


Folic Acid, Microfine			
(Asam Folat)			
No. : RPB 181	Rev : 01	Eff. date : 17 06 20	Sign : 

- 1 **Quality** : USP 39, 2016
Internal Specification
- 2 **Additional Requirements**
 - 2.1 Particle size : ≤ 45 µm Min. 90.0%
 - 2.2 Arrival Date : Max. 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 USP 39 and Internal Specification
 - 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 Practise Certificate
- 5 **Package**
Vat @ 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 well – closed containers.
- 5 **Labelling**
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
 - 6.2 Internal Specification
- 7 **History**
Purchasing specification revision of RPB 181 revision 00 with change in the quality of USP 35 to USP 39 and format document.
- 8 **Review**
This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager.

Folic Acid, Microfine (Asam Folat)			
No. : RPB 181	Rev : 01	Eff. date : 17 06 20	Sign : <i>[Signature]</i>

9 Distribution

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

- 9.1 Procurement Dept.
- 9.2 Quality Control Dept.

10 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	<i>[Signature]</i>	17 06 20
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	17 06 20
Approved by	Quality Control Manager	AM	<i>[Signature]</i>	17 06 20
	Research & Development Manager	LB	<i>[Signature]</i>	17 06 20
	Quality Assurance Manager	PM	<i>[Signature]</i>	17 06 20

11 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			