Eudragit®
An Evonik product.

Technical Information

EUDRAGIT® Polymers and PLASTOID® B

Pharmacopoeial Monographs and Drug Master Files

EUDRAGIT® L 100	Methacrylic Acid - Methyl Methacrylate Copolymer (1:1) – Ph. Eur. Methacrylic Acid and Methyl Methacrylate Copolymer (1:1) – NF Methacrylic Acid Copolymer L – JPE US DMFs 027796 (Quality) and 026602 (Safety)
EUDRAGIT® L 12,5	polymer conforms to: Methacrylic Acid - Methyl Methacrylate Copolymer (1:1) – Ph. Eur. polymer conforms to: Methacrylic Acid and Methyl Methacrylate Copolymer (1:1) – NF polymer conforms to: Methacrylic Acid Copolymer L - JPE US DMFs 027796 (Quality) and 026602 (Safety)
EUDRAGIT® S 100	Methacrylic Acid - Methyl Methacrylate Copolymer (1:2) – Ph. Eur. Methacrylic Acid and Methyl Methacrylate Copolymer (1:2) – NF Methacrylic Acid Copolymer S – JPE US DMFs 027796 (Quality) and 026602 (Safety)
EUDRAGIT® S 12,5	polymer conforms to: Methacrylic Acid - Methyl Methacrylate Copolymer (1:2) – Ph. Eur. polymer conforms to: Methacrylic Acid and Methyl Methacrylate Copolymer (1:2) – NF polymer conforms to: Methacrylic Acid Copolymer S - JPE US DMFs 027796 (Quality) and 026602 (Safety)
EUDRAGIT® L 100-55	Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A – Ph. Eur. Methacrylic Acid and Ethyl Acrylate Copolymer – NF Dried Methacrylic Acid Copolymer LD – JPE US DMF 002584 (Quality & Safety)
EUDRAGIT® L 30 D-55	Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Dispersion 30 Per Cent – Ph. Eur. Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion – NF Methacrylic Acid Copolymer LD – JPE US DMF 002584 (Quality & Safety)

EUDRAGIT® FS 100	Under preparation. Will be included into US DMF 013941 (Quality & Safety)
EUDRAGIT® FS 30 D	US DMF 013941 (Quality & Safety)
EUDRAGIT® RL 100	Ammonio Methacrylate Copolymer, Type A – Ph. Eur. Ammonio Methacrylate Copolymer, Type A – NF Ammonioalkyl Methacrylate Copolymer, Type A – JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RL PO	Ammonio Methacrylate Copolymer, Type A – Ph. Eur. Ammonio Methacrylate Copolymer, Type A – NF Ammonioalkyl Methacrylate Copolymer, Type A – JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RL 12,5	polymer conforms to: Ammonio Methacrylate Copolymer, Type A – Ph. Eur. polymer conforms to: Ammonio Methacrylate Copolymer, Type A – NF polymer conforms to Ammonioalkyl Methacrylate Copolymer, Type A - JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RL 30 D	polymer conforms to: Ammonio Methacrylate Copolymer, Type A – Ph. Eur. Ammonio Methacrylate Copolymer Dispersion, Type A – NF Ammonioalkyl Methacrylate Copolymer Dispersion, Type A – JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RS 100	Ammonio Methacrylate Copolymer, Type B – Ph. Eur. Ammonio Methacrylate Copolymer, Type B – NF Ammonioalkyl Methacrylate Copolymer, Type B – JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RS PO	Ammonio Methacrylate Copolymer, Type B – Ph. Eur. Ammonio Methacrylate Copolymer, Type B – NF Ammonioalkyl Methacrylate Copolymer, Type B – JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RS 12,5	polymer conforms to: Ammonio Methacrylate Copolymer, Type B – Ph. Eur. polymer conforms to: Ammonio Methacrylate Copolymer, Type B – NF polymer conforms to Ammonioalkyl Methacrylate Copolymer, Type B - JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® RS 30 D	polymer conforms to: Ammonio Methacrylate Copolymer, Type B – Ph. Eur. Ammonio Methacrylate Copolymer Dispersion, Type B – NF Ammonioalkyl Methacrylate Copolymer Dispersion, Type B – JPE US DMFs 027404 (Quality) and 026773 (Safety)
EUDRAGIT® E 100	Basic Butylated Methacrylate Copolymer – Ph. Eur. Amino Methacrylate Copolymer – NF Aminoalkyl Methacrylate Copolymer E – JPE US DMFs 027877 (Quality) and 027770 (Safety)

EUDRAGIT® E PO	Basic Butylated Methacrylate Copolymer – Ph. Eur. Amino Methacrylate Copolymer – NF Product differs from NF-Monograph only in the description (appearance). Aminoalkyl Methacrylate Copolymer E – JPE US DMFs 027877 (Quality) and 027770 (Safety)
EUDRAGIT® E PO ReadyMix	US DMF 030738 (Quality & Safety) (selected EUDRAGIT® E PO ReadyMix types)
EUDRAGIT® E 12,5	polymer conforms to: Basic Butylated Methacrylate Copolymer – Ph. Eur. polymer conforms to: Amino Methacrylate Copolymer – NF polymer conforms to: Aminoalkyl Methacrylate Copolymer E - JPE US DMFs 027877 (Quality) and 027770 (Safety)
EUDRAGIT® NE 30 D	Polyacrylate Dispersion 30 Per Cent – Ph. Eur. Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion – NF Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion – JPE US DMF 002822 (Quality & Safety)
EUDRAGIT® NE 40 D	Variation on solid substance content of: Polyacrylate Dispersion 30 Per Cent – Ph. Eur. Variation on solid substance content of: Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion–NF Variation on solid substance content of: Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion–JPE US DMF 002822 (Quality & Safety)
EUDRAGIT® NM 30 D	Polyacrylate Dispersion 30 Per Cent – Ph. Eur. Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion-NF EUDRAGIT® NM 30 D is described in these monographs. It differs only with regard to the slightly lower weight average molar mass of EUDRAGIT® NM 30 D. US DMF 002822 (Quality & Safety)
PLASTOID® B	US DMF 012102 (Quality & Safety)

Additional Information on Drug Master Files

Open part of the U.S. Drug Master Files (DMF)

The concept of open part of a DMF is not applicable to Type IV or Type V US DMFs. Instead Evonik offers to issue a Letter of Authorization (LoA).

A Letter of Authorization permitting the FDA to refer to the relevant Drug Master File in connection with the customers´ application can be issued upon written request. For the issuance of the Letter of Authorization customers are kindly asked to inform Evonik about

- the official company name and address;
- the EUDRAGIT® type in question;
- the DMF name/ type in question (in case Quality data and Safety data are separated); and
- the type of application planned (e.g. NDA, ANDA or IND).

Since the DMFs are updated regularly it is most appropriate to request a LoA only short time before the application will be filed with the FDA. Please also note that as per FDA requirement, LoAs have to be submitted electronically. Please allow for at least two weeks for completion of the Evonik submission of a LoA.

European Drug Master Files

Drug Master Files for excipients are currently not accepted by the European drug regulatory authorities. Therefore EU-DMFs for EUDRAGIT® types are not available. Instead the documentation of the quality of excipients is filed with the submission for the pharmaceutical preparation. If the excipient is described in one of the internationally accepted pharmacopeias, preferably in the European Pharmacopoeia, evidence that the excipient conforms to the monograph is generally regarded as sufficient.

Therefore please kindly refer to the Ph. Eur. monographs describing the products of interest.

Further regulatory information is provided in the Excipient Information Protocols/Packages (EIP) for the respective products which are available on request.

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