



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### ANALYTICAL SPECIFICATION FOR MAGNESIUM STEARATE IP

<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> : N/A	
<b>Control No./ A.R. No.</b> :		<b>Retest Date</b> :	

**Reference** : IP 1996 Page No 450-451

**Description** : Very fine, light, white powder; odourless or with a very faint odour of stearic acid; unctuos and free from grittiness; free from foreign particles.  
Complies/Does Not Comply

**Solubility** : Practically insoluble in water , in ethanol and in *ether* (1 in More than 10000).  
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1	Identification  A. Freezing point  B. Test for magnesium salts	IP		A. The <i>freezing point</i> of the residue is not lower than 53°C.  B.The white precipitate dissolves in 2M ammonium chloride and a white, crystalline precipitate is formed on addition of 0.25M disodium hydrogen phosphate.	
2	Acidity or alkalinity	IP		Not more than 0.05 ml of either 0.1M hydrochloric acid or 0.1M sodium hydroxide is required to change the colour of the solution.	
3	Colour of solution	IP		Solution A is not more intensely coloured than the reference solution YS6.	



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### ANALYTICAL SPECIFICATION FOR MAGNESIUM STEARATE IP

4	Clarity and colour of solution of fatty acids	IP		The solution is clear and not more intensely coloured than the reference solution YS5.	
5	Acid value of the fatty acids	IP		Between 195 and 210	
6	Free stearic acid	IP		Not More Than 3.0 %	
7	Zinc stearate	IP		No violet precipitate is formed.	
8	Heavy Metals	IP		Not More Than 20 ppm	
9	Chloride	IP		Not More Than 250 ppm	
10	Sulphate	IP		Not More Than 0.6%	
11	Loss on drying	IP		Not More Than 6.0%	
12	Assay as Mg (dried substance)	IP		Not Less Than 3.8 % And Not More Than 5.0 %	

#### 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 : \_\_\_\_\_