INDOFARMA

PURCHASING SPECIFICATION

Tramadol Hydrochloride (Injectable Grade)			
No. : RPB 301	**Rev : 01**	**Eff. date :** 18 07 10	**Sign :**

1 **Quality**

1.1 USP 39, 2016

1.2 CoA Sun Pharmaceuticals Industries Ltd, India

2 **Additional Requirements**

2.1	Endotoxine Bacteria	: NMT. 2,1	Eu/mg
2.2	Microbial Limit Test		
	– Total plate count	: NMT. 1000	kol/g
	– Amounts of fungi and yeast	: NMT. 100	kol/g
	– E. Coli	: Negative	
	– Samlmonella sp	: Negative	
	– Pseudomonas Aeroginosa	: Negative	
	– Staphylococcus Aureus	: Negative	
2.3	Arrival Date	: NMT. 6 months from manufacturing date	

3 **Certificate of Analysis from Manufacturer**

To be stated on the certificate

3.1 Manufacturer name and address

3.2 Product name, batch/lot number

3.3 Results of test and assays

3.4 Compliance with Quality and Additional Requirements

3.5 Quality designation

3.6 Date of manufacturing, expiration (year-month) and date of released (year- month-day)

3.7 Approval/signature of QA/QC responsibility

4 **Package**

Cardboard drum @25kg, double plastic PE, with original seal (inside and outside) from manufacture.
To be stated on goods, label original from manufacture at primary and secondary package each.
Preserve in tight containers.

5 **Labeling**

To be stated on goods **label original from manufacturer**, packing list and invoice:

5.1 Name of manufacturer and address

5.2 Product name, batch/lot number, manufacturing and expiration date

5.3 Quality designation

5.4 Gross/net weight

5.5 Number of packages

6 **Reference Documents**

6.1 USP 39, 2016

6.2 CoA Sun Pharmaceuticals Industries Ltd, India

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7 **History**

This specification is revision of RPB 301 revision 00 with change in the quality of USP 34 to USP 39, format document, and deleting the review point.

8 **Distribution**

In general, a copy of this specification is distributed to :

8.1 Procurement Dept.

8.2 Quality Control Dept.

9 **Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	**AM**		180710
Checked by	Analytical Method Assistant Manager	**LB**		180710
Approved by	Quality Control Manager	**AM**	an.	180710
	Research & Development Manager	**LB**		180710
	Quality Assurance Manager	**PM**		180710