


Domperidone			
No. : RPB 281	Rev : 02	Eff. date : 18 01 17	Sign : 

- 1 **Quality** : BP 2016
- 2 **Additional Requirements**
 - 2.1 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 BP 2016
 - 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 Plastic @ 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.
- 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
- 7 **Reference Documents**
BP 2016
- 8 **History**
Purchasing specification is revision of RPB 281 revision 01 with change in the quality of BP 2009 to BP 2016 and format document.
- 9 **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.



PURCHASING SPECIFICATION

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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		180117
Checked by	Analytical Method Assistant Manager	LB		180117
Approved by	Quality Control Manager	AM	^{an.}	180117
	Research & Development Manager	LB		180117
	Quality Assurance Manager	PM		180117

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			