Halal Ingredients: The Pharmaceutical Sector

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Preamble

- Pharmaceuticals are highly regulated….
- Quality, safety, efficacy …& halal
- Halal ecosystem/paradigm
- ‘Halal built-in rather than tested for’
- MS2424:2012 Guidelines….

POTENTIAL GLOBAL HALAL PRODUCT

No.	Halal Product	Percentage
1	Raw meat	10%
2	Chocolate and sweets	5%
3	Bread and cake Product	12%
4	Processed Food and Drinks	35%
5	Cosmetics and health care	9%
6	Pharmaceuticals	23%
7	Nutraceuticals	6%

(Source HDC)

Table 1: Application of this Guide to API Manufacturing

Type of Manufacturing	Application of this Guide to steps (shown in grey) used in this type of manufacturing				
Chemical Manufacturing	Production of the API Starting Material	Introduction of the API Starting Material into process	Production of Intermediate(s)	Isolation and purification	Physical processing, and packaging
API derived from animal sources	Collection of organ, fluid, or tissue	Cutting, mixing, and/or initial processing	Introduction of the API Starting Material into process	Isolation and purification	Physical processing, and packaging
API extracted from plant sources	Collection of plant	Cutting and initial extraction(s)	Introduction of the API Starting Material into process	Isolation and purification	Physical processing, and packaging
Herbal extracts used as API	Collection of plants	Cutting and initial extraction		Further extraction	Physical processing, and packaging
API consisting of comminuted or powdered herbs	Collection of plants and/or cultivation and harvesting	Cutting/ comminuting			Physical processing, and packaging
Biotechnology:fermentation / cell culture	Establishment of master cell bank and working cell bank	Maintenance of working cell bank	Cell culture and/or fermentation	Isolation and purification	Physical processing, and packaging
"Classical" Fermentation to produce an API	Establishment of cell bank	Maintenance of the cell bank	Introduction of the cells into fermentation	Isolation and purification	Physical processing, and packaging

MALAYSIAN STANDARD

MS 2424:2012

Halal pharmaceuticals - General guidelines

ICS: 11.120.99

Descriptors: halal, pharmaceutical products, preparation, handling, guidelines

MS 2424:2012

CONCEPT

Halal pharmaceuticals /medicinals

Products that contain ingredients permitted under the *Shariah* law and fulfill the following conditions:

- **do not contain any parts or products of animals that are non-*halal* or not slaughtered according to *Shariah* law;**
- **do not contain *najs* according to *Shariah* law;**
- **safe for consumption, non-poisonous, non-intoxicating or non-hazardous to health according to prescribed dosage;**

CONCEPT

Halal pharmaceuticals /medicinals (cont.)

- not prepared, processed or manufactured using equipment contaminated with *najs* according to *Shariah* law;
- do not contain any human parts or its derivatives that are not permitted by *Shariah* law; and
- during its preparation, processing, handling, packaging, storage and distribution, the *halal* pharmaceutical products are physically separated from any other pharmaceutical products that do not meet the requirements as stated in the item a), b), c), d) or e) or any other items that nave been decreed as non-halal and najs by Shariah law.

CONTENTS

Pharmacopoeia

- A book containing directions for the identification of samples and the preparation of compound medicines,
- Published by the authority of a government or a medical or pharmaceutical society.
- A reference work for pharmaceutical drug specifications

Pharmaceutical Drug Specifications

- Pharmaceutical products can usually be tested and qualified by various Pharmacopoeia. Current available standards include:
- British Pharmacopoeia
- European Pharmacopoeia
- Japanese Pharmacopoeia
- The International Pharmacopoeia
- The United States Pharmacopoeia
- If any pharmaceutical product is not covered by the above standards, it can be evaluated by the additional source from other nations, from industrial specifications or from standardized formulary such as
- British National Formulary
- National Formulary

2013 British Pharmacopoeia

Introduction

- The British Pharmacopoeia 2013 supersedes the British Pharmacopoeia 2012. It has been prepared by the British Pharmacopoeia Commission, with the collaboration and support of its Expert Advisory Groups, Panels of Experts and Working Parties and contains almost 3400 monographs for substances, preparations and articles used in the practice of medicine.

BP 2013

The BP 2013 comprises six volumes as follows.

- Volumes I and II Medicinal Substances
- Volume III Formulated Preparations: General Monographs
  Formulated Preparations: Specific Monographs
- Volume IV Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products Materials for use in the Manufacture of Homoeopathic Preparations Blood-related Products Immunological Products Radiopharmaceutical Preparations Surgical Materials
- Volume V Infrared Reference Spectra Appendices
  Supplementary Chapters Index
- Volume VI British Pharmacopoeia (Veterinary) 2013

2013 British Pharmacopoeia

Substances for pharmaceutical use

DEFINITION

….are any organic or inorganic substances that are used as active substances or excipients for the production of medicinal products for human or veterinary use. They may be obtained from natural sources or produced by extraction from raw materials, fermentation or synthesis.

This general monograph does not apply to herbal drugs, herbal drugs for homoeopathic preparations, herbal drug preparations, extracts, or mother tinctures for homoeopathic preparations, ……

Where a substance for pharmaceutical use not described in an individual monograph of the Pharmacopoeia is used in a medicinal product prepared for the special needs of individual patients, the need for compliance with the present general monograph is decided in the light of a risk assessment that takes account of the available quality of the substance and its intended use.

Where medicinal products are manufactured using substances for pharmaceutical use of human or animal origin, the requirements of chapter *5.1.7. Viral safety* apply.

Substances for pharmaceutical use may be used as such or as starting materials for subsequent formulation to prepare medicinal products. Depending on the formulation, certain substances may be used either as active substances or as excipients. Solid substances may be compacted, coated, granulated, powdered to a certain fineness, or processed in other ways. A monograph is applicable to a substance processed with an excipient only where such processing is mentioned in the definition section of the monograph.

Substance for pharmaceutical use of special grade

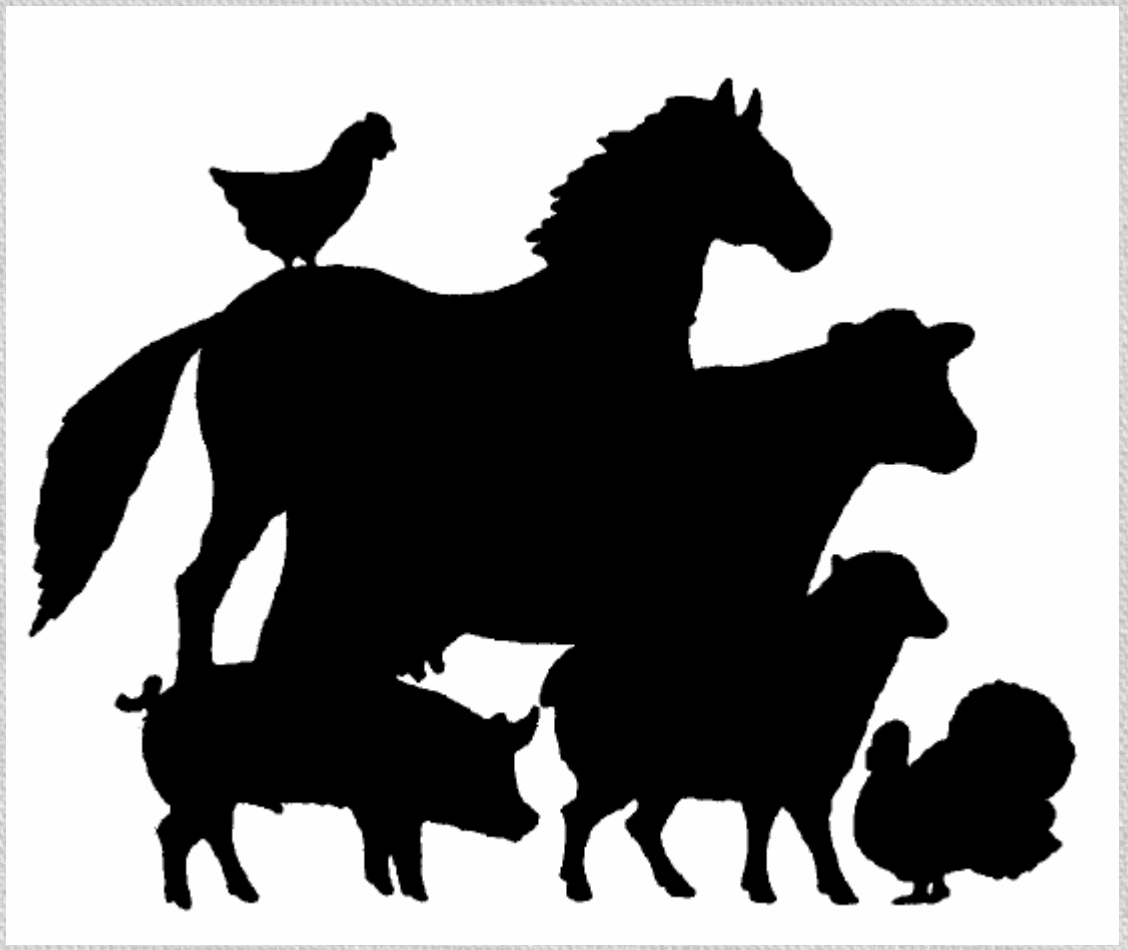
Unless otherwise indicated or restricted in the individual monographs, a substance for pharmaceutical use is intended for human and veterinary use, and is of appropriate quality for the manufacture of all dosage forms in which it can be used.

