indofarma	**PURCHASING SPECIFICATION** Oxytetracycline Hydrochloride, Microfine (Oksitetrasiklin Hidroklorida)	No : RPB149a Revisi : 00 Berlaku : 28 SEP 2018 Paraf :

1 **Quality**

1.1 USP 39, 2016

1.2 Farmakope Indonesia V, 2014

1.3 Inhouse Indofarma

2 **Additional Requirements**

2.1	Potency	: NLT. 835 µg/mg
2.2	Particle Size Microfine ≤ 45 µm	: NLT. 90 %
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 @ 25 kg, with original seal (inside and outside) from manufacture.

To be stated on goods, original label from manufacture at both of primary and secondary package. each. Preserve in well-closed containers.

5 **Labeling**

To be stated on goods **original label 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 Farmakope Indonesia V, 2014

6.3 Inhouse Indofarma

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7 **History**

Revision	Eff. Date	Change
00	28 SEP 2018	1. The first publication (substitute of RPB149 with change in separation of particle size)

8 **Distribution**

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		28 Sep 2018
Checked by	Analytical Method Assistant Manager	LB		28 Sep 2018
Approved by	Quality Control Manager	AM	a/n	28 Sep 2018
	Research & Development Manager	LB		28 Sep 2018
	Quality Assurance Manager	PM		28 Sep 2018