TO WHOM IT MAY CONCERN

SUMMARY OF REGULATORY INSPECTIONS AND APPROVALS

S.No	YEAR	DATE(S) OF INSPECTION	OUTCOME OF THE INSPECTION	STATUS OF EIR	REMARKS
USFDA					
1	2009	21st -25th Sep 2009	Form 483 Issued and Response Submitted	EIR Received	Bioanalytical Phase
2	2009	16th - 20th Nov 2009	Form 483 Issued and Response Submitted	EIR Received	Clinical Phase
3	2011	10th -14th Oct 2011	Form 483 Issued and Response Submitted	EIR Received	All Phases
4	2014	16th -20th June 2014	Form 483 Issued and Response Submitted	EIR Received	Clinical Phase
5	2014	08th -19th Sep 2014	**No form 483**	EIR Received	All Phases
6	2017	25th -31st Jan 2017	**No form 483**	EIR Received	Bioanalytical Phase
7	2017	13th -17th Feb 2017	**No form 483**	EIR Received	Clinical Phase
8	2019	05th-09th Aug 2019	**No form 483**	EIR Received	Bioanalytical Phase
9	2019	14th-18th Oct 2019	**No form 483**	EIR Received	Clinical Phase

S.No	YEAR	DATE(S) OF INSPECTION	OUTCOME OF THE INSPECTION	STATUS	REMARKS
WHO					
1	2011	20th -23rd Jun 2011	Approved, No major and critical findings	Close out letter Received	All Phases
2	2020	29th January 2020 (Desk Assessment)	Approved, No observations	Desk Assessment Report Received	All Phases
THAILAND-GLP INSPECTION					
1	2010	12th -15th Oct 2010	Approved, No major and critical findings	GLP Certificate Received	Bioanalytical Phase
DCGI					
1	2007	July 2007	Approved, No major and critical findings	Permission Letter Received	All Phases
2	2009	April-2009	Approved, No major and critical findings	Permission Letter Received	All Phases
3	2011	June-2011	Approved, No major and critical findings	Permission Letter Received	All Phases
4	2012	June-2012	Approved, No major and critical findings	Permission Letter Received	All Phases
5	2013	2013	Approved, No major and critical findings	Permission Letter Received	All Phases
6	2014	2014	Approved, No major and critical findings	Permission Letter Received	All Phases
7	2015	June-2015	Approved, No major and critical findings	Inspection Report Received	All Phases

S.No	YEAR	DATE(S) OF INSPECTION	OUTCOME OF THE INSPECTION	STATUS	REMARKS
DCGI					
8	2016	November-2016	Approved	Permission Letter Received	All Phases
9	2020	January -2020	Approved, No observations	Permission Letter Received	All Phases
ANAMED_CHILE					
1	2013	10th-11th Jun 2013	Approved, No observations	Inspection Report Received	Facility Audit, All Phases
GCC					
1	2020	Not Applicable	Approved, No observations	Not Applicable	Listed in Approved Centers
EMA (NETHERLANDS & FRANCE)					
1	2014	11th-13th Jun 2014	Approved, No critical findings	Closing Inspection Report Received	All Phases
NABL INSPECTION_CLINICAL LABORATORY					
1	2013	27th Jan 2013	Approved, No critical findings	Pre Assessment	All Departments
2	2013	02nd - 03rd Mar 2013	Approved, No critical findings	Final Assessment	All Departments
3	2014	12th - 13th Apr 2014	Approved, No critical findings	Surveillance Audit	All Departments
4	2015	17th -18th Jan 2015	Approved, No critical findings	Renewal Audit	All Departments

S.No	YEAR	DATE (S) OF INSPECTION	OUTCOME OF THE INSPECTION	STATUS	REMARKS
5	2015	11th -12th Sep 2015	Approved, No critical findings	Final Assessment	All Departments
6	2016	17th-18th Sep 2016	Approved, No critical findings	Surveillance Audit	All Departments
7	2017	21st -22nd Oct 2017	Approved, No critical findings	Renewal Audit	All Departments
8	2019	06th Feb 2019	Approved, No critical findings	Surveillance Audit (Desktop Audit)	All Departments
9	2020	01st & 02nd Feb 2020	Approved, No critical findings	Renewal Audit	All Departments

Project based approvals – Costa Rica, Lebanon, Algeria, Libya, Indonesia, Health -Canada, EMA-Germany, TGA- Australia & other ROW countries.

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