CONTENTS

INGREDIENTS ORIGIN

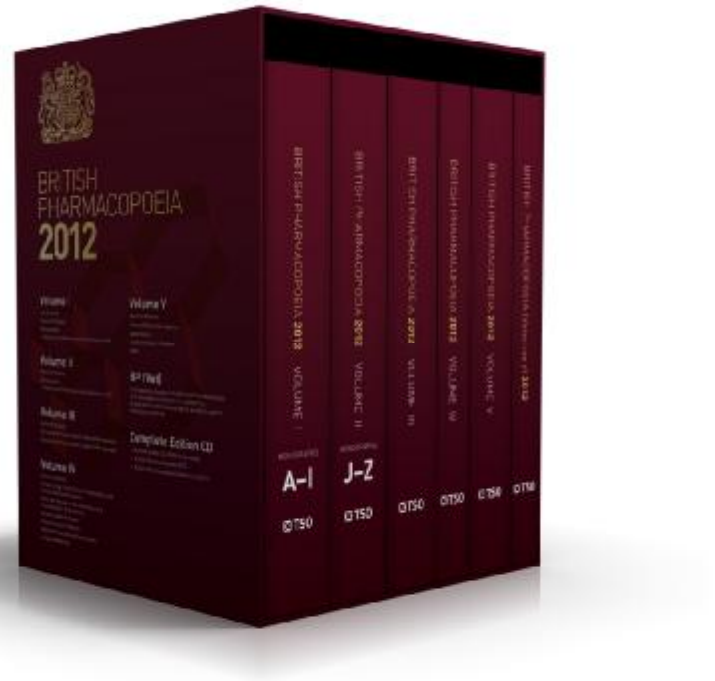
- RED LISTS (HARAM): PIG BASED
- GREY LISTS (MASBOOH): ANIMALS, HUMAN, INSECTS, OTHERS
- GREEN LISTS: SYNTHETIC, PLANTS, SEMISYNTHETIC, MICROBES, RECOMBINANT DNA

MEDICINES FROM ANIMAL ORIGIN IN THE BRITISH PHARMACOPOEIA 2012.



Prepared by:
Zhari bin Ismail PhD
Mohammed Ali Al-Sheikh Wace

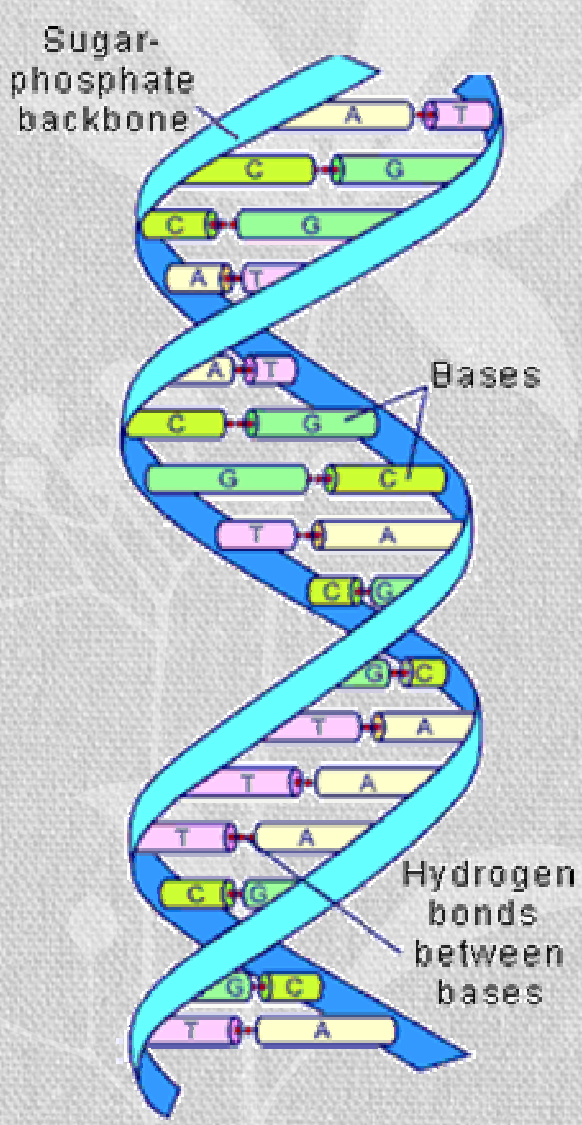
- BP 2012 contains around 3200 monographs.
- Only 129 considered as haram substances.
- Vaccines, blood preparations, and homeopathic preparations were not included in this study because it needed more investigations.



- 27 monographs prepared from specifically porcine or pig. (Red list).

- 13 monographs were prepared from Bovine source.
- 55 monographs were prepared from various animal sources (all mammalian including porcine and bovine).

- There are some medicines categorized as red to green medicines that can have halal alternatives. Currently the haram source is also available.
- The halal sources are from chemical synthesis and chemical analogues (44 monographs) and from recombinant DNA technology (11 monograph)



- There are few monographs that needed more investigations:
- 2 monographs from insects.
- 13 monographs from animals obtained live (without killing the animal) from bear, horse, rabbit.

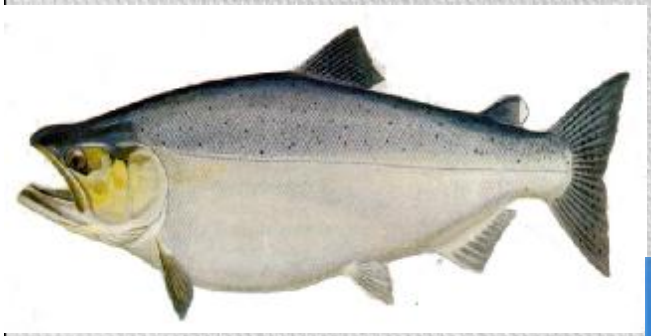


- 13 monographs from human (woman urine and blood plasma).

- 1 monograph from bird and chicken.

Halal Pharmaceuticals from Marine sources.

- There are few monographs from halal sources and from other animal sources:
- 16 monographs from marine sources (fish, salmon, shark, shrimp, and crab).



Pharmacopoeia		BP	EUP	JP	USP
Edition		BP 2012	7th Edition	16th Edition	USP 35 – NF 30
Publication date		August 2011	July 2010 7.6 2012	April 2011	November 2011
Monographs number		3200		1764	4500
Haram active ingredients or excipients					
Red list (from porcine sources only)		**27**	**21**	**4**	
From bovine only		**13**	**9**	**3**	
Grey list (from animal sources (all mammalian and include porcine and bovine also).		**55**	**35**	**20**	
Red to green	chemical synthesis and analogues	**44**	**26**	**9**	
	Recombinant DNA technology	**11**	**7**	**11**	

Pharmacopoeia	BP	EUP	JP	USP
Need more investigations esp. on opinion of the ulama				
From animals without killing the animal (bear, horse, rabbit).	**13**	**10**	**3**	
From human (woman urine and blood plasma).	**13**	**9**	**4**	
From bird and chicken.	**1**	**1**	**1**	
From insects	**2**	**1**	**0**	
Halal from animal sources				
From marine sources (fish, salmon, shark, shrimp, and crab).	**16**	**13**	**9**	

RED LISTS (HARAM): PIG BASED..1

Search: Porcine, British and European articles only

*European
†Internationally harmonised

- Dalteparin Sodium*
- Danaparoid Sodium*
- Enoxaparin Sodium*
- Bovine Insulin*
- Human Insulin*
- Porcine Insulin*
- Parnaparin Sodium*
- Tinzaparin Sodium*
- Injectable Insulin Preparations*
- Insulin Injection*
- Biphasic Insulin Injection*
- Biphasic Isophane Insulin Injection*
- Isophane Insulin Injection*
- Protamine Zinc Insulin Injection
- Insulin Zinc Suspension*
- Insulin Zinc Suspension (Amorphous)*
- Insulin Zinc Suspension (Crystalline)*

- Appendix XIV J. Blood and Related Products
- Appendix XXI B. Approved Synonyms
- Veterinary Vaccines*
- Porcine Actinobacillosis Vaccine, Inactivated*
- Porcine Enzootic Pneumonia Vaccine (Inactivated)*
- Porcine E. Coli Vaccine, Inactivated*
- Porcine Parvovirus Vaccine, Inactivated*
- Porcine Progressive Atrophic Rhinitis Vaccine, Inactivated*
- Swine Influenza Vaccine, Inactivated*
- Appendix XV K (Vet) 3. Evaluation of Safety of each Batch of Veterinary Vaccines and Immunosera
- Appendix XXI B (Vet). Approved Synonyms
-

RED LISTS (HARAM): PIG BASED..2

Search: Pig, British and European articles only

*European

†Internationally harmonised

- Human Insulin*
- Anthrax Vaccine for Human Use (Adsorbed, Prepared from Culture Filtrates)*
- Bacillus Calmette-Guérin Vaccine*
- Cholera Vaccine*
- Cholera Vaccine, Freeze-dried*
- Adsorbed Diphtheria Vaccine*
- Pneumococcal Polysaccharide Vaccine*
- Smallpox Vaccine (Live)*
- Typhoid Vaccine*
- Typhoid Vaccine, Freeze-dried*
- Yellow Fever Vaccine, Live*
- Old Tuberculin*
- Tuberculin Purified Protein Derivative*
- Appendix XIV G. Test for Histamine
- Appendix XIV J. Blood and Related Products
- Appendix XIV K. Immunological Products
- Appendix XVI B. Microbiological Examination of Non-sterile Products
- SC IV G. 5. Examples

