



COPY No. 9

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

|   |                         |
|---|-------------------------|
| Title : Ribavirin USP (Item No. 41033030) | Spec. No. : SP-AK30-R30 |
| Reference(s) : USP 37 p. 4561-4562        | Rev. No. : 01           |
| Other Requirements : GPO specification    | Page : 1/2              |

USP 37

| Test Items                    | Specification  |
|-------------------------------|--|
| Description                   | White, crystalline powder.   |
| Solubility                    | Freely soluble in water; slightly soluble in dehydrated alcohol.   |
| Identification                |  |
| A. Infrared absorption <197K> | Conforms to IR standard spectrum.  |
| B. TLC                        | The R <sub>f</sub> value of the principal spot obtained from the sample solution corresponds to that of the standard solution. |
| Residue on ignition           | Not more than 0.25%.   |
| Heavy metals                  | Not more than 10 µg/g (10 ppm), Method II.   |
| Specific optical rotation     | (-33.5°) to (-37.0°) at 20 °C.   |
| pH                            | 4.0 – 6.5.   |
| Loss on drying                | Not more than 0.5%.  |
| Organic impurities            | Any individual impurity : Not more than 0.25%.   |
|                               | Total impurities : Not more than 1.0%.   |
| Assay                         | 98.9% - 101.5% of ribavirin (C <sub>8</sub> H <sub>12</sub> N <sub>4</sub> O <sub>5</sub> ), calculated on the dried basis.    |

GPO specification

| Test Items           | Specification                             |
|----------------------|---|
| Melting point by DSC | 165.0 °C to 171.0 °C (Form II).           |
| Residual solvents    | Ethanol : Not more than 5000 ppm (0.5%).  |
|                      | Methanol : Not more than 3000 ppm (0.3%). |

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

|  |   |   |   |                       |
|--|---|---|---|-----------------------|
| Prepared by :<br>Sunanee, 31/07/18<br>Head of Raw Material<br>Standard Section I | Reviewed by :<br>Suntharee, 31/07/18<br>Director of Raw Material<br>Standard Division | NAR2P2N, 31/07/18<br>Director of Regulatory<br>Compliance and<br>Documentation Division | Approved by :<br>Yichin Kiangnongroj, 01/08/18<br>Director of Quality<br>Assurance Department<br>(Acting) | Eff. Date<br>31/08/18 |
|--|---|---|---|-----------------------|



COPY No. 2

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

|   |                         |
|---|-------------------------|
| Title : Ribavirin USP (Item No. 41033030) | Spec. No. : SP-AK30-R30 |
| Reference(s) : USP 37 p. 4561-4562        | Rev. No. : 01           |
| Other Requirements : GPO specification    | Page : 2/2              |

## Product Information

|                     |  |
|---------------------|--|
| Approved source (s) | Refer to current version of Approved Vendor List of Ribavirin USP (Item No. 41033030). |
| Sampling plan       | 1. N Plan ( $\sqrt{N} + 1$ ) : for other tests.<br>2. 100% Identification.             |
| Testing procedure   | Tests to be performed as per current version of WI-AK30-R30.                           |
| Storage condition   | Preserve in tight containers.  |
| Retest period       | 1 year after first testing date.   |

## History of changes

| Rev. No. | Description   | Effective date |
|----------|---|----------------|
| 01       | First issue, อ้างอิง USP 37 ตามที่สถาบันวิจัยฯ ยื่นขึ้นทะเบียน อ้างอิง Spec. No. : RMS-RA-79N520450 Rev. No. 01 และ source ที่สถาบันวิจัยฯ อ้างอิงคือ BASF/ Switzerland | 31/08/18       |

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

|   |  |  |   |                       |
|---|--|--|---|-----------------------|
| Prepared by :<br>Sumanee , 31/07/18<br>Head of Raw Material<br>Standard Section 1 | Reviewed by :<br>Sinthavee , 31/07/18<br>Director of Raw Material<br>Standard Division | VARIPIN , 31/07/18<br>Director of Regulatory<br>Compliance and<br>Documentation Division | Approved by :<br>Vichin , 01/08/18<br>Director of Quality<br>Assurance Department<br>(Acting) | Eff. Date<br>31/08/18 |
|---|--|--|---|-----------------------|