NO.DCD/D&D/LA/2022-2023/13896
ADMINISTRATION OF DNH, DAMAN AND DIU,
DRUGS LICENSING AUTHORITY,
DRUGS CONTROL DEPARTMENT,
PRIMARY HEALTH CENTRE,
MOTI DAMAN-396 220

DATED: - 29 /11/2022.

TO
M/S. MACLEODS PHARMACEUTICALS LIMITED. PHASE-II.
PLOT NO. 366, SURVEY NO. 366,
PREMIER INDUSTRIAL ESTATE,
KACHIGAM, DAMAN-396 210.

SUB: - APPLICATION FOR GRANT OF CGMP CERTIFICATE AS PER WHO GUIDELINES UNDER LICENCE NO. DD/375 & DD/376 IN FORM NO. 25 AND FORM NO. 28.

IN REFERENCE TO YOUR APPLICATION ON THE SUBJECT CITED ABOVE AND THE JOINT INSPECTION CARRIED OUT ON 17/10/2022 TO 19/10/2022, YOUR REQUEST FOR GRANT OF WHO GMP CERTIFICATE AS PER WHO GUIDELINES HAS BEEN CONSIDERED FOR THE PRODUCT AS PER LIST ANNEXED AT ANNEXURE-II-A & B.

(DR. V. K. DAS)
DIRECTOR,
MEDICAL & HEALTH SERVICES,
DRUGS LICENSING AUTHORITY,
UT OF DAMAN, DIU & DNH,
DAMAN.

C.C. FOR INFORMATION TO:

1) THE DY. DRUGS CONTROLLER (INDIA), WEST ZONE, CDSCO, OFFICE OF THE DY. DRUGS CONTROLLER (INDIA), 4TH FLOOR, FDA BHAVAN, GMSD COMPOUND, BELLASIS ROAD, MUMBAI CENTRAL, MUMBAI-400 008 W. R. T. HIS LETTER NO. 17/WHO-GMP/DN/WZ-2022/4149 DATED 27/10/2022 AND NO. 17/WHO-GMP/DAMAN/WZ-2022/4612 DATED 16/11/2022.

Digitally signed by Moraru Grigore
Date: 2023.10.09 10:31:45 EEST
Reason: MoldSign Signature
Location: Moldova

UT ADMINISTRATION OF DNH, DAMAN & DIU
DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTER
DAMAN – 396 220

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NO. DCD/D&D/LA/2022-2023/13897 DATED: 29 /11/2022.

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WHO-GMP CERTIFICATE

THIS IS TO CERTIFY THAT ***M/S. MACLEODS PHARMACEUTICALS LIMITED.***, PHASE-II, PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN -396210, INDIA IS HOLDING VALID DRUG MANUFACTURING LICENCES IN ***FORM NO. 25 & FORM NO. 28*** BEARING LICENCE NO. ***DD/375 & DD/376,*** DATED 18/03/2003 RESPECTIVELY, ISSUED BY THIS ADMINISTRATION UNDER THE PROVISIONS OF DRUGS & COSMETICS ACT, 1940 AND RULES THEREUNDER. UNDER THE SAID LICENCES THE FIRM IS PERMITTED TO MANUFACTURE AND SELL THEIR PRODUCTS COVERED UNDER THE CATEGORIES OF GENERAL: TABLETS, CAPSULES, GRANULES AND PELLETS.

THE FIRM HAS EMPLOYED COMPETENT PERSONS IN MANUFACTURING AND QUALITY CONTROL DEPARTMENTS. THE FIRM IS FOLLOWING ***GOOD MANUFACTURING PRACTICES AS PER WORLD HEALTH ORGANIZATION RECOMMENDATIONS*** IN THE MANUFACTURING AND TESTING OF THE SAID CATEGORIES OF GENERAL: TABLETS, CAPSULES, GRANULES AND PELLETS.

THE MANUFACTURING PLANT IS SUBJECT TO REGULAR INSPECTION BY THE COMPETENT AUTHORITY UNDER THE ACT.

THIS CERTIFICATE IS VALID UP TO THREE YEARS FROM THE DATE OF ISSUE.

LICENSING AUTHORITY
लाइसन्सींग प्राधिकारी
सत्यमेव जयते
दमण/Daman
संघप्रदेश दमण एवं दीव
U.T. OF DAMAN & DIU

(DR. V. K. DAS)
DIRECTOR,
MEDICAL & HEALTH SERVICES
DRUGS LICENSING AUTHORITY,
UT OF DNH, DAMAN & DIU,
DAMAN.