

## SAT OPERATIONAL QUALIFICATION PROTOCOL

**CUSTOMER** : Indian Immunologicals Limited

**EQUIPMENT** : 150L Blending Vessel

**REFERENCE DOCUMENTS** : Design Qualification Protocol  
2000.1666. DQ.001

**PROJECT SPECIFICATIONS** :

|                   |                      |
|-------------------|----------------------|
| Project Number    | 2000.1666.IIL        |
| Document Number   | 2000.1666.OQ.001     |
| Document Revision | R00                  |
| Document Title    | SAT OQ Protocol      |
| Equipment Name    | 150L Blending Vessel |
| Vessel ID         | D1666-001            |

**PROTOCOL APPROVALS** :

| OQ PROTOCOL       | NAME             | DEPARTMENT        | DATE       | SIGN           |
|-------------------|------------------|-------------------|------------|----------------|
| Prepared by : DB  | Nilesh Lavate    | Quality Assurance | 22.11.2016 | <i>Nilesh</i>  |
| Reviewed by : DB  | Rahul Kamble     | Quality Assurance | 22.11.2016 | <i>RAH</i>     |
| Approved by : DB  | Vijay Patil      | Projects          | 22.11.2016 | <i>Vijay</i>   |
| Reviewed by : IIL | R. Govinda Rao   | Engineering       | 22.12.16   | <i>Govinda</i> |
| Reviewed by : IIL | P.R. Fakumar     | Engineering       | 22.12.16   | <i>PRF</i>     |
| Approved by : IIL | Mahesh S. Neldar | QA                | 22.12.16   | <i>Mahesh</i>  |

**REVISION HISTORY** :

| REVISION NUMBER | DATE       | ISSUED BY | DESCRIPTION             |
|-----------------|------------|-----------|-------------------------|
| R00             | 22.11.2016 | QA        | For review and approval |

SAT OPERATIONAL QUALIFICATION PROTOCOL

SUMMARY REPORT: The Operational Qualification test are completed with test results, records, verifications with reference documents.

CONCLUSION: The execution operational Qualification is completed and found satisfactory.

POST APPROVAL:

| COMPANY                       | NAME              | DEPARTMENT  | SIGN & DATE                 |
|-------------------------------|-------------------|-------------|-----------------------------|
| Dyna Biotech                  | Manas Bhatta      | Automation  | <i>[Signature]</i> 23.12.16 |
| Dyna Biotech                  | Kokate Vicky      | QA          | <i>[Signature]</i> 27.12.16 |
| Dyna Biotech                  | —                 | —           | —                           |
| Indian Immunologicals Limited | R. Govinda Rao    | Engineering | <i>[Signature]</i> 27.12.16 |
| Indian Immunologicals Limited | H.V.R. Sai Kumar  | Production  | <i>[Signature]</i> 27.12.16 |
| Indian Immunologicals Limited | Mahesh S. Neelgar | QA          | <i>[Signature]</i> 27.12.16 |

END OF DOCUMENT