



High Quality – from Source to Final Product

Our Refined Soybean Oil IV is a highly purified soybean oil fully compliant with the **European Pharmacopoeia (1473)** and **United States Pharmacopoeia/National Formulary (USP/NF) monographs and general notices** intended for use in the manufacturing of pharmaceutical products.



Unmatched Quality for Use as API or Excipient in Formulation of Lipophilic Drugs

REFINED SOYBEAN OIL IV CAN BE USED IN HUMAN AND VETERINARY APPLICATIONS SUCH AS:



parenteral
nutrition



injectables



syrup



softgels

Active Pharmaceutical Ingredient (API), in parenteral nutrition (e.g. large volume lipid emulsion)
Excipient, for the formulation of poorly soluble drugs



Full Compliance with the Most Demanding Regulations

Manufactured under cGMP according to the ICH-Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

A 9-step purification process is applied to the starting material (crude soybean oil) to deliver a high-quality purified oil. Final steps of the process, including **fine filtration and drum filling under nitrogen, are performed in an ISO 8 class cleanroom.**

Supported with Certificate of Suitability to the European Pharmacopoeia (CEP) granted by the European Directorate for the Quality of Medicines & HealthCare (EDQM) certifying that the substance is suitably manufactured and controlled according to the current version of the monograph Soybean Oil, refined (1473).

No. R1-CEP 2011-115.

Supported with Drug Master File (DMF) type IV for excipients submitted to the U.S. Food and Drug Administration (FDA).

DMF # 028 528.

Compliant
with EP & USP
requirements

Manufactured
under cGMP
according to
ICH-Q7

Supported
with CEP and
DMF type IV



Process Control for High-Quality Pharmaceutical Ingredients

The precise control of our refining process enables us to guarantee the best **batch-to-batch consistency**.

BATCH-TO-BATCH CONSISTENCY

As with many plant-based excipients, source variability could be a concern. Therefore, we manage the variability of our Refined Soybean Oil IV by closely working with source suppliers. Our 9-step purification process guarantees high quality and consistency of the final product for your formulations, from topical to intravenous applications.

MANUFACTURING PROCESS CONTROL

- Specific sourcing & control of the starting material
- Adjustment of purification process parameters
- Real-time process monitoring
- In-process control tests
- Out-of-trend monitoring

MANAGEMENT OF CONTAMINANTS & NATURAL IMPURITIES

- Control of bacterial endotoxins
- Elemental impurities according to ICH Q3D
- Residual solvents: compliance with ICH Q3C and EP 5.4 requirements
- Absence of TSE/BSE risk

HIGH STABILITY GUARANTEE

Stability studies performed according to the International Conference on Harmonization (ICH) Q1A Quality Guideline show that **Refined Soybean Oil IV is perfectly stable over a 36-month shelf life period.**



Insight on Regulatory Evolution

Over the several last years, there has been an increasing focus on securing the quality and safety of excipients and today, **excipients are a top priority among regulatory agencies like the International Pharmaceutical Excipients Council (IPEC) and the United States Pharmacopeia (USP)**. The pharmaceutical manufacturers are required to assess the GMP compliance of their excipient suppliers to satisfy the outcome of the formalized risk assessment. At ADM-SIO, we are at the forefront of regulatory monitoring and we offer best-in-class solutions for excipients that have been classified as critical.



ADM-SIO's Refined Soybean Oil IV is available in 56,5 Kg or 200 Kg tight-head metal drums that are filled under nitrogen in an ISO 8-classified cleanroom.

ADM DELIVERS FOR YOU

With more than a century of experience, dedicated production lines and specialized R&D and Regulatory teams, ADM-SIO offers its customers innovative global solutions tailored to the specific challenges of the Pharmaceutical industry. At ADM-SIO, we offer an extensive range of highly purified oils, derived from vegetable origins that meet major relevant pharmaceutical regulations and are manufactured according to cGMP standards. We make delivering compliance and consistency a reality, giving you an edge to innovate with confidence.

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