



## OPERATIONAL QUALIFICATION

Client: Indian Immunologicals Limited

Location: Hyderabad, Telangana

Doc. No.: IDMC/ IIL/ IQ\_100L JMV/ 00

### 1. PROTOCOL APPROVAL

#### Protocol preparation

Preparation of this qualification plan is the responsibility of documentation of IDMC Limited.

	NAME	SIGNATURE & DATE
PREPARED BY	Mr. Shivesh Upadhyay	Sany 12.10.15
CHECKED BY	Ms. Sivabalan Kannan	Sivabalan 12.10.15

#### Protocol approval

Approval of this qualification plan is done by QA of INDIAN IMMUNOLOGICALS LIMITED HYDERABAD.

DEPARTMENT	NAME & DESIGNATION	SIGNATURE & DATE
REVIEWED BY ENGINEERING	P. Rajakumar - Manager-Eng	P. Rajakumar 12.10.15
REVIEWED BY PRODUCTION	V. Srinivas - Manager	V. Srinivas 12.10.15
APPROVED BY QUALITY ASSURANCE	M. Tahir - Sr. Executive	M. Tahir 12.10.15

### 2. ABBREVIATIONS

SHORT FORM	DESCRIPTION
ASME	American Society of Mechanical Engineers
BPE	Bio processing Equipment
AISI	American Iron & Steel Institute
CFR	Code Of Federal Regulation
DQ	Design Qualification
EU cGMP	European Union current Good Manufacturing Practices
G. A. Drawing	General Arrangement Drawing
I/O	Input Output
Mm	Millimetre
OQ	Operational Qualification
P & ID	Piping and Instrumentation Diagram

Prepared by : Shivesh Upadhyay	Equipment : 100L JACKETED MIXING VESSEL	Page 3 of 12
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### C. Justification for Acceptance of Deviation:

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### D. Impact of Deviation on Operation:

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## 11. OPERATIONAL QUALIFICATION REPORT APPROVAL

This Operational Qualification Protocol is studied, executed and approved by the Undersigned Authorized Personnel.

### M/s IDMC Limited

S. No.	Name	Department	Signature	Date
01	Mr. Shivesh Upadhyay	MIS IDMC, projects		15.10.15

### M/s Indian Immunologicals Limited

S. No.	Name	Department	Signature	Date
01	P. Rajakumar	Engg.		15.10.15
02	V. Srinivas	Production		15.10.15
03	M. Tareke	QA		15.10.15

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