COPY NO. 3

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

| | |
|---|---|
| **Title** : Flowlac 90 (Lactose monohydrate BP)(Item No. 41010705) | **Spec. No.** : SP-AK30-F16 |
| **Reference(s)** : BP 2016 p. II-65 to II-66 | **Rev. No.** : 02 |
| **Other Requirements** : GPO Specification | **Page** : 1/2 |

**BP 2016**

| Test Items | Specification | |
|---|---|---|
| Description | White or almost white, crystalline powder, odourless. | |
| Solubility | Freely but slowly soluble in water, practically insoluble in ethanol (96%). | |
| Identification<br>A. Infrared absorption spectrophotometry | The IR absorption spectrum of sample exhibits the same spectrum as Standard. | |
| B. Water | 4.5% to 5.5%. | |
| Appearance of solution | The solution is clear and not more intensely coloured than Reference solution $BY_7$. | |
| Acidity or alkalinity | Not more than 0.4 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink or red. | |
| Specific optical rotation | +54.4 to +55.9 (anhydrous substance). | |
| Absorbance | - at 400 nm | : maximum 0.04 for Test solution (a). |
| | - from 210 nm to 220 nm | : maximum 0.25 for Test solution (b). |
| | - from 270 nm to 300 nm | : maximum 0.07 for Test solution (b). |
| Heavy metals | Maximum 5 ppm, Test A. | |
| Water | 4.5% to 5.5%, determined on 0.50 g. | |
| Sulfated ash | Maximum 0.1%, determined on 1.0 g. | |
| Microbial contamination | Total aerobic microbial count | : acceptance criterion $10^2$ CFU/g. |
| | *Escherichia coli* | : Absence. |

**GPO Specification**

| Test Items | Specification | |
|---|---|---|
| Fineness | Retain on sieve No. 70 | : Not more than 15%. |
| | Retain on sieve No. 140 | : Between 60 and 75%. |
| | Pass through sieve No. 400 | : Not more than 5%. |

| Prepared by : | | Reviewed by : | | | Approved by : | Eff. Date |
|---|---|---|---|---|---|---|
| Siwaree / 09/05/17 | Umpon W. / 11/05/17 | | Popy 11/05/17 | VARIPEN / 16/05/17 | Vichian Puangpunglj 23/05/17 | 04/07/17 |
| Head of Raw Material Standard Section 1 | Head of Microbiological Analysis Section 2 | Director of Raw Material Standard Division | Director of Microbiological Analysis Division | Director of Regulatory Compliance and Documentation Division | Director of Quality Assurance Department (Acting) | |

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**Product Information**

| | |
|---|---|
| Approved source (s) | Refer to current version of Approved Vendor List of Flowlac 90 (Lactose monohydrate BP) (Item No. 41010705). |
| Sampling plan | P plan : for Identification.<br>$\sqrt{N}+1$ : for other tests. |
| Testing procedure | Tests to be performed as per current version of WI-AK30-F16. |
| Storage condition | To be stored in an airtight container. |
| Retest period | 1 year after first testing date. |

**History of changes**

| Rev. No. | Description | Effective date |
|---|---|---|
| 01 | ประกาศใช้ครั้งแรก spec เป็น BP 2009 | 30/09/10 |
| 02 | Up spec เป็น BP 2016 โดยเนื้อหาของ BP 2009 และ BP 2016 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปีจำเป็นต้องทบทวน | 04/07/17 |

| Prepared by : | | Reviewed by : | | | Approved by : | Eff. Date |
|---|---|---|---|---|---|---|
| Head of Raw Material Standard Section 1 | Head of Microbiological Analysis Section 2 | Director of Raw Material Standard Division | Director of Microbiological Analysis Division | Director of Regulatory Compliance and Documentation Division | Director of Quality Assurance Department (Acting) | 04/07/17 |