

# DRUGS CONTROL ADMINISTRATION Government of Telangana



L.Dis.No.978/A4/2017. To

Dated 19 - 04 - 2017

M/s. Sri Krishna Pharmaceuticals Ltd, Unit-II, A-35, IDA., Nacharam, Hyderabad – 500 076, Telangana, INDIA.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder - Issue of World

Health Organization Good Manufacturing Practice Certificate - Regarding.

Ref: 1. Your applications dated 12.01.2017.

2. Joint Inspection Report dated 24.03.2017 & 25.03.2017.

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I forward herewith WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE CERTIFICATE for the products recommended by the Joint Inspection Team consisting of officers of Drugs Control Administration, Telangana for Export Purpose.

This Certificate is valid for a period of Two years from the date of issue.

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Yours faithfully,

M AMRUTH RAO
JOINT DIRECTOR

LICENSING & CONTROLLING AUTHORITY



# DRUGS CONTROL ADMINISTRATION Government of Telangana



L.Dis.No.978/A4/2017

Dated 19 -04-2017.

#### LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

	POR EXPORT PURPOSE
1	Paracetamol Granules 90% w/w KRISOPAP-90F
	(Compression grade granules containing Paracetamol Ph.Eur.90% w/w)
2	Paracetamol Granules 90%
	KRISOPAP-90C
	(Compression grade granules containing Paracetamol Ph.Eur.90% w/w)
3	Paracetamol granules 96%
	KRISOPAP-96P
4	(Compression grade granules containing paracetamol Ph. Eur. 96% w/w) Paracetamol granules 97%
	KRISOPAP-97P
	(Compression grade granules containing paracetamol Ph. Eur. 97%w/w)
5	Paracetamol Granules 77%
	KRISOPAP-77P
	(Compression grade granules containing Paracetamol Ph.Eur.77% w/w)
6	Metformin HCl Granules DC 90%
	KRISOMFH-90P
	(Direct compression grade granules containing Metformin Hydrochloride Ph.Eur.90%w/w)
7	Metformin Hydrochloride Granules DC 95% w/w KRISOMFH-95P
8	(Direct compression grade granules containing Metformin Hydrochloride Ph.Eur 95%w/w) Ibuprofen Granules DC 90%
	KRISOIBU-90P
	(DC grade granules containing Ibuprofen BP/USP 90% w/w)
9	Ibuprofen Granules DC 63%
	KRISOIBU-63P
	(DC grade granules containing Ibuprofen BP/USP 63% w/w)
	Paracetamol Granules DC 83% KRISOPAP-83S
10	(Direct compression grade granules containing Paracetamol BP/EP 83%)
	(Sheet compression grade grandles containing Paracetamor BP/EP 83%)
11	Ibuprofen Granules DC 73%
	KRISOIBU-73P
	(Direct compression grade granules containing Ibuprofen EP/BP/USP 73%w/w)
12	Paracetamol Granules DC 90%
	KRISOPAP-90CS
13	(Direct compression grade granules containing Paracetamol BP/EP 90%w/w)
	Microencapsulated Acetaminophen granules 93% KRISOMICROPAP
10	(Microencapsulated Acetaminophen granules containing Acetaminophen 93%w/w)
14	Aspirin Granules 90%
	KRISOASP-90M
	(Direct compressible grade granules containing Aspirin Ph.Eur.90%)
	Paracetamol granules 96%
15	KRISOPAP-96G
	(Free flowing granules containing Paracetamol BP/Ph.Eur.96%)

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16	Ibuprofen DC Granules 70% KRISOIBU-70P
	(Each 1 gram of DC Granules contains Ibuprofen Ph.Eur 700.0mg)
4.7	Acetaminophen Granules DC 90% w/w
17	KRISOPAP-90F
	(Each 1 gram of granules contains Acetaminophen USP 900mg)
18	Acetaminophen Granules DC 90% w/w KRISOPAP-90C
19	
	(Each 1 gram of granules contains Acetaminophen USP 900mg) Furosemide DC Granules 71.00% w/w
	KRISOFUR-71.0%
20	Each 1 gram of Furosemide DC Granules contains Furosemide Ph.Eur-71.00 mg
	Paracetamol Directly compressible granules 96% w/wDC Granules
	KRISOPAP-96PS
21	Ciprofloxacin HCl Directly compressible Granules -65% w/w Granules
	KRISOCIP-65
	Paracetamol 89.60% DC Granules KRISOPAP-89.6U
22	Each 1 gram of Paracetamol 89.60% granules contains Paracetamol Ph. Eur. 896mg
	Paracetamol Granules 77%
23	KRISOPAP-77S
	(Compression grade granules containing Paracetamol Ph.Eur.77% w/w)
	Guaifenesin DC Granules 95%w/w
24	KRISOGGF-95MS
	(Each 1gram of Guaifenesin DC Granules 95% contains Guaifenesin Ph.Eur 950mg)
25	Sodium phenyl Butyrate granules 100% KRISOSPB-100
/	Acetaminophen Granules 90%
26	KRISOPAP-90FH
27	Paracetamol Tablets 500mg IP/BP
28	Acetaminophen tablets 500mg USP

Manufacturer

M/s. Sri Krishna Pharmaceuticals Ltd,

Unit - II, A-35, IDA., Nacharam,

Hyderabad - 500 076, Telangana, INDIA.

When applicable

Placing the products on the market as detailed

above.

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It is certified that these products had been authorized to be placed on the market for use in the country ROL ADM

and exporting countries.

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Dated 19 -04-2017.

### <u>LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATION SCHEME</u> <u>FOR EXPORT PURPOSE</u>

Drug Licence No.

14/RR/AP/2003/F/R, dated 24.03.2003,

in Form - 25

The Unit of M/s. SRI KRISHNA PHARMACEUTICALS LTD, Unit -II, A-35, IDA., Nacharam, Hyderabad – 500 076, Telangana, INDIA was inspected by G. Sreenivas, Assistant Director, and Mr. G. Anil, Drugs Inspector, Drugs Control Administration, Hyderabad on 24.03.2017 and 25.03.2017.

The manufacturer conforms to requirement for Good Manufacturing Practices in the manufacturing and quality control (As recommended by the World Health Organization) in respect of the products mentioned above (Twenty Eight in number) for Export in the international market.

This certificate is valid for a period of Two years from the date of issue.

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M AMRUTH RAO
JOINT DIRECTOR
LICENSING & CONTROLLING AUTHORITY

To

M/s. SRI KRISHNA PHARMACEUTICALS LTD, Unit –II, A-35, IDA., Nacharam, Hyderabad – 500 076, Telangana, INDIA.