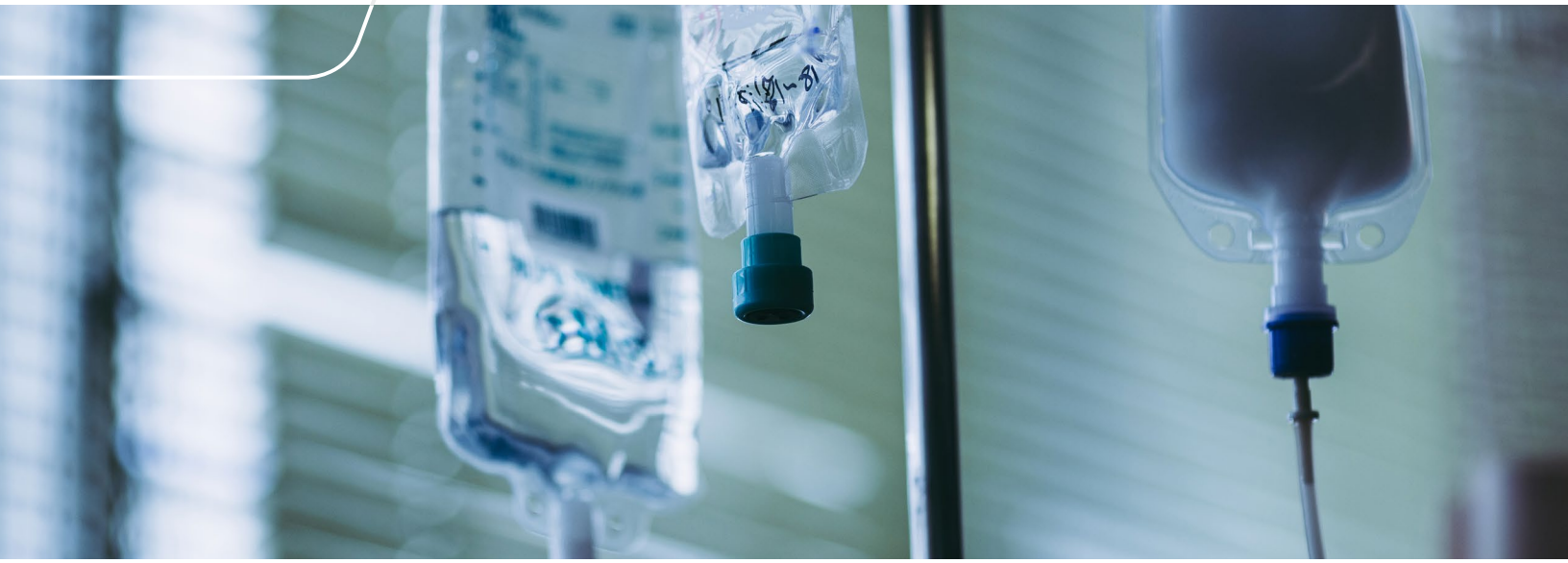
REFINED OLIVE OIL IV



High Quality – from Source to Final Product

Our Refined Olive Oil IV is a highly purified olive oil fully compliant with the **European Pharmacopoeia (1456) and United States Pharmacopeia/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 OLIVE 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

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BDEM23(HN-222445)

REFINED OLIVE OIL IV

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 (virgin olive 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 Olive Oil, refined (1456).
No. R0-CEP 2015-167.

Supported with Drug Master File (DMF) type IV for excipients submitted to the U.S. Food and Drug Administration (FDA).
(DMF # 034 152)

Compliant with EP & USP requirements

Manufactured under cGMP according to ICH-Q7

Supported with CEP and DMF type IV

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REFINED OLIVE OIL 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 Olive 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 Olive Oil IV is perfectly stable over a 36-month shelf life period**.

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REFINED OLIVE OIL IV

Insight on Regulatory Evolution

Over the last several 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.

The current European Pharmacopeia of vegetable fatty oils for olive oil (Olea europaea L.) indicates that **only alkali-refined (chemical refining) oils can be used in the manufacturing of parenteral preparations.**

packaging

ADM-SIO's Refined Olive 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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