

No.: BPBE-610-B-00/3.0

Product Specification

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|-------------------------|---------------------|------------------|----------------|
| Product Name | Diosmin | Code | BPBE-610-B |
| Botanical Source | Citrus Aurantium L. | Used Part | Immature fruit |
| Specification | EP8.3 | | |

| ITEM | SPECIFICATION | METHOD |
|--|---|--------------------|
| Appearance | Greyish-yellow or light yellow, hygroscopic powder | Visual |
| Solubility | Practically insoluble in water, soluble in dimethyl sulfoxide, practically insoluble in ethanol (96%), it dissolves in dilute solution of alkali hydroxides | EP8.3 |
| Identification | A) IR: Complies diosmin CRS HPLC: Complies to the reference solution | HPLC |
| Iodine | ≤0.1% | Potentiostat |
| Related Substances | | |
| Impurity A(Acetoisovanillone) | ≤0.5% | HPLC |
| Impurity B(Hesperidin) | ≤4.0% | HPLC |
| Impurity C(Isorhoifolin) | ≤3.0% | HPLC |
| Impurity D(6-iododiosmin) | ≤0.6% | HPLC |
| Impurity E (Linarin) | ≤3.0% | HPLC |
| Impurity F(Diosmetin) | ≤2.0% | HPLC |
| Unspecified Impurities(each) | ≤0.4% | HPLC |
| Total Impurities | ≤8.5% | HPLC |
| Heavy Metals | ≤20ppm | Visual Colorimetry |
| Water | ≤6.0% | Karl Fischer |
| Sulphated Ash | ≤0.2% | EP8.3 |
| Assay (HPLC, Anhydrous substance) | 90.0%~102.0% | HPLC |
| Residual Solvents | | |
| Methanol | ≤3000ppm | HPGC |
| Ethanol | ≤5000ppm | HPGC |
| Pyridine | ≤200ppm | HPGC |
| Total Plate Count | ≤1000cfu/g | AOAC |
| -Yeast & Mold | ≤100cfu/g | AOAC |
| -E.Coli | Negative | AOAC |
| -Salmonella | Negative | AOAC |

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| Version No. | 3.0 | Revision Date | Feb-03-2020 |
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