

BACTERIOPHAGE MANUFACTURING PARTNER FROM R&D TO CLINICAL BATCH PRODUCTION



**PARTNERSHIP ALREADY
AT R&D LEVEL**

**PRODUCTION OF
PRE-CLINICAL MATERIAL**



**OPTIMIZATION OF
MANUFACTURING PROCESS
FOR SPECIFIC PHAGE**

**PRODUCTION
OF CLINICAL BATCH
ASPETIC FILLING**



**FULL ANALYTICAL
TESTING**

**VARIOUS
STABILITY PROGRAMS**



**PREPARATION OF
IND/CTA**

JAFRAL'S TRACK RECORD

Produced more than:

- 80** BANKS
- 20** DSs/APIs
- 10** DPs For Clinical Trails



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JAFRAL Ltd.,

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BACTERIOPHAGE MANUFACTURING PARTNER FROM R&D TO CLINICAL BATCH PRODUCTION



FEW WEEKS:

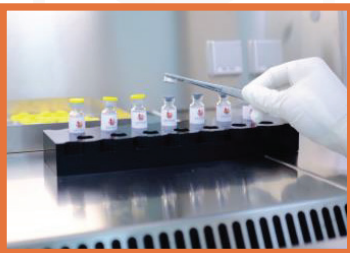
FROM R&D LEVEL TO GMP MATERIAL

INCOMING
RAW MATERIAL TESTING



MASTER /WORKING
CELL PHAGE /BANKS

API/DS
MANUFACTURING



QC ANALYSIS

DP MANUFACTURING

QP RELEASE



PREPARATION OF
CMC SECTION (IND/CTA)

STABILITY
TESTING



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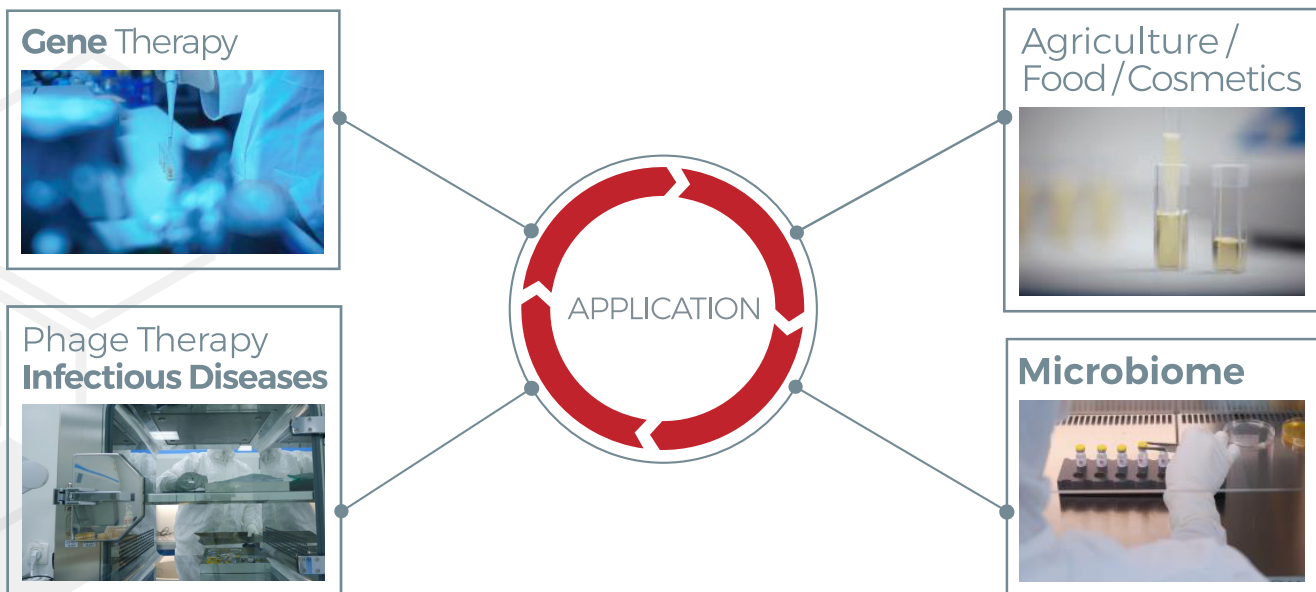


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ANALYTICAL METHODS

(Development, IPC, Release and Stability)

DEVELOPMENT



QUALIFICATION



VALIDATION



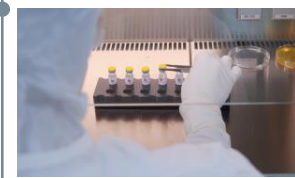
ROUTINE USE



Release Testing



In-Process Testing



Stability Testing



PURPOSE

Stress Testing



POSSIBLE ANALYTICAL METHODS (not all listed)

Potency Testing

Endotoxin (LAL) Testing

Bioburden Testing

DLS Analysis

HPLC Analysis

MAT Testing

Sterility Testing

ELISA Testing

AGE Testing

SDS-PAGE Testing

JAFRAL'S TRACK RECORD

Developed more than **50** SPECIFIC METHODS

Qualified more than **200** METHODS

Running more than **100** STABILITY PROGRAMS

TEM / SEM Testing

PCR / qPCR Testing

BCA Testing

Sequencing



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