|  |
| --- |
| **GENERAL INFORMATION** |
| Pharmacopeial reference | : | USP |
| Special requirement of pack | : | Material should be packed in HDPE drum. |
| Approved vendor | : | Please refer current approved vendor list. |
| Handling hazards | : | Refer Material Safety Data Sheet |
| Quantity to be sampled |  |

|  |  |
| --- | --- |
| Analysis Sample | Control sample |
|  50 g | 100 g |

 |
| Retest Period | : | 12 Months  |
| Storage | : | Preserve in well closed container. Do not store above 55˚ C. |

| **Sr. No.** | **TEST** | **SPECIFICATIONS** | **REFERENCE** |
| --- | --- | --- | --- |
|  | Description # | White to yellowish liquid, , fatty solid to semisolid  | USP  |
|  | Solubility | Insoluble in water | USP |
|  | Identification Test |
|  | A) By Fatty Acid Composition | Carbon chain length  | No. of double bonds | Percentage  | USP |
| ≤ 12 | 0 | ≤ 2.5 |
| 14 | 0 | 0.5 – 5.9 |
| 16 | 0 | 39.0 –47.0 |
| 18 | 0 | 2.0 – 8.0 |
| 16 | 1 | ≤ 0.5 |
| 18 | 1 | 36.0 – 44.0 |
| 18 | 2 | 7.0 – 12.0 |
| 18 | 3 | ≤ 0.5 |
| ≥20 | 0 or 1 | ≤ 1.0 |
| B) Melting Range or Temperature | 30° C-40° C | USP |
| C) By Triglyceride Profile | The Rf values of the principal spots of the sample solution should correspond to those of the standard solution. | USP |
|  | Residue On Ignition | NMT 0.1% | USP |
|  | Alkaline Impurities | NMT 0.1 ml of 0.01 N Hydrochloric acid is required | USP |
|  | Melting Range or Temperature | 30°C - 40°C | USP |
|  | Fats And Fixed oils | USP |
| 1. Acid Value
 | Not more than 2.0  |
| 1. Fatty Acid Composition
 | Carbon chain length  | No. of double bonds | Percentage  |
| ≤ 12 | 0 | ≤ 2.5 |
| 14 | 0 | 0.5 – 5.9 |
| 16 | 0 | 39.0 –47.0 |
| 18 | 0 | 2.0 – 8.0 |
| 16 | 1 | ≤ 0.5 |
| 18 | 1 | 36.0 – 44.0 |
| 18 | 2 | 7.0 – 12.0 |
| 18 | 3 | ≤ 0.5 |
| ≥20 | 0 or 1 | ≤ 1.0 |
| 1. Peroxide Value
 | NMT 5.0  |
| 1. Unsaponifiable Matter
 | NMT 1.0 % |
|  | Water Determination  | NMT 0.1 % | USP |

#: Re-evaluation tests

**REVISION HISTORY FOR SPECIFICATION:**

|  |  |  |
| --- | --- | --- |
| **Revision No.** | **Revision Description** | **Effective Date** |
| 01 | Specification prepared as per Approved Change control CC/PD/23/011 |  |