INDOFARMA

PURCHASING SPECIFICATION

Vitamin E Dry Powder 50 % SD (4580166080420)			
No. : RPB 286	**Rev : 02**	**Eff. date :** 170103	**Sign :**

1 **Quality**

1.1 Internal specification

1.2 Clark's Analysis of Drug and Poisons, fourth edition, 2011

2 **Additional Requirements**

2.1 Assay : NMT 50 %

2.2 Microbial Limit Test

2.2.1 Total Plate Count	: NMT .100	kol /g
2.2.2 Fungi	: NMT. 10	kol/g
2.2.3 Salmonella sp	: Negative	
2.2.4 Staphylococcus Aureus	: Negative	
2.2.5 Pseudomonas aeruginosa	: Negative	
2.2.6 Escherichia coli	: NMT. 10	kol/g
2.2.7 Heat resistant bacterial	: NMT.10	kol/g

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 Attached update Good Manufacture Practice Certificate

5 Package

Zack @20 kg, 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.

6 ***Labeling***

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

6.1 Name of manufacturer and address

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

6.3 Quality designation

6.4 Gross/net weight

6.5 Number of packages

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7 **Reference Documents**

7.1 Internal specification

7.2 Clark"s Analysis of Drug and Poisons, Fourth edition, 2011

8 **History**

Purchasing specification is revision of RPB 286 revision 01 with change in the quality and format document

9 **Review**

This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager and Research & Development Manager and Quality Assurance Manager

10 **Distribution**

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

10.1 Procurement Dept.

10.2 Quality Control Dept.

11 **Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	**AM**		16 12 30
Checked by	Analytical Method Assistant Manager	**LB**		16 12 30
Approved by	Quality Control Manager	**AM**	an.	16 12 30
	Research & Development Manager	**LB**		16 12 30
	Quality Assurance Manager	**PM**		17 01 03

12 **Review**

No.	Position	Date	Signature	Recommendation
1	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			