- Anthrax Vaccine, Living*
- Aujeszky's Disease Vaccine, Inactivated*
- Aujeszky's Disease Vaccine, Living*
- Canine Parvovirus Vaccine, Inactivated*
- Clostridium Chauvoei Vaccine *
- Clostridium Tetani Vaccines*
- Equine Influenza Vaccine, Inactivated*
- Feline Infectious Enteritis Vaccine, Inactivated*
- Bovine Leptospirosis Vaccine (Inactivated)*
- Porcine Actinobacillosis Vaccine, Inactivated*
- Porcine Enzootic Pneumonia Vaccine (Inactivated)*
- Porcine E. Coli Vaccine, Inactivated*
- Porcine Parvovirus Vaccine, Inactivated*
- Porcine Progressive Atrophic Rhinitis Vaccine, Inactivated*
- Swine Erysipelas Vaccine, Inactivated*
- Swine-Fever Vaccine (Live, Prepared in Cell Cultures), Classical*
- Swine Influenza Vaccine, Inactivated*
- Avian Tuberculin Purified Protein Derivative*
- Bovine Tuberculin Purified Protein Derivative*
-

GREY LISTS (MASBOOH): ANIMALS, HUMAN, INSECTS, OTHERS..1

- Search: animal, British and European articles only
- *European
- †Internationally harmonised
- Part II
- Substances for Pharmaceutical Use*
- Allergen Products*
- Aluminium Stearate*
- Botulinum Toxin Type A for Injection*
- Botulinum Toxin Type B for Injection*
- Bovine Serum*
- Cetostearyl Alcohol*
- Cetyl Alcohol*
- Chondroitin Sulfate Sodium*
- Chorionic Gonadotrophin*
- Diethylene Glycol Palmitostearate*
- Erythropoietin Concentrated Solution*
- Ethylene Glycol Monopalmitostearate*
- Products of Fermentation*
- Glycerol Distearate*
- Glycerol Mono-oleate*
- Glycerol Monostearate 40-55*
- Heparin Calcium*
- Heparin Sodium*
- Substances for Pharmaceutical Use*
- Macrogol Oleate*
- Magnesium Stearate*
- Menotrophin
- Oleic Acid*
- Oleyl Alcohol*
- Palmitic Acid*
- Propylene Glycol Monopalmitostearate*
- Products of Recombinant DNA Technology*
- Sorbitan Oleate*
- Sorbitan Sesquioleate*
- Sorbitan Trioleate*
- Products with Risk of Transmitting Agents of Animal Spongiform Encephalopathies*
- Squalane*
- Stearic Acid*
- Stearyl Alcohol*
- Urofollitropin*
- Vitamin A*
- PARENTERAL PREPARATIONS*
- TOPICAL SEMI-SOLID PREPARATIONS*
- Unlicensed Medicines
- Chorionic Gonadotrophin Injection
- Erythropoietin Injection
- Injectable Insulin Preparations*
- Herbal Drugs*
- EXTRACTS*
- Homoeopathic Preparations*
- Herbal Drugs for Homoeopathic Preparations*
- Methods of Preparation of Homoeopathic Stocks and Potentisation*

GREY LISTS (MASBOOH): ANIMALS, HUMAN, INSECTS, OTHERS..2

- Mother Tinctures for Homoeopathic Preparations*
- Monoclonal Antibodies for Human Use*
- Immunosera*
- Anti-T Lymphocyte Immunoglobulin for Human Use, Animal*
- Diphtheria Antitoxin*
- Tetanus Antitoxin*
- VACCINES*
- Anthrax Vaccine for Human Use (Adsorbed, Prepared from Culture Filtrates)*
- Bacillus Calmette-Guérin Vaccine*
- BCG for Immunotherapy*
- Adsorbed Diphtheria Vaccine*
- Diphtheria Vaccine (Adsorbed, Reduced Antigen Content)*
- Adsorbed Diphtheria and Tetanus Vaccine*
- Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content)*
- Diphtheria, Tetanus and Hepatitis B (rDNA) Vaccine (Adsorbed)*
- Diphtheria, Tetanus and Pertussis (Whole Cell) Vaccine (Adsorbed)*
- Adsorbed Diphtheria, Tetanus and Pertussis (Acellular Component) Vaccine*
- Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Haemophilus Type b Conjugate Vaccine*
- Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Hepatitis B (rDNA) Vaccine*
- Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine*
- Diphtheria, Tetanus and Poliomyelitis (Inactivated) Vaccine (Adsorbed, Reduced Antigen(s) Content)*
- Diphtheria, Tetanus, Pertussis (Acellular, Component) and Poliomyelitis (Inactivated) Vaccine (Adsorbed, Reduced Antigen(s) Content)*
- Diphtheria, Tetanus, Pertussis (Acellular, Component), Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine (Adsorbed)*
- Diphtheria, Tetanus, Pertussis (Acellular, Component), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine (Adsorbed)*
- Diphtheria, Tetanus, Pertussis (Whole Cell), Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine (Adsorbed)*
- Diphtheria, Tetanus, Pertussis (Whole Cell) and Poliomyelitis (Inactivated) Vaccine (Adsorbed)*
- Haemophilus Type b Conjugate Vaccine*
- Inactivated Hepatitis A Vaccine*
- Hepatitis A Vaccine (Inactivated, Virosome)*
- Hepatitis B Vaccine (rDNA)*
- Influenza Vaccine (Whole Virion, Inactivated, Prepared in Cell Cultures)*
- Influenza Vaccine (Surface Antigen, Inactivated, Prepared in Cell Cultures)*
- Measles Vaccine, Live*
- Mumps Vaccine, Live*
- Pertussis Vaccine (Whole Cell, Adsorbed)*
- Adsorbed Pertussis Vaccine (Acellular Component)*
- Adsorbed Pertussis Vaccine (Acellular, Co-purified)*
- Inactivated Poliomyelitis Vaccine*
- Poliomyelitis Vaccine, Live (Oral)*
- Rabies Vaccine*
- Rotavirus Vaccine (Live, Oral)*
- Rubella Vaccine, Live*
- Shingles (Herpes Zoster) Vaccine (Live)*
- Smallpox Vaccine (Live)*
- Adsorbed Tetanus Vaccine*
- Varicella Vaccine (Live)*
- Yellow Fever Vaccine, Live*
- Old Tuberculin*
- Tuberculin Purified Protein Derivative*
- Radiopharmaceutical Preparations*
- Technetium (<superscript>99m</superscript>Tc) Albumin Injection*
- Technetium (<superscript>99m</superscript>Tc) Colloidal Sulfur Injection*

GREY LISTS (MASBOOH): ANIMALS, HUMAN, INSECTS, OTHERS..3

- Technetium (<superscript>99m</superscript>Tc) Colloidal Tin Injection*
- Sterile Catgut*
- Sterile Non-absorbable Sutures*
- Contents of the Appendices
- European Pharmacopoeia Equivalent Texts
- Plasma Substrate R1
- Thromboplastin
- Appendix XI D. Foreign Matter
- Appendix XIV D. Test for Pyrogens
- Appendix XIV E. Test for Abnormal Toxicity
- Appendix XIV F. Test for Depressor Substances
- Appendix XIV K. Immunological Products
- Appendix XV A. Terminology used in Monographs on Biological Products
- Appendix XV F. Neurovirulence
- Appendix XV J. Cell Substrates for the Production of Vaccines for Human Use
- Appendix XVI B. Microbiological Examination of Non-sterile Products
- Appendix XVIII Methods of Sterilisation
- Appendix XXII A. Viral Safety
- Appendix XXII B. Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents Via Human and Veterinary Medicinal Products
- SC I A. Control of Impurities
- SC IV C. Certification Scheme
- SC IV D. Residual Solvents
- SC IV G. 3. Assays depending upon quantitative responses
- SC IV J. Control of Impurities in Substances for Pharmaceutical Use
- SC IV N. Gene Transfer Medicinal Products for Human Use
- SC IV N. RECOMBINANT VECTORS
- SC IV N. ADENOVIRUS VECTORS FOR HUMAN USE
- SC IV N. POXVIRUS VECTORS FOR HUMAN USE
- SC IV N. RETROVIRIDAE-DERIVED VECTORS FOR HUMAN USE
- SC IV N. ADENO-ASSOCIATED-VIRUS VECTORS FOR HUMAN USE
- SC V Unlicensed Medicines
- SC VII Traditional Herbal Medicines
- Preface
- Introduction
- Part II
- Substances for Pharmaceutical Use*
- Serum Gonadotrophin*
- Veterinary Liquid Preparations for Cutaneous Application*
- Liquid Preparations for Cutaneous Application of the British Pharmacopoeia (Veterinary)
- INTRAMAMMARY INFUSIONS*
- PARENTERAL PREPARATIONS*
- PREMIXES*
- VETERINARY IMMUNOSERA*
- Clostridium Tetani Antitoxin*
- Veterinary Vaccines*
- Anthrax Vaccine, Living*
- Aujeszky's Disease Vaccine, Inactivated*
- Bovine Viral Diarrhoea Vaccine (Inactivated)*
- Calf Coronavirus Diarrhoea Vaccine (Inactivated)*
- Calf Rotavirus Diarrhoea Vaccine (Inactivated)*
- Clostridium Botulinum Vaccine*
- Clostridium Chauvoei Vaccine *
- Clostridium Novyi Type B Vaccine*

