Medicines and Healthcare Products Regulatory Agency

Report No: ***Insp GMP 20181/88564-0006 NCR***

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer [1]

Part 1

Issued following an inspection in accordance with :
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of United Kingdom confirms the following:
The manufacturer: ***RUSAN PHARMA LTD***
Site address: ***Plot 59 to 65, Sector II Kandla Special Economic Zone, Kutch, Gandhidham, Gujarat, 370230, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-01-22*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

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Part 2

Human Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS	
Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.17 Other: Granule and Dry syrup(en)
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Part 3

1. Nature of non-compliance:
The Pharmaceutical Quality system was not operating in an adequate manner to ensure that patient safety was adequately protected and there was not adequate evidence that the root causes of critical data integrity issues raised at the last inspection had been addressed. 1. There was a widespread failure of the Quality Management System including core systems. 2. The control of electronic data and laboratory systems was not adequately robust and could not assure data traceability or security. 3. Systems to control contamination were deficient and could not assure adequate assessment of the risk of cross contamination. 4. Critical controls within the packaging areas were not adequately robust or controlled. 5. Training was deficient in that there was no robust process for managing training and untrained analysts were performing analyses.
Action taken/proposed by the NCA **Prohibition of supply** The site has been issued with a statement of non-compliance and should not be named on any marketing authorisations whilst this statement remains in place.
Additional comments Any request for further information via teleconference should be made to the MHRA by email to IAGSecretariat@mhra.gsi.gov.uk A previous statement of non-compliance was issued for the site in November 2012. This inspection was the first since the issuance of that statement. This Statement is an updated full scope Statement of noncompliance to reflect the latest inspection; no products have been imported into the EU since November 2012

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Products manufactured at site, if known	Products	Dosage Form	Reference Member State, National or EMA
Human Medicinal Products	PL 12762/0042 Dyazide 25mg / 50mg	Tablet	UK National
	PL 17521/0034 Metoclopramide 10mg	Tablet	UK National
	PL 17521/0037 NITRAZEPAM 5MG	Tablet	UK National
	PL 17521/0057 DIAZEPAM 2MG	Tablet	UK National
	PL 17521/0058 DIAZEPAM 5MG	Tablet	UK National
	PL 17521/0059 DIAZEPAM 10MG	Tablet	UK National
	PL 17521/0068 VERAPAMIL 40MG	Tablet	UK National
	PL 17521/0069 VERAPAMIL 80MG	Tablet	UK National
	PL 17521/0070 VERAPAMIL 120MG	Tablet	UK National
	PL 17907/0455 PREDNISOLONE 1MG	Tablet	UK National
	PL 17907/0456 PREDNISOLONE 5MG	Tablet	UK National
	PL 20395/0018 IMIPRAMINE 25MG	Tablet	UK National
	PL 28444/0013 ADDNOK 0.4 MG	Sublingual Tablet	UK National
	PL 28444/0014 ADDNOK 2MG	Sublingual Tablet	UK National
	PL 28444/0015 ADDNOK 8MG	Sublingual Tablet	UK National
	PL 33414/0129 CHLORPROMAZINE 10MG	Tablet	UK National
	PL 44893/0032 ISOGEL	Sachet	UK National
	PL 17521/0001 CHLORDIAZEPOXIDE 5MG	Capsule	UK National
	PL 17521/0002 CHLORDIAZEPOXIDE 10MG	Capsule	UK National

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PL 17521/0019 BENDROFLUMETHIAZIDE 5MG	Tablet	UK National
PL 17521/0074 METFORMIN 850MG	Tablet	UK National
PL 17907/0355 NITRAZEPAM 5MG	Tablet	UK National
PL 20395/0029 AMITRIPTYLINE 25MG	Tablet	UK National
PL 28444/0141 CO-DYDRAMOL	Tablet	UK National
PL 33414/0007 AMOXICILLIN 125 MG/5 ML	Oral Suspension	UK National
PL 33414/0008 AMOXICILLIN 250 MG/5 ML	Oral Suspension	UK National
PL 33414/0128 AMOXICILLIN 500MG	Capsule	UK National
PL 33414/0130 CHLORPROMAZINE 25MG	Tablet	UK National
PL 33414/0131 CHLORPROMAZINE 50MG	Tablet	UK National
PL 33414/0157 AMOXICILLIN 250MG	Capsule	UK National
PL 39484/0012 CAPTOPRIL 12.5MG	Tablet	UK National
PL 39484/0013 CAPTOPRIL 25MG	Tablet	UK National
PL 39484/0014 CAPTOPRIL 50MG	Tablet	UK National
PL 39484/0021 FUROSEMIDE 20MG	Tablet	UK National
PL 39484/0022 FUROSEMIDE 40MG	Tablet	UK National
PL 39484/0042 PROPRANOLOL 10MG	Tablet	UK National
PL 39484/0043 PROPRANOLOL 40MG	Tablet	UK National
PL 39484/0044	Tablet	UK National

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	PROPRANOLOL 80MG		
PL 42311/0003 DIAZEPAM 5MG	Tablet	UK National	

2016-04-04

Name and signature of the authorised person of the Competent Authority of United Kingdom

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