# Sabinsa Poland Sp. z o.o.

*Pharmaceuticals *Phytochemicals
*Fine Chemicals *Herbal Extracts
*Cosmeceuticals *Specialty Chemicals

## CERTIFICATE OF ANALYSIS



| | |
|---|---|
| **Product Name** | **DGL** |
| **Product Code** | **0510** |
| **Batch No.** | **C231160** |
| **TR No.** | **KL23F0467** |
| **Date of Manufacture** | **July 2023** |
| **Date of Expiry** | **June 2028** |

| | |
|---|---|
| Category | Intended for Nutraceutical application |
| Botanical/Scientific name | Glycyrrhiza glabra |
| CAS No | 84775-66-6 |
| Plant part | Roots |
| Preparation type | Extraction |
| Solvent used for extraction | DM Water |
| Solvent used in manufacture | None |
| Final extract ratio | 3:1 to 5: 1 |
| Standardization | Glycyrrhizinic acid |
| Excipient used | Brown dextrin |

| **Excipient name** | **%Used** | **CAS No.** |
|---|---|---|
| Brown dextrin | 70% | 9004-53-9 |

| **Parameters** | **Result** | **Limit** | **Reference** |
|---|---|---|---|
| **PHYSICAL** | | | |
| Description | Complies | Pale brown powder with characteristic odour | Visual and Organoleptic |
| Identification | Complies | To comply by HPLC | SLL/STP-G-008 |
| Solubility | | | |
| -Water solubles (1% w/v solution in water) | 92.55 % w/w | Not less than 90.0% w/w | SLL/STP-S-028 |
| -Alcohol solubles | Complies | Insoluble in alcohol | USP |
| Loss on drying | 1.47 % w/w | Not more than 6.0% w/w (dried at 105°C) | EP 2.2.32 |
| Ash content | 1.55 % w/w | Not more than 5.0% w/w | EP 2.4.16 Method - II |

*ul. Myska 16/ pitro 8 ,*
*61-730 Pozna, Poland*
*Tel: +49 61 03/270 11-11*
*Fax: +49 61 03/270 11-17*
*Email: info.poland@sabinsa.com*

## CERTIFICATE OF ANALYSIS



| | |
|---|---|
| **Product Name** | **DGL** |
| **Product Code** | **0510** |
| **Batch No.** | **C231160** |
| **TR No.** | **KL23F0467** |
| **Date of Manufacture** | **July 2023** |
| **Date of Expiry** | **June 2028** |

| Parameters | Result | Limit | Reference |
|---|---|---|---|
| Tapped bulk density | 0.67 g/ml | Between 0.40g/ml and 0.70g/ml | EP 2.9.34 Method - I |
| Loose bulk density | 0.50 g/ml | Between 0.30g/ml and 0.50g/ml | EP 2.9.34 Method - I |
| Sieve Test (Passes through) | | | USP <786> |
| - 20 mesh | 100.00 % w/w | Not less than 100% w/w | |
| - 40 mesh | 100.00 % w/w | Not less than 90% w/w | |
| - 80 mesh | 100.00 % w/w | Not less than 80% w/w | |
| **CHEMICAL** | | | |
| Assay | | | |
| -Content of Glycyrrhizinic acid by HPLC | 1.74 % w/w | Not more than 3.0% w/w | SLL/STP-G-008 |
| **OTHERS** | | | |
| Lead | <0.2 ppm (µg/g) | Not more than 3ppm (µg/g) | USP <2232> |
| Arsenic | <0.2 ppm (µg/g) | Not more than 1ppm (µg/g) | USP <2232> |
| Cadmium | <0.2 ppm (µg/g) | Not more than 1ppm (µg/g) | USP <2232> |
| Mercury | <0.0.2 ppm (µg/g) | Not more than 0.1ppm (µg/g) | USP <2232> |
| Residual solvents | Complies | To comply as per EU Directive 2009/32/EC | USP <467> |
| Residual pesticides | Complies | To comply as per EP | USP <561> |
| Poly Aromatic Hydrocarbons (PAH) | | | SLL/STP-P-066 |