GREY LISTS (MASBOOH): ANIMALS, HUMAN, INSECTS, OTHERS..4

- Clostridium Perfringens Vaccines*
- Clostridium Septicum Vaccine *
- Clostridium Tetani Vaccines*
- Contagious Pustular Dermatitis Vaccine, Living
- Equine Herpesvirus Vaccine, Inactivated*
- Feline Chlamydiosis Vaccine (Inactivated)*
- Foot and Mouth Disease (Ruminants) Vaccine*
- Infectious Chicken Anaemia Vaccine (Live)*
- Bovine Leptospirosis Vaccine (Inactivated)*
- Canine Leptospirosis Vaccine (Inactivated)*
- Louping-ill Vaccine
- Lungworm (Dictyocaulus Viviparus) Oral Vaccine, Living
- Mannheimia Vaccine (Inactivated) for Cattle*
- Mycoplasma Gallisepticum Vaccine (Inactivated)*
- Ovine Enzootic Abortion Vaccine, Inactivated
- Porcine Actinobacillosis Vaccine, Inactivated*
- Porcine Enzootic Pneumonia Vaccine (Inactivated)*
- Porcine E. Coli Vaccine, Inactivated*
- Porcine Progressive Atrophic Rhinitis Vaccine, Inactivated*
- Rabies Vaccine for Foxes, Living*
- Rabies Veterinary Vaccine, Inactivated*
- Rabbit Haemorrhagic Disease Vaccine (Inactivated)*
- Ruminant E. Coli Vaccine, Inactivated*
- Salmonella Enteritidis Vaccine (Inactivated) for Chickens*
- Salmonella Typhimurium Vaccine (Inactivated) for Chickens*
- Avian Tuberculin Purified Protein Derivative*
- Bovine Tuberculin Purified Protein Derivative*
- Sterile Non-absorbable Strands in Distributor*
- Contents
- European Pharmacopoeia Equivalent Texts
- Appendix XV A (Vet). Terminology used in Monographs on Biological Products
- Appendix XV J (Vet) 1. Cell Cultures for the Production of Veterinary Vaccines
- Appendix XV J (Vet) 2. Substances of Animal Origin for the Production of Immunological Veterinary Medicinal Products
- Appendix XV K (Vet) 1. Evaluation of Safety of Veterinary Vaccines and Immunosera
- Appendix XV K (Vet) 2. Evaluation of Efficacy of Veterinary Vaccines and Immunosera
- Appendix XV K (Vet) 3. Evaluation of Safety of each Batch of Veterinary Vaccines and Immunosera
-

SEMISYNTHETIC, MICROBES, RECOMBINANT DNA..1

- Search: synthetic, British and European articles only
-
- *European
- †Internationally harmonised
-
- Substances for Pharmaceutical Use*
- Adrenaline / Epinephrine*
- Synthetic Air*
- Aluminium Sodium Silicate*
- Amikacin*
- Amikacin Sulfate*
- Amoxicillin Sodium*
- Amoxicillin Trihydrate*
- Ampicillin*
- Ampicillin Sodium*
- Ampicillin Trihydrate*
- Azithromycin*
- Bacampicillin Hydrochloride*
- Buserelin*
- Calcitonin (Salmon)*
- Cefaclor*
- Cefadroxil Monohydrate*
- Cefalexin Monohydrate*
- Cefalotin Sodium*
- Cefamandole Nafate*
- Cefapirin Sodium*
- Cefazolin Sodium*
- Cefepime Hydrochloride Monohydrate*
- Cefixime*
- Cefoperazone Sodium*
- Cefotaxime Sodium*
- Cefoxitin Sodium*
- Cefpodoxime Proxetil*
- Cefprozil Monohydrate*
- Cefradine*
- Ceftazidime Pentahydrate*
- Ceftazidime Pentahydrate with Sodium Carbonate for Injection*
- Ceftriaxone Sodium*
- Cefuroxime Axetil*
- Cefuroxime Sodium*
- Chloramphenicol Palmitate*
- Chloramphenicol Sodium Succinate*
- Clarithromycin*
- Clindamycin Hydrochloride*
- Clindamycin Phosphate*
- Cloxacillin Sodium*
- Colistimethate Sodium*
- Desmopressin*
- Dicloxacillin Sodium*
- Dirithromycin*
- Doxycycline Hyclate*
- Doxycycline Monohydrate*
- Erythromycin Estolate*
- Erythromycin Ethyl Succinate*

GREEN LISTS: SYNTHETIC, PLANTS, SEMISYNTHETIC, MICROBES, RECOMBINANT DNA..2

- Felypressin*
- Flucloxacillin Magnesium Octahydrate*
- Flucloxacillin Sodium*
- Galantamine Hydrobromide*
- Goserelin*
- Imipenem*
- Ivermectin*
- Substances for Pharmaceutical Use*
- Josamycin Propionate*
- Leuprorelin*
- Lymecycline*
- Meropenem Trihydrate*
- Minocycline Hydrochloride Dihydrate*
- Netilmicin Sulfate*
- Oxacillin Sodium Monohydrate*
- Oxytocin*
- Oxytocin Concentrated Solution*
- Paclitaxel*
- Piperacillin*
- Piperacillin Sodium*
- Pivampicillin*
- Pivmecillinam Hydrochloride*
- Poloxamers*
- Protirelin*
- Synthetic Retinol Concentrate (Oily Form)*
- Synthetic Retinol Concentrate (Powder Form)*
- Synthetic Retinol Concentrate, Solubilisate/Emulsion*
- Rifabutin*
- Rifaximin*
- Roxithromycin*
- Somatostatin*
- Sulbactam Sodium*
- Sultamicillin*
- Sultamicillin Tosilate Dihydrate*
- Tetracosactide*
- Ticarcillin Sodium*
- Vegetable Fatty Oils*
- Vitamin A*
- Wool Fat*
- MEDICATED CHEWING GUMS*
- OROMUCOSAL PREPARATIONS*
- TOPICAL SEMI-SOLID PREPARATIONS*
- TABLETS*
- Ifosfamide Injection
- Homoeopathic Preparations*
- VACCINES*
- Poliomyelitis Vaccine, Live (Oral)*
- Typhoid Polysaccharide Vaccine*
- Typhoid (Strain Ty 21a) Vaccine, Live (Oral)*
- Old Tuberculin*
- Tuberculin Purified Protein Derivative*
- Fluorodopa (<superscript>18</superscript>F) Injection*
- L-Methionine ([<superscript>11</superscript>C]Methyl) Injection*
- SUTURES*

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Recombinant DNA

Search: Recombinant DNA, British and European articles only

*European

†Internationally harmonised

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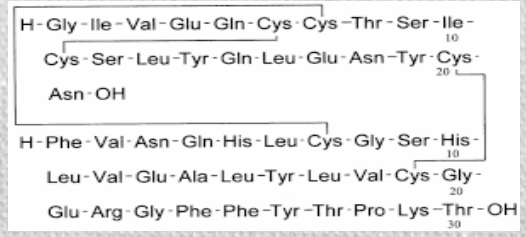
Human insulin

$C_{257}H_{383}N_{65}O_{77}S_6$ 5808 *11061-68-0*



Action and use

Hormone; treatment of diabetes mellitus.

Preparations

Insulin Preparations

Ph Eur

DEFINITION

Human insulin is a 2-chain peptide having the structure of the antidiabetic hormone produced by the human pancreas.

Content

95.0 per cent to 105.0 per cent of human insulin $C_{257}H_{383}N_{65}O_{77}S_6$ plus A21 desamido human insulin (dried substance).

By convention, for the purpose of labelling insulin preparations, 0.0347 mg of human insulin is equivalent to 1 IU of insulin.

Human insulin is produced either by enzymatic modification and suitable purification of insulin obtained from the pancreas of the pig or by a method based on recombinant DNA (rDNA) technology.

Where applicable, the animals from which human insulin is derived must fulfill the requirements for the health of animals suitable for human consumption.

Human insulin is produced under conditions designed to minimise the degree of microbial contamination.

For human insulin produced by enzymatic modification of insulin obtained from the pancreas of the pig, the manufacturing process is validated to demonstrate removal of any residual proteolytic activity. The competent authority may require additional tests.

For human insulin produced by a method based on rDNA technology, prior to release the following tests are carried out on each batch of the final bulk product, unless exemption has been granted by the competent authority.

Calcitonin (Salmon)

General Notices

(Ph Eur monograph 0471)

C145H240N44O48S2 ıı3432ıı *47931-85-1*

Action and use

Hormone.

Preparation

Calcitonin (Salmon) Injection

Ph Eur

DEFINITION

Polypeptide having the structure determined for salmon calcitonin I. It lowers the calcium concentration in plasma of mammals by diminishing the rate of bone resorption. It is obtained by chemical synthesis or by a method based on recombinant DNA (rDNA) technology. It is available as an acetate.

Content

90.0 per cent to 105.0 per cent of the peptide C145H240N44O48S2 (anhydrous and acetic acidfree

substance).

By convention, for the purpose of labelling calcitonin (salmon) preparations, 1 mg of calcitonin (salmon) (C145H240N44O48S2) is equivalent to 6000 IU of biological activity.

PRODUCTION

The following requirements apply only to calcitonin (salmon) produced by a method based on rDNA technology.

Heparin Calcium

General Notices

(Ph Eur monograph 0332)

Action and use

Anticoagulant.

Preparation

Heparin Injection

Ph Eur

DEFINITION

Heparin calcium is a preparation containing the calcium salt of a sulphated glucosaminoglycan present in mammalian tissues. On complete hydrolysis, it liberates Dglucosamine, D-glucuronic acid, L-iduronic acid, acetic acid and sulphuric acid. It has the characteristic property of delaying the clotting of freshly shed blood. The potency of heparin calcium intended for parenteral administration is not less than 150 IU/mg, calculated with reference to the dried substance. The potency of heparin calcium not intended for parenteral administration is not less than 120 IU/mg, calculated with reference to the dried substance.

