

**CERTIFICATE OF ANALYSIS**  
**BICALUTAMIDE Ph.Eur.**
*28/08/2023*

Format No. : QA/FM-235/01

|                   |                          |                        |            |
|-------------------|--------------------------|------------------------|------------|
| <b>Batch No.</b>  | : BL-22013(JM-01)-001    | <b>Date of Mfg.</b>    | : JUN-2022 |
| <b>AR. No.</b>    | : FG/0383/22             | <b>Date of Exp.</b>    | : MAY-2027 |
| <b>Batch Qty.</b> | : 111.240 Kg             | <b>Date of Release</b> | : 23/07/22 |
| <b>CEP No.</b>    | : R1-CEP 2012-223-Rev 01 |                        |            |

| Sr. No. | TESTS                                 | RESULTS               | SPECIFICATION                                                                                                               |
|---------|---------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------|
| 1.      | Description                           | White powder.         | White or almost white powder.                                                                                               |
| 2.      | Solubility                            | Complies              | Practically insoluble in water, freely soluble in acetone, slightly soluble in anhydrous ethanol and in methylene chloride. |
| 3.      | Identification (By IR)                | Complies              | The Infra Red spectrum of Sample should concordant with similar preparation of that of Bicalutamide WS.                     |
| 4.      | Loss on drying (at 105°C for 4 hours) | 0.21 %                | Not more than 0.5%                                                                                                          |
| 5.      | Sulfated ash                          | 0.04 %                | Not more than 0.1%                                                                                                          |
| 6.      | Related substances (By HPLC) Test- A  | Not detected          | Impurity C : Not more than 0.15%                                                                                            |
|         |                                       | Below disregard limit | Unspecified impurities                                                                                                      |
|         |                                       | Below disregard limit | Impurity A : Not more than 0.10%                                                                                            |
|         |                                       | Below disregard limit | Impurity B : Not more than 0.10%                                                                                            |
|         |                                       | Not detected          | Impurity D : Not more than 0.10%                                                                                            |
|         |                                       | Not detected          | Impurity E : Not more than 0.10%                                                                                            |
|         |                                       | Not detected          | Impurity F : Not more than 0.10%                                                                                            |
|         |                                       | Not detected          | Impurity J : Not more than 0.10%                                                                                            |
|         |                                       | Not detected          | Impurity M : Not more than 0.10%                                                                                            |
|         |                                       | Below disregard limit | Any other impurity : Not more than 0.10%                                                                                    |
|         |                                       | Below disregard limit | Total impurities : Not more than 0.5%                                                                                       |
|         | Test -B                               | Not detected          | 4-Amino-2- Trifluoromethylbenzonitrile (ATM) : Not more than 10 ppm                                                         |
|         |                                       | Not detected          | 4-Amino-3-trifluoromethylbenzonitrile (ATM isomer) : Not more than 10 ppm                                                   |
|         |                                       | Not detected          | 2,3-Epoxy-2-methyl-N-[4-cyano-3- (trifluoromethyl) phenyl] propanamide(BA-II) : Not more than 10 ppm                        |
| 7.      | Assay (By HPLC)                       | 99.82 %               | Not less than 98.5% w/w and Not more than 101.0% w/w on dried basis.                                                        |

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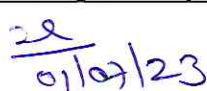
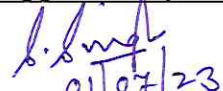
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| Sr. No. | TESTS                          | RESULTS      | SPECIFICATION                                                                                                                                 |
|---------|--------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| 8.      | Residual Solvents<br>(By HSGC) | 3 ppm        | Acetone : Not more than 5000 ppm                                                                                                              |
|         |                                | 124 ppm      | Ethyl formate : Not more than 5000 ppm                                                                                                        |
|         |                                | 8 ppm        | Dichloromethane : Not more than 600 ppm                                                                                                       |
|         |                                | Not detected | Ethyl Acetate : Not more than 5000 ppm                                                                                                        |
|         |                                | Not detected | Toluene : Not more than 890 ppm                                                                                                               |
| 9.      | Polymorphism<br>(By XRD)       | Complies     | The XRD peak at 2 Theta value at 12.3 ( $\pm$ 0.2) should be present. Pattern matches with that of standard XRD spectrum of polymorph form I. |

**Additional Test**

|    |               |              |                                |
|----|---------------|--------------|--------------------------------|
| 1. | Particle Size | 6.83 $\mu$ m | D(90):Not more than 10 $\mu$ m |
|----|---------------|--------------|--------------------------------|

Remark: The material Complies as per Ph.Eur. and above specification.

| Prepared By                                                                                     | Checked By                                                                                      | Approved By                                                                                       |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <br>01/07/23 | <br>01/07/23 | <br>01/07/23 |
| <b>Executive/Designee</b><br>Quality Assurance                                                  | <b>Manager/Designee</b><br>Quality Assurance                                                    | <b>Head Quality Assurance/<br/>Quality Control/Designee</b>                                       |

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**AARTI PHARMALABS LIMITED**

 Unit-IV, Plot No. E-50, 50/1 & 59/1,  
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