

## Company Statement

### No Separate Audit or Observations by Health Canada

Bengaluru, Karnataka, India, Oct 6, 2017 -

- There has been no separate regulatory audit of Biocon's facilities by Health Canada and they have not issued any observations regarding Data Integrity or GMP issues.
- This is a cross reference to US FDA audit observations disclosed earlier.
- We have clarified to Health Canada there are no Data Integrity issues and shared with them the Corrective and Preventive Actions (CAPAs) submitted to US FDA earlier.
- We have not received any communication from Health Canada with respect to the CAPAs.

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