



OPERATIONAL QUALIFICATION

Client: Indian Immunologicals Limited

Location: Hyderabad, Telangana

Doc. No.: IDMC/ IIL/ OQ_50L 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	
CHECKED BY	Mr. Sivabalan Kannan	

Protocol approval

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

DEPARTMENT	NAME & DESIGNATION	SIGNATURE & DATE
REVIEWED BY ENGINEERING	M. Mageshkumar	18-01-17
REVIEWED BY PRODUCTION	NSR Anjaneyulu Manager	18-01-17
APPROVED BY QUALITY ASSURANCE	M. Tagore	18-01-17

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 : 50L JACKETED MIXING VESSEL	Page 3 of 11
		Date & Rev: 06.10.2015 & R0



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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	M/S IDMC Project		18-01-17

M/s Indian Immunologicals Limited

S. No.	Name	Department	Signature	Date
1	VSR Anjaneyulu	production		18-01-17
2	M. Magesh Kumar	Engineering		18-01-17
3	M. Raju	QA		18-01-17

Prepared by :
Shivesh Upadhyay

Equipment :
50L JACKETED MIXING VESSEL

Page 11 of 11

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