PRODUCTION

It is prepared from the lungs of oxen or from the intestinal mucosae of oxen, pigs or sheep. It is produced by methods of manufacturing designed to minimise or eliminate substances lowering blood pressure.

CHARACTERS

A white or almost white powder, hygroscopic, freely soluble in water.

IDENTIFICATION

ıA. It delays the clotting of recalcified citrated sheep plasma (see Assay).

ıB. Dissolve 0.40 g in *water R and dilute to 10.0 ml with the same solvent. The specific* optical rotation *(2.2.7) is not less than + 35.*

ıC. Examine by zone electrophoresis *(2.2.31) using agarose for electrophoresis R as the* supporting medium. To equilibrate the agarose and as electrolyte solution use a mixture of 50 ml of *glacial acetic acid R and 800 ml of water R adjusted to pH 3 by addition of lithium hydroxide R and diluted to 1000.0 ml with water R.*

*Test solution*ı*Dissolve 25 mg of the substance to be examined in water R and dilute to 10 ml* with the same solvent.

Stearic Acid

General Notices

(Ph Eur monograph 1474)

Action and use

Excipient.

Ph Eur

DEFINITION

Mixture consisting mainly of stearic (octadecanoic) acid ($C_{18}H_{36}O_2$; *M r 284.5) and palmitic* (hexadecanoic) acid ($C_{16}H_{32}O_2$; *M r 256.4) obtained from fats or oils of vegetable or animal* origin.

Content

CHARACTERS

Appearance

White or almost white, waxy, flaky crystals, white or almost white hard masses or white or

yellowish-white powder.

Solubility

Practically insoluble in water, soluble in ethanol (96 per cent) and in light petroleum (50-70°C).

IDENTIFICATION

Capsules

General Notices

(Ph. Eur. monograph 0016)

Capsules comply with the requirements of the European Pharmacopoeia. These requirements are reproduced below.

Ph Eur

The requirements of this monograph do not necessarily apply to preparations that are presented as capsules intended for use other than by oral administration. Requirements for such preparations may be found, where appropriate, in other general monographs, for example Rectal preparations (1145) and Vaginal preparations (1164).

DEFINITION

Capsules are solid preparations with hard or soft shells of various shapes and capacities, usually containing a single dose of active substance(s). They are intended for oral administration.

The capsule shells are made of gelatin or other substances, the consistency of which may be adjusted by the addition of substances such as glycerol or sorbitol. Excipients such as surface-active agents, opaque fillers, antimicrobial preservatives, sweeteners, colouring matter authorised by the competent authority and flavouring substances may be added. The capsules may bear surface markings.

The contents of capsules may be solid, liquid or of a paste-like consistency. They consist of one or more active substances with or without excipients such as solvents, diluents, lubricants and disintegrating agents. The contents do not cause deterioration of the shell. The shell, however, is attacked by the digestive fluids and the contents are released.

Where applicable, containers for capsules comply with the requirements of *Materials used for the manufacture of containers* (*3.1* and subsections) and *Containers* (*3.2* and subsections).

Several categories of capsules may be distinguished:

— hard capsules;

— soft capsules;

— gastro-resistant capsules;

— modified-release capsules;

— cachets.

PRODUCTION

In the manufacture, packaging, storage and distribution of capsules, suitable measures are taken to ensure their microbial quality; recommendations on this aspect are provided in the text on *Microbiological quality of pharmaceutical preparations* (*5.1.4*).

TESTS

Uniformity of dosage units

Capsules comply with the test for uniformity of dosage units (*2.9.40*) or, where justified and authorised, with the tests for uniformity of content and/or uniformity of mass shown below. Herbal drugs and herbal drug preparations present in the dosage form are not subject to the provisions of this paragraph.

Uniformity of content (*2.9.6*)

Unless otherwise prescribed or justified and authorised, capsules with a content of active substance less than 2 mg or less than 2 per cent of the fill mass comply with test B for uniformity of content of single-dose preparations. If the preparation has more than one active substance, the requirement applies only to those ingredients which correspond to the above conditions.

Gelatin

(Ph. Eur. monograph 0330)

Action and use

Excipient.

Ph Eur

DEFINITION

Purified protein obtained either by partial acid hydrolysis (type A), partial alkaline hydrolysis (type B) or enzymatic hydrolysis of collagen from animals (including fish and poultry); it may also be a mixture of different types.

The hydrolysis leads to gelling or non-gelling product grades. Both product grades are covered by this monograph.

Gelatin described in this monograph is not suitable for parenteral administration or for other special purposes.

CHARACTERS

Appearance

Faintly yellow or light yellowish-brown, solid, usually occurring as translucent sheets, shreds, granules or powder.

Solubility

Practically insoluble in common organic solvents; gelling grades swell in cold water and give on heating a colloidal solution which on cooling forms a more or less firm gel.

The isoelectric point is a relevant quality parameter for use of gelatin in different applications: for type A gelatin it is typically between pH 6.0 and pH 9.5 and for type B gelatin is typically between pH 4.7 and pH 5.6. These ranges cover a variety of different gelatins and for specific applications a narrower tolerance is usually applied.

Different gelatins form aqueous solutions that vary in clarity and colour. For a particular application, a suitable specification for clarity and colour is usually applied.

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Different gelatins form aqueous solutions that vary in clarity and colour. For a particular application, a suitable specification for clarity and colour is usually applied.

IDENTIFICATION

A. To 2 mL of solution S (see Tests) add 0.05 mL of *copper sulfate solution R*. Mix and add 0.5 mL of *dilute sodium hydroxide solution R*. A violet colour is produced.

B. To 0.5 g in a test-tube add 10 mL of *water R*. Allow to stand for 10 min, heat at 60 °C for 15 min and keep the tube upright at 0 °C for 6 h. Invert the tube; the contents immediately flow out for non-gelling grades and do not flow out immediately for gelling grades.

TESTS

Solution S

Dissolve 1.00 g in *carbon dioxide-free water R* at about 55 °C, dilute to 100 mL with the same solvent and keep the solution at this temperature to carry out the tests.

pH (*2.2.3*)

3.8 to 7.6 for solution S.

Conductivity (*2.2.38*)

WHO Monographs: Pharmaceutical substances: Gelatina.

Faintly yellow to amber-coloured sheets, flakes, granules, or powder; practically odourless; in solution it has a slight, characteristic, bouillon-like odour.Solubility. Practically insoluble in most organic solvents. In cold water it swells and softens, absorbing 5-10 times its own mass of water. After swelling, soluble in hot water, in acetic acid (~300 g/l) TS, and in a hot mixture of glycerol R and water.Category. Encapsulating agent; tablet binder; coating agent; suspending agent; viscosity-increasing agent.Storage. Gelatin should be kept in a well-closed container.Additional information. These specifications do not necessarily apply to gelatin for parenteral use or other particular application. Attention should be paid to the microbiological quality since gelatin is of natural origin. Cool the test-tubes and allow them to stand at 4 °C for 24 hours; the type of gelatin is recognized by the resulting opalescence - a maximum opalescence appearing at pH 5.0 indicates gelatin type B, while a maximum opalescence between pH 7.0 and pH 9.0 indicates gelatin type A.

Requirements

Definition. Gelatin is a purified protein obtained either by the partial acid hydrolysis (type A) or by the partial alkali hydrolysis (type B) of animal collagen. It can exist as a mixture of both types.

Identity tests A. Dissolve 1 g in carbon-dioxide-free water R, heat to about 55 °C, and dilute to 100 ml with the same solvent. Keep the solution at this temperature throughout the following test (retain the solution for test C): to 2 ml add 0.05 ml of copper(II) sulfate (160 g/l) TS, mix, and add 0.5 ml of sodium hydroxide (~80 g/l) TS; a violet colour is produced.

B. Transfer 0.5 g to a test-tube, add 10 ml of water, and allow to stand for 10 minutes. Heat at 60 °C for 15 minutes and keep the tube in a vertical position at 0 °C for 6 hours. Invert the tube; the content does not immediately flow out.C. Acidify 2 ml of the solution prepared for test A and add 0.5 ml of potassium dichromate (100 g/l) TS; a yellow precipitate is formed.Heavy metals. Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals,

USP 32 Gelatin

» Gelatin is a product obtained by the partial hydrolysis of collagen derived from the skin, white connective tissue, and bones of animals.

Gelatin derived from an acid-treated precursor is known as Type A, and Gelatin derived from an alkali-treated precursor is known as Type B.

Gelatin, where being used in the manufacture of capsules, or for the coating of tablets, may be colored with a certified color, may contain not more than 0.15 percent of sulfur dioxide, and may contain a suitable concentration of sodium lauryl sulfate and suitable antimicrobial agents.

Packaging and storage— Preserve in well-closed containers in a dry place.

Identification— A: Dissolve 1 g of Gelatin in 100 mL of hot water. To this solution add about 20 mL of a mixture of 0.2 M potassium dichromate and 3 N hydrochloric acid (4:1): a yellow precipitate is formed.

B: To a hot solution (0.2 mg per mL) add tannic acid TS: turbidity is produced.

Microbial enumeration tests 61 and Tests for specified microorganisms 62— The total bacterial count does not exceed 1000 cfu per g, and the tests for Salmonella species and Escherichia coli are negative.

Arsenic, Method I 211— Pepsin solution— Dissolve 0.5 g of pepsin in 80 mL of 0.1 N hydrochloric acid, dilute with 0.1 N hydrochloric acid to 100 mL, and mix.

