**BATCH ANALYSES**

1. **INTRODUCTION**

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.

1. **BATCHES STUDIED**

|  |  |  |  |
| --- | --- | --- | --- |
| Information | Batch No. | | |
| 2050717 | 2050957 | 2051204 |
| Date of manufacture | March 2021 | March 2021 | March 2021 |
| Batch size (tablets) | 4.500.000 | 4.500.000 | 4.500.000 |
| Batch use | Industrial batches | | |
| Manufacturing site | LES LABORATOIRES | | |

1. **RESULTS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tests** | **Specifications** | **Results** | | |
| 2050717 | 2050957 | 2051204 |
| **Appearance** | White, rod-shaped, film-coated tablet | Complies | Complies | Complies |
| **Average mass (mg)** | 88.4 to 97.6 (95 % to 105 % of theoretical mass) | 92.5 mg | 93.1 mg | 93.1 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 | Complies | Complies |
| **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 |  |  |  |  |
| - S949  - S152 | 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 |  |  |  |  |
| - S949  - S152 | Must be identical to standard | Positive Positive | Positive Positive | Positive Positive |
| **Assay of the drug substances**  **(LC Ph.Eur.2.2.29): 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%) | 4.94 mg  1.24 mg | 4.95 mg  1.24 mg | 4.95 mg  1.24 mg |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tests** | **Specifications** | **Results** | | |
| 2050717 | 2050957 | 2051204 |
| **Control test for purity** (LC) |  |  |  |  |
| S9780-1 | ≤ 0.75 | <0.10 % | <0.10 % | <0.10 % |
| Y32 | ≤ 0.2 | <0.10 % | <0.10 % | <0.10 % |
| Y33 | ≤ 0.2 | <0.10 % | <0.10 % | <0.10 % |
| Y31  Y36  Y38 | ≤ 0.5  ≤ 0.5  ≤ 0.5 | <0.10 %  <0.10 %  <0.10 % | 0.11 %  <0.10 %  <0.10 % | 0.11 %  <0.10 %  <0.10 % |
| Any other degradation products | ≤ 0.2 | <0.10 % | <0.10 % | <0.10 % |
| Sum of degradation products | ≤ 1.0 | <0.10 % | 0.11 % | 0.11 % |

*nq: equal to or below the reporting threshold (* *0.1 %)*

*AV: Acceptance value*