ALKEM LABORATORIES LTD.
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• CIN: L00305MH1973PLC174201

19th November, 2026

To,

The Corporate Relationship Department BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai 400 001. ***Scrip Code: 539523***	**National Stock Exchange of India Limited** Exchange Plaza, Bandra Kurla Complex, Bandra East, Mumbai 400 051. ***Scrip Symbol: ALKEM***

Sub: Update on US FDA Inspection at Company's manufacturing facility located at Amaliya, Daman

Dear Sir/Madam,

This is in continuation of our earlier intimations dated August 6, 2026 and May 2, 2026, regarding the US FDA inspection conducted at the Company's manufacturing facility located at Amaliya, Daman, from April 20, 2026 to May 1, 2026. The US FDA had classified the inspection status of the said facility as Official Action Indicated (OAI).

This is to inform you that US FDA has issued a warning letter dated November 18, 2026 for Company's manufacturing facility located at Amaliya, Daman. The Company shall be responding to the US FDA within stipulated timeline.

The Company continues to manufacture and supply approved products from the said facility to the U.S. market.

The details as required under Clause 20 of Para A of Part A of Schedule III of SEBI Listing Regulations is enclosed herewith as Annexure A.

Kindly take the same on record.

Sincerely,
For Alkem Laboratories Limited

MANISH NARANG
Digitally signed by MANISH NARANG
Date: 2026.11.19 13:19:46 +05'30'

Manish Narang
President- Legal, Company Secretary and Compliance Officer

Annexure A

Disclosure under Para (A) of Part (A) of Schedule III to the Regulation 30 SEBI (Listing Obligation and Disclosure Requirements) Regulations, 2015

Sr. No	Particulars	Details
1	Name of Authority	U.S. Food and Drug Administration (USFDA)
2	Nature and details of the action(s) taken, initiated or order(s) passed	Receipt of warning letter issued by the USFDA pursuant to the inspection conducted at the Company's Amaliya, Daman manufacturing facility from April 20, 2026 to May 1, 2026.
3	Date of receipt of direction or order, including any ad-interim or interim orders, or any other communication from the authority	18th November, 2026
4	Details of the violation(s) / contravention(s) committed or alleged to be committed	The warning letter pertains to observations made by the USFDA during the inspection of Company's Amaliya, Daman manufacturing facility and requires the Company to implement appropriate corrective and preventive actions to address the observations and prevent recurrence.
5	Impact on financial, operation or other activities of the listed entity, quantifiable in monetary terms to the extent possible	There is no material impact on current operation, financial or other activities of the Company.