Janssen Cilag S.p.A., Via C. Janssen (Borgo S. Michele),
04100 Latina (LT), Italy
Telephone : +39 0773 6161 - Fax : +39 0773 241312

Certificate of Analysis

C19070071/1

ZYTIGA Film-coated Tablets 500 mg

Product Code :	417634	Date of Manufacture :	04-2019
Batch Number :	JDZS900	Expiry Date :	03-2021
Batch ID :	JDZS900	Order :	000020699629
Importing Country :	Chile	Quantity :	562.000 PC

Test	Specification	Result
Appearance	Purple oval shaped film-coated tablet debossed with "AA" on one side and "500" on the other side	Pass
Identification IR	Complies with reference spectrum	Pass
Assay (HPLC)	90.0% - 110.0% of label claim	98.3 %
Chromatographic Purity		
R601249	<= 0.50 %	<0.01 %
R601252	<= 0.40 %	<0.01 %
R601251	<= 0.80 %	<0.01 %
R601250	<= 0.80 %	<0.01 %
Any Unspecified Degradation Product	<= 0.20 %	<0.05 %
Total Degradation Products	<= 2.0 %	<0.1 %
Uniformity of Dosage Units		
Acceptance value	<= 15.0 %	2.1 %
Mass/Weight Variation	Conforms to Current Ph. Eur. 2.9.40 and USP <905>	Pass
Dissolution	Q=85% at 30 min.	100 %

Information

Conclusion: **Approved**

Packaging Type : Bottle

Formula Description : Abiraterone Acetate 500 mg; Lactose Monohydrate; Microcrystalline Cellulose; Croscaramellose Sodium; Povidone; Sodium Lauryl Sulfate; Silica,Colloidal Anhydrous; Magnesium Stearate.

Market Authorization Number: F-23613/17

Microbial monitoring statement: Microbiological testing is performed on an established frequency

Manufacturing License number and Certificate GMP Compliance no.aM – 89/2018 and no. IT/184/H/2018

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We hereby certify that the above information is authentic and accurate.
This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country.
The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP.
This certificate of analysis has been created on 16-SEP-2019 and the batch release has been authorized by ANGELA COSTANTINO, Latina Qualified Person, by means of an electronic signature on 10-SEP-2019 12:34 CET. This certificate is produced by a validated Laboratory Information Management System and therefore bears no handwritten signature.