

LIST OF ATYPICAL ACTIVE PHARMACEUTICAL INGREDIENT (API)

Examples of Atypical API:

| No. | Substance Name |
|------------|-------------------------------------|
| 1 | Aluminum Hydroxide |
| 2 | Ammonium Chloride |
| 3 | Ascorbic Acid |
| 4 | Calcium carbonate |
| 5 | Calcium chloride |
| 6 | Cetylpyridinium Chloride |
| 7 | Fish Oil, Rich in Omega-3-Acids |
| 8 | Glucose / Dextrose |
| 9 | Glycerol / Glycerin |
| 10 | Glycine |
| 11 | Histidine Hydrochloride Monohydrate |
| 12 | L-Alanine |
| 13 | L-Alanyl-L-Glutamine |
| 14 | L-Arginine |
| 15 | L-Aspartic Acid |
| 16 | L-Cysteine |
| 17 | L-Glutamic Acid |
| 18 | L-Glutathione |
| 19 | L-Histidine |
| 20 | L-Isoleucine |
| 21 | L-Leucine |
| 22 | L-Lysine Acetate |
| 23 | L-Methionine |
| 24 | L-Phenylalanine |
| 25 | L-Proline |
| 26 | L-Serine |
| 27 | L-Threonine |
| 28 | L-Tyrosine |
| 29 | L-Valine |
| 30 | Lysine Hydrochloride |
| 31 | Lysine Monohydrate |
| 32 | Magnesium Carbonate |
| 33 | Magnesium Chloride |
| 34 | Magnesium Hydroxide |
| 35 | Magnesium Oxide |
| 36 | Magnesium Acetate |
| 37 | Magnesium Sulphate |
| 38 | Malic Acid |
| 39 | Mannitol |
| 40 | Medium Chain Triglyceride |
| 41 | Olive Oil |
| 42 | Potassium Acetate |
| 43 | Potassium Chloride |
| 44 | Potassium Dihydrogen Phosphate |

This Document shall be read together with Drug Registration Guidance Document (DRGD): Appendix 11: Regulatory Control of Active Pharmaceutical Ingredients (APIs) & Guidance Notes for API Information for Product Registration Application

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| 45 | Potassium Phosphate |
| 46 | Sodium Acetate |
| 47 | Sodium Bicarbonate |
| 48 | Sodium Chloride |
| 49 | Sodium Citrate |
| 50 | Sodium Dihydrogen Phosphate Dihydrate |
| 51 | Sodium Glycerophosphate |
| 52 | Sodium Hydroxide |
| 53 | Sodium Lactate |
| 54 | Sodium Phosphate |
| 55 | Soybean Oil |
| 56 | Taurine |
| 57 | Zinc Acetate |
| 58 | Zinc Carbonate |
| 59 | Zinc Chloride |
| 60 | Zinc Citrate |
| 61 | Zinc Gluconate |
| 62 | Zinc Oxide |
| 63 | Zinc Pyrithione |
| 64 | Zinc Sulfate |

Note: This list is not meant to be exhaustive and will be reviewed from time to time.