



21<sup>st</sup> November, 2016

The Manager, Listing Department  
National Stock Exchange of India Ltd.  
Exchange Plaza, Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051  
Fax No.:022-26598237 / 38  
NSE Symbol: PANACEABIO

Bombay Stock Exchange Ltd.  
Phiroze Jeejeebhoy Towers,  
Dalal Street,  
Mumbai – 400 001  
Fax No.:022-22721919, 3121  
BSE Scrip Code: 531349

**Re.: Press Release - Panacea Biotec Announces Receipt of Establishment Inspection Report (EIR) from USFDA for its pharmaceutical facilities at Baddi**

Dear Sir,

The Company is pleased to announce receipt of Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (USFDA) indicating the formal closure of the cGMP and Pre-Approval Inspection conducted by USFDA, at the Company's Oncology Parenteral and Oral Solids Dosage formulation facilities at Malpur, Baddi, District Solan, Himachal Pradesh, India.

A copy of the Press Release titled "Panacea Biotec Announces Receipt of Establishment Inspection Report (EIR) from USFDA" being issued to the media, etc. in this regard is enclosed for your kind reference and record please. Kindly acknowledge the receipt.

Thanking you,  
Sincerely yours,  
for **Panacea Biotec Ltd.**

  
**Vinod Goel**  
**Group CFO and Head Legal**  
**& Company Secretary**

B1 Extn. /G3, Mohan Co-op Indl. Estate,  
Mathura Road, New Delhi -110044  
Email: vinodgoel@panaceabiotec.com  
Phone: D.I.D. +91-11-4167 9015  
Fax: +91-11-4167 9075

**Panacea Biotec Ltd.**

CIN: L33117PB1984PLC022350

Registered Office: Ambala-Chandigarh Highway, Lairo - 140 501, Punjab, India. Ph.: +91-1762-505900, Fax: +91-1762-505906.

e-mail: corporate@panaceabiotec.com website: www.panaceabiotec.com



**Panacea Biotec**

*Innovation in support of life*

**Press Release:**

**For Immediate Distribution**

**Panacea Biotec Ltd. Announces Receipt of Establishment Inspection Report (EIR)  
from USFDA**

**New Delhi: November 21, 2016:** Panacea Biotec, one of India's leading research based health management company, is pleased to announce receipt of Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (USFDA) indicating the formal closure of the cGMP and Pre-Approval Inspection conducted by USFDA, at its Oncology Parenteral and Oral Solids Dosage formulation facilities at Malpur, Baddi, District Solan, Himachal Pradesh, India.

Panacea Biotec has state-of-the-art pharmaceutical formulation facility located at Baddi for Oral Solids and Oncology Parenteral Formulations. The Company has been supplying products in US markets for approved ANDAs manufactured in Oral Solids Dosage Facility. A number of abbreviated new drug applications (ANDAs) submitted by the Company, referring these facilities, are also at various stages of approval by USFDA.

The Oral Solids manufacturing facility located at above site has a history of completion of 4 consecutive successful cGMP and Pre-Approval Inspections by USFDA in last 7 years. The manufacturing facility of Oncology Parenteral Formulations has been inspected successfully for the first time by USFDA.

Both Oral Solids and Oncology Parenteral formulation facilities were inspected by USFDA at the same time during the period November 30 – December 11, 2015.

The release of EIR notification by USFDA indicating inspection activity "Closed" means, the USFDA has concluded review of firm's manufacturing activities and the company is allowed to continue supply of all approved drug products by USFDA into inter-state commerce. The EIR notification also accelerates approval process for submitted drug product applications.

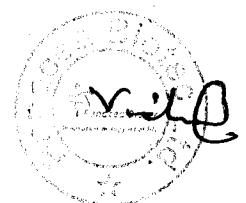
Commenting on the development, Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec said "This EIR notification demonstrates the company's ability to produce drugs in cGMP compliant environment in a sustainable manner. We remain committed to continue to manufacture and supply quality products to cater to patients' needs across several markets including US."

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Corp Office: B-1 EXT. / A-27, MCIE, Mathura Road, New Delhi 110044, India;

Tel: +91 11 41679000, Extn. 1406; DID: +91 11 41578080, Fax: +91 11 41578002;

Mobile: +91 9312693040; Email: [pdkaran@panaceabiotec.com](mailto:pdkaran@panaceabiotec.com) ; Web: [www.panaceabiotec.com](http://www.panaceabiotec.com)





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#### **About Panacea Biotec Ltd.**

Panacea Biotec is one of India's leading research based health management companies with established research, manufacturing and marketing capabilities. Panacea Biotec is one of the largest vaccine producers in India and is one of the leading Biotechnology Companies. The Company has also been ranked amongst the top 60 pharmaceutical companies (AIOCD AWACS-MAT MAR-2016) in India. The product portfolio of Panacea Biotec includes innovative products in therapeutic areas of oncology, organ transplantation, nephrology, diabetes, osteoporosis, cardiovascular diseases and paediatric immunization vaccines. Panacea Biotec is working on a robust pipeline of high barrier to entry generics and 505(b)(2) products, thus leveraging its capabilities in the areas of nanotechnology and platform drug delivery technologies like micro-particles, liposomes, gastroretentive systems. Panacea Biotec has introduced its products in over 20 countries across the world including USA and Germany through a combination of strategic collaborations and direct presence in select geographies. The Company has research collaborations with leading national and international research organizations and corporations. The company's state-of-the-art manufacturing facilities for vaccines and pharmaceutical formulations comply with the US-FDA, European and WHO cGMP standards. The company has around 2,500 employees including around 120 scientists working across 4 R&D centers of the Company.

#### **Caution Statement:**

Certain statements made above may be "forward looking statements" within the meaning of applicable laws and regulations.

For more information, please contact –

**P. D. Karan**

**Vice President - Corporate Communication & Business Development**

**B-1 Extn. / A-27, Mohan Co-Operative Industrial Estate,**

**Mathura Road, New Delhi – 110044, INDIA**

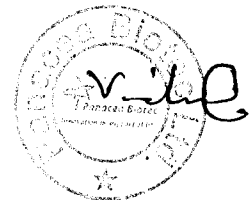
**Tel: + 91 11 41679000 Extn. 1406, 41578080 (Direct)**

**Fax + 91 11 41578002**

**Mobile: + 91 9312693040**

**Email: [pdkaran@panaceabiotec.com](mailto:pdkaran@panaceabiotec.com)**

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