**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. | | |
| Information | 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 | Industrial batches | Industrial batches |
| Manufacturing sites | Laboratoires | Laboratoires | Laboratoires |

1. **RESULTS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tests** | **Specifications** | **Results** | | |
| Tests | Specifications | 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 ≤ RTES1520 ≤ 1.05  RTTS1520 | 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 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tests** | **Specifications** | **Results** | | |
| Tests | Specifications | 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 %)*

*AV: Acceptance value*

=== Mise à jour par REG X ===

Les données du document 2 ont été intégrées dans la section 'Batch Analyses'.

Comparaison des impuretés :

• Document 1 : 5 impuretés détectées

• Document 2 : 3 impuretés détectées

• Inversion de l'ordre des impuretés : Oui