Standard preparation— Transfer 3.0 mL of Standard Arsenic Solution to an arsine generator flask, and dilute with Pepsin solution to 52 mL. Add 3 mL of hydrochloric acid and 4 mL of isopropyl alcohol, and mix.

Test preparation— Mix 3.75 g with 40 mL of Pepsin solution in an arsine generator flask. Heat cautiously to a temperature between 65 and 70, and, while maintaining this temperature for 30 minutes, sonicate the solution for 2 minutes at each 10-minute interval of heating time. Cool, wash down the sides of the generator with Pepsin solution, and dilute with Pepsin solution to 52 mL. Add 3 mL of hydrochloric acid and 4 mL of isopropyl alcohol, and mix.

Procedure— Proceed as directed for Procedure except omit the addition of 20 mL of 7 N sulfuric acid and 1 mL of isopropyl alcohol to the Standard preparation and to the Test preparation. The resulting solution obtained from the Test preparation meets the requirements of the test: the limit is 0.8 ppm.

Heavy metals 231— To the residue obtained in the test for Residue on ignition add 2 mL of hydrochloric acid and 0.5 mL of nitric acid, and evaporate on a steam bath to dryness. To the residue add 1 mL of 1 N hydrochloric acid and 15 mL of water, and warm for a few minutes. Filter, and wash with water to make the filtrate measure 100 mL. Dilute 8 mL of the solution with water to 25 mL: the limit is 0.005%.

Glycerol monostearate

General Notices

(Ph. Eur. monograph 0495)

31566-31-1

Action and use

Excipient.

Ph Eur

DEFINITION

Mixture of monoacylglycerols, mainly monostearoylglycerol, together with variable quantities of di- and triacylglycerols. It is obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of palmitic (hexadecanoic) or stearic (octadecanoic) acid or by esterification of glycerol with stearic acid. The fatty acids may be of vegetable or animal origin.

Content:

— *monoacylglycerols*: 40.0 per cent to 55.0 per cent;

— *diacylglycerols*: 30.0 per cent to 45.0 per cent;

— *triacylglycerols*: 5.0 per cent to 15.0 per cent.

CHARACTERS

Appearance

Hard, waxy mass or unctuous powder or flakes, white or almost white.

Solubility

Practically insoluble in water, soluble in ethanol (96 per cent) at 60 °C.

IDENTIFICATION

First identification *C, D*.

Second identification *A, B*.

A. Melting point (*2.2.15*): 54 °C to 66 °C.

Introduce the melted substance into the capillary tubes and allow to stand for 24 h in a well-closed container.

B. Thin-layer chromatography (*2.2.27*).

Test solution Dissolve 0.5 g of the substance to be examined in *methylene chloride R*, with gentle heating, and dilute to 10 mL with the same solvent.

Reference solution Dissolve 0.5 g of *glycerol monostearate 40-55 CRS* in *methylene chloride R*, with gentle heating, and dilute to 10 mL with the same solvent.

Plate *TLC silica gel plate R*.

Mobile phase *hexane R*, *ether R* (30:70 *V/V*).

Application 10 µL.

Development Over a path of 15 cm.

Detection Spray with a 0.1 g/L solution of *rhodamine B R* in *ethanol (96 per cent) R* and examine in ultraviolet light at 365 nm.

Glycerol monostearate

Suitability system Reference solution:

— the chromatogram shows 4 clearly separated spots.

Results The spots in the chromatogram obtained with the test solution are similar in position to those in the chromatogram obtained with the reference solution.

C. Composition of fatty acids (see Tests) according to the type stated on the label.

D. It complies with the limits of the assay (monoacylglycerol content).

Glycerol monostearate 40-55	Composition of fatty acids
Type I	*Stearic acid*: 40.0 per cent to 60.0 per cent
	Sum of the contents of palmitic and stearic acids: minimum 90.0 per cent
Type II	*Stearic acid*: 60.0 per cent to 80.0 per cent
	Sum of the contents of palmitic and stearic acids: minimum 90.0 per cent
Type III	*Stearic acid*: 80.0 per cent to 99.0 per cent
	Sum of the contents of palmitic and stearic acids: minimum 96.0 per cent

TESTS

Acid value (*2.5.1*)

Maximum 3.0, determined on 1.0 g.

Use a mixture of equal volumes of *ethanol (96 per cent) R* and *toluene R* as solvent and heat gently.

Iodine value (*2.5.4, Method A*)

Maximum 3.0.

Saponification value (*2.5.6*)

158 to 177, determined on 2.0 g. Carry out the titration with heating.

Free glycerol

Maximum 6.0 per cent, determined as described under Assay.

Composition of fatty acids (*2.4.22, Method C*)

Use the mixture of calibrating substances in Table 2.4.22.-1.

Composition of the fatty-acid fraction of the substance:

Nickel (*2.4.31*)

Maximum 1 ppm.

Water (*2.5.12*)

Maximum 1.0 per cent, determined on 1.00 g. Use *pyridine R* as the solvent and heat gently.

Total ash (*2.4.16*)

Maximum 0.1 per cent.

Glyceryl Monostearate

Self-emulsifying Monostearin; Self-emulsifying Mono-and Diglycerides of Food Fatty Acids

Action and use

Excipient.

DEFINITION

Self-emulsifying Glyceryl Monostearate is a mixture consisting principally of mono-, di- and triglycerides of stearic and palmitic acids and of minor proportions of glycerides of other fatty acids; it may also contain free glycerol, free fatty acids and soap. It contains not less than 30.0% of monoglycerides, calculated as $C_{21}H_{42}O_4$, not more than 7.0% of free glycerol, calculated as $C_3H_8O_3$, and not more than 6.0% of soap, calculated as sodium oleate, $C_{18}H_{33}NaO_2$, all calculated with reference to the anhydrous substance.

CHARACTERISTICS

A white to cream coloured, hard, waxy solid.

Dispersible in hot *water*; soluble in hot *absolute ethanol* , in hot *liquid paraffin* and, subject to turbidity at concentrations below 20%, in hot vegetable oils.

TESTS

Acid value

Not more than 6, Appendix X B.

Iodine value

Not more than 3 *(iodine monochloride method)*, Appendix X E.

Alkalinity

Shake 1 g with 20 mL of hot *carbon dioxide-free water* and allow to cool with continuous shaking. The pH of the aqueous layer is 8.0 to 10.0, Appendix V L.

Heavy metals

2.0 g complies with *limit test C for heavy metals*, Appendix VII. Use 2 mL of *lead standard solution (10 ppm Pb)* to prepare the standard (10 ppm).

Water

Not more than 2.0% w/w, Appendix IX C. Use 0.5 g and a mixture of 10 mL of *anhydrous methanol* and 10 mL of anhydrous *chloroform* as the solvent.

ASSAY

For free glycerol

Dissolve 0.4 g in 50 mL of *dichloromethane* in a ground-glass-stoppered separating funnel, cool if necessary, add 25 mL of *water* and shake vigorously for 1 minute; add 0.2 mL of *glacial acetic acid* , if necessary, to break the emulsion. Repeat the extraction a further three times using 25-, 20- and 20- mL quantities of *water* and reserve the dichloromethane solution for the Assay for monoglycerides. Filter the combined aqueous extracts through a filter paper moistened with *water*, wash the filter with two 5 mL quantities of *water* and dilute the combined filtrate and washings to 100 mL with *water*. To 50 mL of this solution add 25 mL of *periodic acetic acid solution*, shaking cautiously, allow to stand at 25° to 30° for 30 minutes and add 100 mL of *water* and 12 mL of *potassium iodide solution*. Titrate with 0.1M *sodium thiosulfate VS* using 1 mL of *starch solution* as indicator. Repeat the determination using 50 mL of *water* in place of the 50 mL of the solution being examined. The difference between the titrations represents

CONTENTS

Securing market position

- As the bar is raised because of increasing competition and globalization, local companies will have to produce high-quality drugs at lower prices to sustain growth.
- Membership of Malaysia's Pharmaceutical Inspection Cooperation Scheme (PICS) helps local firms increase revenues and maintain market position by increasing their exports to PICS and non-PICS members, as well as Islamic countries with halal-certified products and other potential markets, such as Cambodia and Vietnam.
- On example is USM Malaysian-based Finlay-Heber-Bioven Sdn Bhd, which has teamed up with the Centre for Genetic Engineering and Biotechnology in Cuba to develop a vaccine for meningococcal meningitis that will be marketed globally.
- Halagel (M) Sdn Bhd has also produced halal pharmaceutical products such as halal gelatin and halal empty hard gelatin capsules.
- Other potential markets include natural herbal products, which is projected to reach US$2.5 billion by 2010, and the vitamin and dietary supplements market, which is the largest contributor to

CHALLENGES: MAPPING THE DRIVERS

- RESOURCE –halal certified raw materials
- TECHNOLOGY-”omics” platform technologies
- PRODUCT- formulation of halal branding/classification, processing and testing

Suppliers of Halal Pharmaceuticals

- **CCM Malaysia**
- **Novartis , Finlay/USM, – halal vaccines**
- **Noor Pharmaceuticals**
- **S.I.A Pharma LLC – vitamins & nutraceuticals**
- **Merck -Ph Eur - Pharmacopoeial Material**
- **Fortitech Europe**
- **Mallinckrodt**
- **Amin-Bio China**

NoorVitamins™, a division of Noor Pharmaceuticals

- specializes in developing high quality Halal vitamins and dietary supplements for the health-conscious Muslim consumer. Noor Pharmaceuticals was founded by Muslim physicians and pharmacists, who experienced first-hand the need for Halal vitamins and nutritional supplements.

