



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### ANALYTICAL SPECIFICATION FOR ETHYLCELLULOSE BP

<b>Manufacturer Name:</b>		<b>Supplier Name:</b>
<b>Manufacturer's Batch No.:</b>		<b>Manufacturer's Batch Size:</b>
<b>Manufacturing Date:</b>		<b>Expiry Date:</b>
<b>Quantity Received:</b>		<b>Test Quantity:</b>
<b>Document No.:</b>	<b>Effective Date:</b>	<b>Change Control No.:</b>
<b>Control No./ A.R. No.:</b>		<b>Retest Date:</b>

**Reference** : BP 2003

**Description** : A white or yellowish- white powder or granular powder, odourless or almost odourless..  
Complies/Does Not Comply

**Solubility** : Practically insoluble in water (1 in More Than 10000), slouble in methylene chloride and in a mixture of 20 g of alcohol and 80 g of toluene ( 1 in 10-30), Slightly Soluble in ethylacetate and in methaol( 1 in 100-1000), practically insoluble in glycerol(85%) and in propylene glycol (1 in more than 10000). The solutions may show a slight opalescence.  
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification A. IR  B.	BP		A. IR absorption spectrum of test is concordent with Ph. Eur. reference spectrum of Ethylcellulose.  B. It complies with the limits of the assay.	
2.	Acidity or alkalinity	BP		To 10 ml add 0.1 ml of phenolphthalein solution R and 0.5 ml of 0.01M sodium hydroxide. The solution is pink. To 10 ml add 0.1 ml of methyl red solution R and 0.5 ml of 0.01M hydrochloric acid. The solution is red.	
3.	Viscosity	BP		8.0 to 12.0 mPas (Not Less Than 80.0 % and Not More Than 120.0 %) (label claim 10 mPas)	



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S.No.	Test	Reference	Result	Specification	Remark
4.	Acetaldehyde	BP		Not More Than 100 ppm	
5.	Chlorides	BP		Not More Than 0.1 %	
6.	Heavy metals	BP		Not More Than 20 ppm	
7.	Loss on drying	BP		Not More Than 3.0 %	
8.	Sulphated ash	BP		Not More Than 0.5 %	
9.	Assay as – OC <sub>2</sub> H <sub>5</sub> (On dried substance)	BP		Not Less Than 44.0 % and Not More Than 51.0 %	

#### Raw Data Reference :

Analyst Name:

Analyst Name:

Analyst Name:

Analyst Hard Book No. :

Page No. :

Analyst Hard Book No. :

Page No. :

Analyst Hard Book No. :

Page No. :

#### Results: Sample Conforms / Does Not Conform to Specification

Analyzed By : \_\_\_\_\_ Date : \_\_\_\_\_

Checked By : \_\_\_\_\_ Date : \_\_\_\_\_

Approved By : \_\_\_\_\_ Date : \_\_\_\_\_