

**DELASS NATURAL PRODUCTS**

Extraction unit

Document of Specification

Product: Rosemary water glycerin extract (1:13-20 (g:g))**Herbal Preparation Form :** Liquid**Category:** Herbal extract (API)**Product Code:** 30SS00113

1. Description

- **Botanical Name**

Rosmarinus officinalis Lamiaceae.

- **Common Names**

Rosmarini folium.

- **Plant part used:**

Whole, dried leaf.

- **Extraction Solvent**

Water- Glycerine.

- **Characteristics**

Brown solution, with characteristic odor and taste of Rosemary.

2. Tests

Test Name	General Test Source	Acceptable Limits
Identification (A) HPLC	HSE	Positive for <i>Rosmarinic acid</i> .
pH	Ph.Eur (2.2.3)	4.0 – 7.0
Weight per milliliter	BP (G245)	1.120 - 1.160 g/ml.
Water Content	Ph.Eur (2.5.12)	40 % – 60 % .
Refractive index	Ph.Eur (2.2.6)	1.395 - 1.420.
Assay of Sodium Benzoate (Preservative)	HSE	0.18 – 0.22 mg/100mg .
Content of <i>Rosmarinic acid</i>	HSE	Not less than 75 mg/100ml.
Microbial limit	Ph. Eur. (5.1.8)	- Total viable aerobic count: NMT 10 ⁴ cfu/ml. - Fungi: NMT 10 ² cfu/ml. - <i>Enterobacteria</i> and other certain gram-negative bacteria: NMT 10 ² cfu/ml. - Absence of <i>Salmonella</i> and <i>E. coli</i> .



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3. Additional Tests

Test Name	General Test Source	Acceptable Limits
Heavy metals	Ph.Eur (2.4.27)	Cadmium: maximum 1.0 ppm. Lead: maximum 5.0 ppm. Mercury: maximum 0.1 ppm.
Aflatoxins	USP <561>	NMT 5ppb for Aflatoxin B1. And NMT 20ppb for the sum of Aflatoxins B1, B2, G1 and G2.
Pesticide Residues	BS EN 15662-2008	Meets the Maximum Residue Limits in CODEX and European Commission Pesticide database
Radiation contamination	USP <821>	Not more than 370Bq/Kg (Cs134+ Cs137).

* Additional tests are ensured by regular monitoring of the herbal drug.

Note: All pharmacopoeial test sources listed conform to the latest pharmacopoeial edition supplement or amendment issued.

LRN: Latest Revision Number.

HSE: House Specification.

4. Available Package Forms

Package Form	Primary Package	Secondary Package
Containers of 30 Kg.	30 Kg HDPE container.	Label.

5. Shelf Life

- Two years.

6. Storage

- Do Not store above 30°C, Protected from light.