablet)**  - S 949  - S 152 | - 4.75 to 5.25 (95 % to 105 % of the theoretical content)  - 1.19 mg to 1.31 mg (95% to 105%) | 9.93 mg  1.29 mg | 9.90 mg  1.99 mg | 9.94 mg  1.93 mg |

RESULTSRESULTSRESULTS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tests** | **Specifications** | **Results** | | |
| 2051416 | 2051102 | 2051417 |
| **Control test for purity** (LC) |  |  |  |  |
| S9780-1 | ≤ 0.75 | 0.10 % | 0.10 % | 0.10 % |
| Y31 | ≤ 0.1 | <0.10 % | <0.10 % | <0.10 % |
| Y32 | ≤ 0.2 | <0.10 % | <0.10 % | <0.10 % |
| Y33 | ≤ 0.4 | <0.10 % | <0.10 % | <0.10 % |
| Any other degradation products | ≤ 0.2 | <0.10 % | <0.10 % | <0.10 % |
| Sum of degradation products | ≤ 1.0 | <0.10 % | <0.10 % | 0.10 % |

nq: equal to or below the reporting threshold ( 0.1 %)nq:nq: equalequal toto oror belowbelow thethe reportingreporting thresholdthreshold (( 0.1 0.1 %)%)

*AV: Acceptance value*

*AV: Acceptance value*