

## Certificat d'analyse

F/SOP/CQ.025.01.01

**Certificat/Version:** ABIR250\_0\_03 000001

**Code:** 5239998

**Désignation:** Abiravitea 250 mg 120 cpr Chile

**Date de fabrication:** 01.06.2020

**Date de péremption:** 06.2022

**Lot Vrac:** 91121

**API:** M190600019, M200300009, M200300010

**Méthode:** MOP/PF.004.02

**Référence:** 5600011

**Lot:** 91130

**CoA:** 000000137189

**Date d'analyse:** 11.06.2020

| Tests                                   | Spécifications                    | Résultats  |
|-----------------------------------------|-----------------------------------|------------|
| <b>General Analysis</b>                 |                                   |            |
| Appearance                              | White to off-white oblong tablets | Complies   |
| Assay                                   | 90,0 - 110,0 %                    | 98,7 %     |
| <b>Identification</b>                   |                                   |            |
| Identification - HPLC                   | Positive                          | Positive   |
| Identification - UV                     | Positive                          | Positive   |
| <b>Uniformity of dosage unit</b>        |                                   |            |
| AV (n=10)                               | <= 15,0                           | 1,9        |
| <b>Dissolution Q=85%, 45 min.</b>       |                                   |            |
| S1 (n=6): individual results            | >= 90 %                           | 93,3 %     |
| S1 (n=6): individual results            | >= 90 %                           | 96,0 %     |
| S1 (n=6): individual results            | >= 90 %                           | 95,7 %     |
| S1 (n=6): individual results            | >= 90 %                           | 94,4 %     |
| S1 (n=6): individual results            | >= 90 %                           | 98,7 %     |
| S1 (n=6): individual results            | >= 90 %                           | 94,6 %     |
| S1 (n=6): average                       | >= 85 %                           | 95 %       |
| <b>Related Compounds</b>                |                                   |            |
| Alpha - Epoxyabiraterone acetate        | <= 0,80 %                         | 0,07 %     |
| Beta - Epoxyabiraterone acetate         | <= 0,80 %                         | 0,05 %     |
| Abiraterone                             | <= 0,40 %                         | n.d.       |
| Unknown impurities (max. indiv.)        | <= 0,20 %                         | < 0,05 %   |
| Total impurities                        | <= 2,0 %                          | 0,1 %      |
| <b>Microbiological Quality</b>          |                                   |            |
| Total aerobic microbial count (TAMC)    | <= 1000 cfu/g                     | < 10 cfu/g |
| Total combined yeast/mould count (TYMC) | <= 100 cfu/g                      | < 10 cfu/g |
| Escherichia coli                        | Absence (1g)                      | Absent     |

**Décision:** Approuvé

**Date de la Décision:** 20.07.2020

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Responsable Contrôle Qualité