Yourway Transport Ltd
Biopharma Services
2 Pulborough Way,
Hounslow, Middlesex,
TW4 6DE UK

QUALIFIED PERSON'S DECLARATION OF EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES (ARTICLE 13(3)(b) OF DIRECTIVE 2001/20/EC)

Protocol Reference	**AR-DEX-22-01**
IRAS ID	**1006607**

Name of IMP(s)
Dexpramipexole 75 mg, 150 mg Tablets, and Placebo Tablets

Manufacturing and/or Importation Authorisation under which this declaration is made:
MIA(IMP): 42563
Part A

Name of IMP(s)	Manufacturing site(s)	Activity Performed
Dexpramipexole 75 mg, 150 mg Tablets, and Placebo Tablets	**Quotient Sciences – Philadelphia, LLC** (Formerly QS Pharma LLC) 3 Chelsea Parkway, Suite 305 Boothwyn, PA 19061, USA	Drug Product manufacture, packaging, release and stability testing
	Quotient Sciences – Philadelphia, LLC 3080 McCann Farm Dr Garnet Valley, PA 19060, USA	Stability storage and testing
	Yourway Transport, Inc. 6681 Snowdrift Road Allentown, PA 18106 USA	Primary clinical packaging and labeling
	Catalent Pharma Solutions 1100 Enterprise Dr. Winchester, KY 40391, USA.	Drug Product manufacture, packaging, release, and stability testing
	Yourway Transport Limited, 2 Pulborough Way, Hounslow, TW4 6DE, United Kingdom	Secondary labeling, storage and EU distribution QP release

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Part B

I confirm that I am a QP and am authorized to make this declaration.

I declare that compliance with GMP at least equivalent to EU GMP has been verified on the basis of:

(i) Audit

Manufacturing site(s)	Auditing Party	Date of last audit (completion)
Quotient Sciences – Philadelphia, LLC (Formerly QS Pharma LLC) 3 Chelsea Parkway, Suite 305 Boothwyn, PA 19061, USA	[redacted] Qualified Person	22nd - 23rd March 2023
Quotient Sciences – Philadelphia, LLC 3080 McCann Farm Dr Garnet Valley, PA 19060, USA	[redacted] Qualified Person	22nd - 23rd March 2023
Yourway Transport, Inc. 6681 Snowdrift Road Allentown, PA 18106 USA	[redacted] Qualified Person	11,13, & 14 July 2022
Catalent Pharma Solutions 1100 Enterprise Dr. Winchester KY 40391, USA.	[redacted] Qualified Person	April 18-19, 2023

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(ii) If an audit of the site has not been performed, please provide a brief justification and explanation on how the QP knows that standards at least equivalent to EU GMP are being followed at the site.

Manufacturing site(s)	Justification
Not Applicable	

This declaration is submitted by:

Signatory: [redacted]

Print Name [redacted] Date: May 24, 2024

Qualified Person

AR-DEX-22-01 QP Declaration Doc No 2214 Rev.02

Final Audit Report 2024-05-24

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