USER REQUIREMENT SPECIFICATION – COMMERCIAL OFF THE SHELF SYSTEM (COTS)

NEXTPHARMA EDINBURGH

Equipment Title	Hot Melt Extruder
URS Number	URS0263
VMP Reference	VMP/EUF Ver 5.0

Prepared by	Signature	Printed Name	Position Held	Date
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Reviewed by	**Signature**	**Printed Name**	**Position Held**	**Date**
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Document History		
Version	**Reason for Revision**	**Approval Date**
1.0	First Issue for Approval	This Document

1. Objective

This document details the requirements for a simple commercially available system that requires little or no modification for use by NextPharma Edinburgh.

2. System Details

A hot melt extruder for pharmaceutical GMP use to produce amorphous dispersions at scales up to around 2kg/hr.

3. Services

230v single phase or 400v 3phase
May require water 4-6bar
Additional services TBC by suppliers

4. Functional requirements

The high-level specification requiring to be met by this URS is:

A twin-screw extruder for GMP Pharma with a screw diameter in the range 10-11mm
A L/D ratio of 40: 1 for the screw size
Production range capability approximately 50g/h to 2kg/h
Segmented screw design with sufficient elements to vary configuration.
6+ heating zones plus die (with heating/cooling at least covering the range 15-280°C)
Rod die output (plus a range of appropriate sized nozzles)
Mobile equipment
Two gravimetric feeders (one for API, one for excipient(s)) capable of feed rates to meet production range.
The surface finish of components will allow easy and thorough cleaning. A standard surface finish of product contact at least 0.6µm Ra will be specified unless the functional characteristics of the specific part dictate that this is not appropriate.
CFR part 11 compliance (including audit trails, individual user accounts and secure data with automatic backup capability possible)
If Windows based software, at least Windows 10 and preferably Windows 11.

5. Health, Safety and Environmental

Equipment is required to meet Provision and Use of Work Equipment Regulations 1998 (PUWER)
Equipment must operate at <80dB(A)

6. Compliance/Quality Systems

To be completed by the supplier:

Does the manufacturing site(s) operate a quality system such as ISO9001? ___ (Yes/No)

Does the assembly site operate a quality system such as ISO9001? ___ (Yes/No)

Does the supplier site operate a quality system such as ISO9001? _____ (Yes/No)

If either question is answered Yes, then please supply the relevant site details below and copies of the relevant site quality certification.

Site details:

Certificate Reference:

To be completed by NextPharma:
If either question is answered No, then please provide justification:

Justification: RETROSPECTIVE ADDED INFORMATION ON QA REVIEW
This section 6 shall be completed on appropriate supplier.
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ic 04Nov24

7. Computerised Systems

Does the system produce electronic records? Yes (Yes/No)

Does the system require electronic signatures? Yes (Yes/No)

If either question is answered Yes then CFR21 Part 11 and Eudralex Vol. 4 Part 1 Annex 11 Reference regulations will apply and any software must be compliant.

8. Validation

See Validation Impact Assessment Number: _____ (TBC)

The supplier will be required to assist with validation of the following phases:

FAT/SAT
Design Qualification
Installation Qualification
Operational Qualification

9. Glossary / Abbreviations

Term	Definition
Client	NextPharma Edinburgh
CSV	Computer System Validation
DQ	Design Qualification
FAT	Factory Acceptance Testing
FDA	Food and Drug Administration
FDS	Functional Design Specification
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
HDS	Hardware Design Specification
GA	General Arrangement
cGMP	Current Good Manufacturing Practice
HMI	Human Machine Interface
IQ	Installation Qualification
OCR	Optical Character Recognition
OQ	Operational Qualification
PQ	Performance Qualification
PUWER	Provision and Use of Work Equipment Regulations
QMS	Quality Management System
Ra	Surface Roughness Parameter/Value
SAT	Site Acceptance Testing
SDS	Software Design Specification
SME	System Matter Expert
UPS	Uninterrupted Power Supply
URS	User Requirement Specification
Vendor	Packaged Equipment Provider
HME	Hot Melt Extrusion

10. Documentation

Installation Operational Maintenance manual (In English) FAT/SAT documentation
DQ/IQ/OQ Documentation
Contact Surface Material certification (GMP appropriate materials) material of construction, area calculations for contact surfaces, and where practicable, surface finish.
Spare Parts List (including critical spares)
Calibration certificates
CE compliance certificate
P&IDs, schematics, isometrics and electric drawings
21 CFR part 11 compliance certificate
PUWER certificate
Equipment / component schedules
CV and appropriate training certificates demonstrating the engineer attending site is competent.

11. Equipment Servicing / Maintenance

Annual Servicing Plan Quote

Specification Check – Commercial Off The Shelf (COTS) System

12. Appendix 1 - Supplier Acknowledgement/Response		
This section must be completed by a representative from the equipment / system supplier. This ensures that all information in the URS has been addressed and that where a required function cannot be delivered, this is documented.		
Can system be provided in accordance with information in this URS? (✓)	**YES**	**NO**
If NO, provide details of any functions which cannot be supported by the equipment / system and proposed solution. Continue on a separate sheet if necessary		

Name		Company		Date	
Signature		Position Held			

13. Appendix 2 – NextPharma documentation approval matrix

Vendor Documentation	Review			Approvers	
	Validation	Facilities	Other	End user / SME[1]	QA
Drawings, GA's, P&IDs, isometrics etc.	N/A	Yes	N/A	Yes	N/A
Design Specifications	Yes	N/A	N/A	Yes	Yes
FAT[2], SAT[2] and / or Commissioning[2]	Yes	Yes	EHS	Yes	Yes

NextPharma Documentation	Review				Approvers
	Validation	Facilities	Other	End user / SME[1]	QA
VIA	Yes	N/A	N/A	Yes	Yes
URS	Yes	Yes	EHS	Yes	Yes
ICA	Yes	Yes	N/A	Yes	Yes
DQ protocol and report	Yes	Yes	N/A	Yes	Yes
IQ protocol and report	Yes	Yes	N/A	Yes	Yes
OQ protocol and report	Yes	Yes	N/A	Yes	Yes
PQ protocol and report	Yes	N/A	N/A	Yes	Yes
SCA	Yes	N/A	IT	Yes	Yes
CSV protocol and report	Yes	N/A	IT	Yes	Yes

[1] The end user or system master expert (SME)
[2] Protocol approval for execution and executed protocol approval