Our mission is to provide the Muslim community with the highest quality Halal vitamins and supplements in order to promote a healthy and Halal lifestyle. We are committed to ensuring that our products meet the highest possible scientific and Halal standards and that our business practices fulfill the highest Islamic principles.

At NoorVitamins™ we certify more than just our vitamins; our US-based manufacturing facilities are both Halal certified and FDA GMP (Good Manufacturing Practices) certified. In addition, we observe Halal business practices, including but not limited to zakat, contracting and financing.

We balance science and Islam in order to provide our consumers Halal vitamins and nutritional supplements of unsurpassed quality and value. Our strong commitment to the Muslim community drives us to continue to work on developing new products and to build partnerships with community pharmacies so that more Muslims have access to Halal NoorVitamins™

S.I.A Pharma LLC

- S.I.A Pharma LLC is dedicated to developing HALAL Dietary supplement products. The people behind the company have extensive experience in the field of Pharmaceutical Research & Development both in the Pharmaceutical industry and the Dietary Supplement industry.
- HalViT™ Adult Multivitamin, is a Complete (from Vitamin A to Zinc) Multivitamin Multimineral Brand with LUTEIN & LYCOPENE, in the retail market, CERTIFIED HALAL by IFANCA (Islamic Food & Nutrition Council of America, http://www.ifanca.org) and carries their Halal certification symbol, Crescent M.
- HalViT™ brand was launched with an Adult Multivitamin Multimineral Dietary Supplement product, which is comparable in nutritional value to any leading multivitamin brand.
- In the second phase, a tasty Children's Chewable Multivitamin Multimineral product HalViT™ Jr, was launched.
- SIA Pharma has several dietary supplement products in its Research & Development (R&D) pipeline and will be launching those in the next several phases. Focus primarily will be on products 'For Men' and 'For Women' tailored for performance and special dietary and physiological needs for *Him & Her.*

Merck Ph Europe – Pharmacopoeia Materials

- Material “Ph Eur” intended for **pharmaceutical production**
- Analytical part with Merck´s high level QC
- **Production** according to **cGMP** status
- **Documentation** according to **current guidelines**
  - Allowing cGMP/customer audits
  - Providing certificates
    - **Allergenes, Aflatoxins, BSE/TSE, GMO, Residual Solvents**
    - **Kosher, Halal, manufacturing procedures**
    - **Validation of process parameters**
    - **control of raw materials used in the production**
    - **control of facilities and equipment**

Fortitech sets sights on Halal market

By Jess Halliday

24/04/2006 - **Fortitech Europe is looking to increase customers and confidence in its nutrient premixes by having its Danish manufacturing and testing facility certified Halal-compliant.**

The worldwide Muslim population tops 1.5 billion, and Fortitech Europe's move is partly an effort to deliver food, beverage and pharmaceutical products that tap into this market.

- But managing director Peter Sørensen said: *"Meeting the rigorous Halal requirements is an excellent move for Fortitech's growing business initiatives in our market."*
- He drew attention to the quality and safety assurance that a Halal guarantee provides, which may increase confidence in products for a diverse group of consumers, not just Muslims.

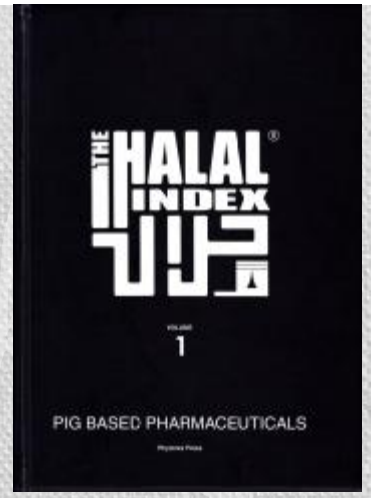
Mallinckrodt

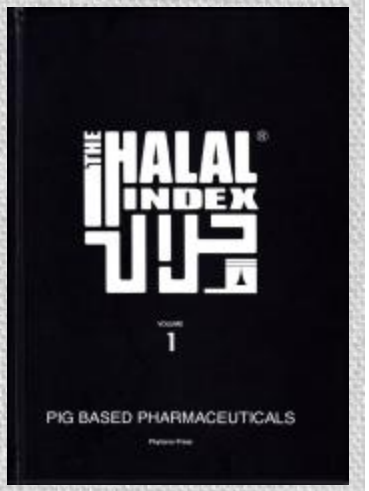
- **Stearates**
- Over 20 billion OTC and prescription tablets are manufactured using Mallinckrodt stearates annually. Mallinckrodt stearates are sold throughout the world including North America, Asia, Europe, Latin America, and the Middle East. In addition to pharmaceutical applications, our stearates are critical ingredients in food, plastic processing, and specialized industrial coatings.
- We offer a wide variety of stearates from three families: magnesium, calcium, and aluminum. We offer Kosher and Halal certified products and a variety of package sizes including bags, drums, cases, or supersacks. Our stearates meet the worldwide compendia of NF, EP, BP, and JP, plus we report results on critical physical parameters including sieve, particle diameter, surface area, and density.

Securing market position

- China’s intention to be Global leader in halal pharmaceuticals
- Shanghai Al-Amin Biotech Co. Ltd
- Halal raw materials (gelatine, collagen, chondroitin Sulfate, glocosamine)
- Halal enzyme (rennin)
- Halal Biopharmaceuticals (heparin, chymotrypsin, hyaluronidase, trypsin, pancreatin)

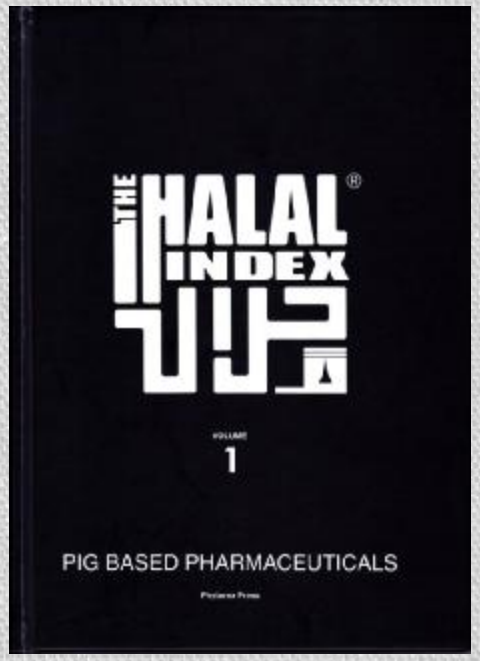
CONTENTS





Pharmaceuticals from pig source

- **Adrenal Glands**
  - Corticosteroids
  - Cortisone
  - Epinephrine
  - Norepinephrine
- **Blood**
  - Blood Albumens
  - Blood Fibrin
  - Fetal Pig Plasma
  - Plasmin
- **Brain**
  - Cholesterol
  - Hypothalamus
- **Gall Bladder**
  - Chenodeoxycholic Acid
- **Heart**
  - Heart Valves
  - Intestines
  - Enterogastrone
  - Heparin
  - Secretin
- **Liver**
  - Cholic Acid Catalase
  - Desiccated Liver
- **Ovaries**
  - Estrogen
  - Progesterone
  - Relaxin



- **Pancreas Gland**
  - Insulin
  - Kallikrein
  - Glucagon
  - Lipase
  - Pancreatin
  - Trypsin
  - Chymotrypsin
- **Pineal Gland**
  - Melatonin
- **Pituitary Gland**
  - ACTH – Adrenocorticotropic Hormone
  - ADH – Antidiuretic Hormone
  - Oxytocin
  - Prolactin
  - TSH – Thyroid Stimulating Hormone
- **Skin**
  - Porcine Burn Dressing
  - Gelatin
  - Spleen
  - Splenic Fluid
  - Stomach
  - Pepsin
  - Mucin
  - Intrinsic Factor
  - Thyroid Gland
  - Thyroxin
  - Calcitonin
  - Thyrogloblin

Pihak Berkuasa Kawalan Dadah
Drug Control Authority
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (95) dlm. BPFK/PPP/0103 Jld 2
Tarikh : 26 DEC 2012

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Y. Bhg. Dato'/ Datin/Tuan/ Puan,

PENGGUNAAN LOGO HALAL BAGI PRODUK FARMASEUTIKAL BERDAFTAR KATEGORI PRODUK BUKAN RACUN (OVER-THE-COUNTER, OTC)

Adalah saya merujuk kepada perkara di atas.

2. Pihak Berkuasa Kawalan Dadah dalam mesyuaratnya yang ke 258 pada 29 November 2012 telah bersetuju dengan penggunaan logo halal bagi produk farmaseutikal berdaftar kategori produk bukan racun (Over-The-Counter, OTC), tetapi tidak termasuk bentuk dos parenteral dan produk veterinar bagi pasaran tempatan dan eksport, **berkuatkuasa mulai 1 Januari 2013.**

3. Sila ambil maklum bahawa hanya logo halal yang diperakui dan dikeluarkan oleh Jabatan Kemajuan Islam Malaysia (JAKIM) atau dari Badan Islam yang diiktiraf oleh pihak JAKIM yang boleh diterima pakai.

4. Untuk makluman semua, penggunaan logo halal ini adalah **secara voluntari** di mana pertimbangan penggunaan logo halal tersebut adalah berdasarkan permohonan dan bukan sebagai keperluan mandatori.

5. Pemegang pendaftaran perlu mengemukakan permohonan variasi jenis II kepada Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) bagi mengemaskini maklumat logo halal pada label produk berdaftar setelah pensijilan halal diperolehi. Sijil halal yang sah perlu dikemukakan semasa permohonan variasi.

