

NEW SUPPLIERS OF DEFINED SIMPLE APIs

Where relevant, standard, rather than complex, fees will be charged as shown in the table below where the application is only concerned with the introduction of new suppliers of defined simple Active Pharmaceutical Ingredients (APIs). These simple APIs, listed below, are substances widely employed as excipients, food additives, reagents in analytical or synthetic chemistry, etc. and are all subjects of Ph. Eur/BP monographs as a prerequisite. As far as Marketing Authorisation variations are concerned, a Type II fee will only be applicable anyway if the change is not a minor variation of Type IA or a minor variation of Type IB within the meaning of Commission Regulation (EC) 1234/2008.

New standard fee for simple APIs from 1st April 2013

Type II variation national/CMS	£816
Type II variation RMS	£989
Type II variation group national/CMS	£1,836
Type II variation group RMS/Reference Authority for worksharing	£2,218
Abridged national	£10,447
Abridged DCP (where UK is RMS)	£18,422
Abridged DCP (where UK is CMS)	£10,087
Abridged incoming MR (where UK is CMS)	£7,056

List of simple Active Pharmaceutical Ingredients

Acetic Acid
Aluminium Chloride
Aluminium Hydroxide
Aluminium Sulphate
Ammonia
Ammonium Bicarbonate
Ammonium Chloride
Ascorbic Acid
Barium Sulphate
Benzoic Acid
Benzoyl Peroxide
Benzyl Alcohol
Benzyl Benzoate
Bismuth Subgallate
Calamine
Calcium Acetate
Calcium Carbonate
Calcium Chloride
Calcium Gluconate
Calcium Glycerophosphate
Calcium Hydroxide
Calcium Lactate
Calcium Phosphate
Charcoal
Chlorobutanol
Chlorocresol
Citric Acid
Coal Tar
Ethanol

Ethanolamine
Ferric chloride
Ferrous fumarate
Ferrous gluconate
Ferrous sulphate
Formaldehyde Solution
Glucose
Glycine
Hydrogen peroxide
Iodine
Isopropyl alcohol
Isopropyl myristate
Kaolin
Lactic Acid
Lactose
Lactulose
Lithium Carbonate
Lithium Citrate
Magnesium Acetate
Magnesium Carbonate
Magnesium Chloride
Magnesium Hydroxide
Magnesium Oxide
Magnesium Sulphate
Magnesium Trisilicate
Malic Acid
Manganese Sulphate
Oleic Acid
Paraffin
Phenol
Phosphoric Acid
Potassium Acetate
Potassium Bicarbonate
Potassium Chloride
Potassium Citrate
Potassium Dihydrogen Phosphate
Potassium Hydrogen Tartrate
Potassium Hydroxide
Potassium Iodate
Potassium Iodide
Potassium Nitrate
Silver Nitrate
Sodium Acetate
Sodium Ascorbate
Sodium Bicarbonate
Sodium Carbonate
Sodium Chloride
Sodium Citrate
Sodium Dihydrogen Phosphate
Sodium Fluoride
Sodium Hydroxide
Sodium Iodide
Sodium Lactate
Sodium Sulphate
Sorbic Acid

Sucrose
Sulphur
Tar
Tartaric Acid
Undecenoic Acid
Urea
Wool Alcohols
Wool Fat
Zinc Acetate
Zinc Chloride
Zinc Oxide
Zinc Sulphate
Zinc Undecenoate

* NB Dried/Anhydrous, Hydrate/Hydrous, Activated, Strong, Light, Heavy and Coloured forms for these APIs are not specifically cited in this list. These specific forms, where relevant, are stated in the title of the European Pharmacopoeia or British Pharmacopoeia monographs.