## CERTIFICATE OF ANALYSIS



| | |
|---|---|
| **Product Name** | **DGL** |
| **Product Code** | **0510** |
| **Batch No.** | **C231160** |
| **TR No.** | **KL23F0467** |
| **Date of Manufacture** | **July 2023** |
| **Date of Expiry** | **June 2028** |

| Parameters | Result | Limit | Reference |
|---|---|---|---|
| -Benzo(a)pyrene | Complies | Not more than 10ppb (µg/kg) | |
| -PAH4 (Sum of Benzo(a)pyrene, Benz(a)anthracene, Benzo(b)fluoranthene and Chrysene) | Complies | Not more than 50ppb (µg/kg) | |
| Ethylene oxide (Sum of Ethylene oxide and 2-Chloroethanol) | Complies | Not more than 100ppb (µg/kg) | SLL/STP-E-015 |
| **MICROBIOLOGICAL PROFILE** | | | |
| Total aerobic microbial count | <100 cfu/g | Not more than 5000cfu/g | EP 2.6.31 |
| Total yeasts and molds count | <10 cfu/g | Not more than 100cfu/g | EP 2.6.31 |
| Escherichia coli | Complies | Negative/10g | EP 2.6.31 |
| Salmonella | Complies | Negative/25g | EP 2.6.31 |
| Staphylococcus aureus | Complies | Negative/10g | EP 2.6.13 |
| Pseudomonas aeruginosa | Complies | Negative/10g | EP 2.6.13 |
| Bile tolerant Gram negative bacteria | <10 cfu/g | Negative/10g | EP 2.6.31 |
| Coliforms | <10 cfu/g | Less than 10cfu/g | BAM Chapter 4 |
| **ADDITIONAL INFORMATION** | | | |
| Sanitising treatment | Non-irradiated and not treated with ETO | | |
| Certification Status (Kosher/Halal) | Kosher and Halal certified | | |
| BSE/TSE status | BSE / TSE free | | |


*ul. Myska 16/ pitro 8 ,*
*61-730 Pozna, Poland*
*Tel: +49 61 03/270 11-11*
*Fax: +49 61 03/270 11-17*
*Email: info.poland@sabinsa.com*

## CERTIFICATE OF ANALYSIS



| | |
|---|---|
| **Product Name** | **DGL** |
| **Product Code** | **0510** |
| **Batch No.** | **C231160** |
| **TR No.** | **KL23F0467** |
| **Date of Manufacture** | **July 2023** |
| **Date of Expiry** | **June 2028** |

| | |
|---|---|
| Genetic Modification Status | GMO free |
| Country of Origin | India |
| Cultivated or wild crafted | Cultivated |
| Storage condition | Store at room temperature |
| Manufactured By | Sami-Sabinsa Group Limited - Peenya<br>19/1, 19/2, I Main II Phase, Peenya Industrial Area, Bangalore. 560 058, Karnataka, India |
| Manufactured At | Sami-Sabinsa Group Limited - Kunigal<br>Plot No. 30-35, KIADB Industrial Area, Kunigal, Tumkur District - 572130 |
| Remarks | *Since it is a herbal product, there is likely to be minor colour variation from batch to batch of the product because of the geographical and seasonal variations of the raw material.<br>*Natural products can be hygroscopic and may agglomerate sometimes. It is suggested to sift the product before use. |

The above certificate of analysis is based on ***Specifications Issue No: 4 Dated: February 09, 2022***

***In-House developed and validated methods**

***NAP:Not Applicable**

***NAV:Not Available**


*ul. Myska 16/ pitro 8 ,*
*61-730 Pozna, Poland*
*Tel: +49 61 03/270 11-11*
*Fax: +49 61 03/270 11-17*
*Email: info.poland@sabinsa.com*