

<b>Red Yeast Selenium</b>			
No. : RPB 285	Rev : 01	Eff. date : 18 07 10	Sign : ↓

**1 Quality**

- 1.1 CoA Lesaffre Human Care
- 1.2 Inhouse Indofarma

**2 Additional Requirements**

- 2.1 Loss on Drying : 1,00 – 6,00 %
- 2.2 Yeast & mould numbers : NMT. 50 kol/g
- 2.3 Salmonella sp : Negative
- 2.4 Assay (selenium ) : 1000 – 1250 bpj
- 2.5 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 release (year- month-day)
- 3.7 Approval/signature of QA/QC responsibility

**4 Package**

Cardboard drum @ 25 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.

**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 CoA Lesaffre Human Care
- 6.2 Inhouse Indofarma

**7 History**

This specification is revision of RPB 285 revision 00 with change in the format document and deleting the review point.



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**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		18 07 10
Checked by	Analytical Method Assistant Manager	LB		18 07 10
Approved by	Quality Control Manager	AM	<sup>an</sup>	18 07 10
	Research & Development Manager	LB		18 07 10
	Quality Assurance Manager	PM		18 07 10