Jalan Universiti, P.O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia
Tel.: +603 7883 5400 Fax: +603 7956 2924/7955 1312
http://www.bpfk.gov.my

THE MALAY MAIL JANUARY 13, 1989

THE PAPER THAT CARES

FRIDAY / JANUARY 13 1989

ALCOHOL IN CURES

USM study finds booze in traditional medicines

By PADMAJA PADMAN

ALCOHOL has been detected in several traditional medicines, cosmetics and 'energy' foods in a research by the School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM).

However, producers of traditional preparations and cosmetics are not required by law to disclose the contents of their products.

Controls over health tonics can only be applied if these are scheduled pharmaceuticals or classified under the Food Act.

A USM lecturer, who declined to be identified, said proposals were submitted to the Health Ministry

traditional medicines.

The proposals, submitted to the National Pharmaceutical Control Laboratory, were based on the experience of countries like Japan and Indonesia where traditional medicine is widely used.

These also cover identification and listing of traditional products in the country, whether they are imported or locally made, and the raw materials that go into them, he told *The Malay Mail*.

It is understood that one proposal is for integration of traditional medicines into the modern health-care system, as is being practised in Japan.

"About 200 traditional medicines, all prepared under modern condi-

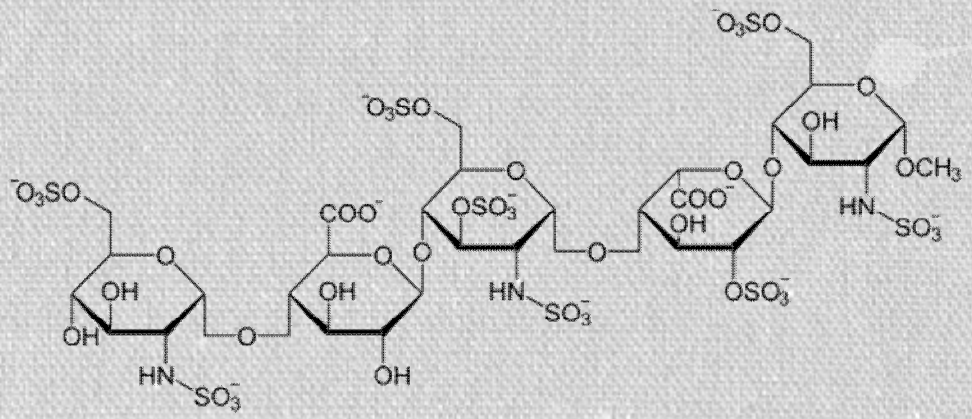
SEE PAGE 2

Anticoagulant Agents

Vitamin K antagonists (inhibit II, VII, IX, X)	*coumarins*: Acenocoumarol · Coumatetralyl · Dicoumarol · Ethyl biscoumacetate · Phenprocoumon · Warfarin#	*1,3-Indandiones*: Clorindione · Diphenadione · Phenindione · *other:* Tioclomarol
Factor Xa inhibitors (with some II inhibition)	**Heparin group/ glycosaminoglycans/ (bind antithrombin)**	***ØLow molecular weight heparin*** ; Bemiparin · Certoparin · Dalteparin · Enoxaparin · Nadroparin · Parnaparin · Reviparin · Tinzaparin ***ØOligosaccharides*** Fondaparinux · Idraparinux ***ØHeparinoid*** Danaparoid · Dermatan sulfate · Sulodexide
	Direct Xa inhibitors	***xabans*** Apixaban · Betrixaban · Edoxaban ·Otamixaban · Rivaroxaban
Direct thrombin (II) inhibitors	*bivalent*: Hirudin .Bivalirudin · Desirudin · Lepirudin	*univalent*: Argatroban · Dabigatran · Melagatran‡ · Ximelagatran‡
Other	Antithrombin III · Defibrotide · Protein C Drotrecogin alfa. Ramatroban · REG1	

Fondaparinux (Arixtra®)

- Synthetic Pentasaccharide



Fondaparinux (Arixtra®)

- is an anticoagulant medication chemically related to low molecular weight heparins. It is marketed by GlaxoSmithKline. A generic version developed by Alchemia is marketed within the US by Dr. Reddy's Laboratories
- Fondaparinux is a synthetic pentasaccharide Factor Xa inhibitor. Apart from the O-methyl group at the reducing end of the molecule, the identity and sequence of the five monomeric sugar units contained in fondaparinux is identical to a sequence of five monomeric sugar units that can be isolated after either chemical or enzymatic cleavage of the polymeric glycosaminoglycans heparin and heparan sulfate (HS). Within heparin and heparan sulfate this monomeric sequence is thought to form the high affinity binding site for the anti-coagulant factor antithrombin III (ATIII). Binding of heparin/HS to ATIII has been shown to increase the anti-coagulant activity of antithrombin III 1000 fold. In contrast to heparin, fondaparinux does not inhibit thrombin.

CAPSUGEL®

- **Products Standards**
- Only pharmaceutical-grade gelatin is utilized in Capsugel brand capsules, enabling our capsules to meet all worldwide Pharmacopoeia standards
- Capsugel provides confidential detailed information about facilities, processes, articles used in manufacturing, processing, packaging, and storing of empty capsules through Type IV (Excipient) Drug Master Files submitted to the Food and Drug Administration in the U.S., and equivalent regulatory agencies worldwide
- Capsugel manufactures gelatin capsules from gelatin that complies with bovine spongiform encephalopathy (BSE) requirements
- Capsugel Vcaps®, Vcaps® Plus and NPcaps® capsules are made of plant origin, are Kosher certified, approved by the Vegetarian Society, and upon request, are Halal certified

Magnesium Stearate NF Kosher Passover HyQual™

ITEM CODE 5712

APPEARANCE

Fine, white powder

IDENTIFICATION

(A) Magnesium: Meets requirements (NF/EP/BP/JP)

(B) Major Peak: Peak retentions match (NF/EP/BP/JP)

Features

Magnesium Stearate NF Kosher Passover HyQual is a fine-particle, precipitated product manufactured with superb control over particle physical attributes, making it the preferred tableting excipient (mold release agent) for most drug applications. This product also imparts improved flow properties when blended with certain ingredients that are also used in pharmaceutical products. This product was developed as the first generation vegetable-derived replacement for animal derived-products. Code 5712 is produced from a high-quality, edible vegetable-derived fatty acid. It meets the requirements of the National Formulary (NF), European Pharmacopoeia (EP), British Pharmacopoeia (BP), and Japanese Pharmacopoeia (JP).

This product is covered by Drug Master File (DMF) #20585.

Quality

Certified to meet NF/EP/BP/JP.

Applications

Acts as an effective lubricant and mold release agent for manufacture of solid dosage drugs and vitamins.

Packaging

75 lb. LVP drum

40 kg. drum

Magnesium Stearate NF Kosher Passover HyQual™

ITEM CODE 5712

APPEARANCE

Fine, white powder

IDENTIFICATION

(A) Magnesium: Meets requirements (NF/EP/BP/JP)

(B) Major Peak: Peak retentions match (NF/EP/BP/JP)

MICROBIAL LIMITS (NF/EP/BP/JP)

1000 CFU/g Max: Total aerobic count

100 CFU/g Max: Total mold and yeast

SALMONELLA

Negative

E. COLI

Negative

ACIDITY OR ALKALINITY (NF/EP/BP/JP)

Meets requirements

LOSS ON DRYING (NF/EP/BP/JP)

4.0% Max

SPECIFIC SURFACE AREA

6.0 – 12.0 m2/g

LIMIT OF CHLORIDE (NF/EP/BP/JP)

0.025% Max

LIMIT OF SULFATE (NF/EP/BP/JP)

0.5% Max

LEAD (NF/EP/BP)

10.0 ppm Max

CADMIUM (EP/BP)

3.0 ppm Max

NICKEL (EP/BP)

5.0 ppm Max

FATTY ACID COMPOSITION

Stearic Acid: 40% Min

Stearic Acid and Palmitic Acid: 90% Min

ASSAY (Mg) (DRIED BASIS)

4.0 – 5.0%

HEAVY METALS (JP)

20 ppm Max

SIEVE TEST US STANDARD NO. 325

99.5% Min through

APPARENT DENSITY

0.07 – 0.17 g/cc

TAPPED DENSITY

0.18 – 0.33 g/cc

PARTICLE SIZE

90th Percentile: 35 µm Max

50th Percentile: 6.0 – 14.0 µm

ACID VALUE

195 – 210

RESIDUAL SOLVENTS

Certified Free

Pharmacopoeia		BP	EUP	JP	USP
Edition		BP 2012	7th Edition	16th Edition	USP 35 – NF 30
Publication date		August 2011	July 2010 7.6 2012	April 2011	November 2011
Monographs number		3200		1764	4500
Haram active ingredients or excipients					
Red list (from porcine sources only)		**27**	**21**	**4**	
From bovine only		**13**	**9**	**3**	
Grey list (from animal sources (all mammalian and include porcine and bovine also).		**55**	**35**	**20**	
Red to green	chemical synthesis and analogues	**44**	**26**	**9**	
	Recombinant DNA technology	**11**	**7**	**11**	

Pharmacopoeia	BP	EUP	JP	USP
Need more investigations esp. on opinion of the ulama				
From animals without killing the animal (bear, horse, rabbit).	**13**	**10**	**3**	
From human (woman urine and blood plasma).	**13**	**9**	**4**	
From bird and chicken.	**1**	**1**	**1**	
From insects	**2**	**1**	**0**	
Halal from animal sources				
From marine sources (fish, salmon, shark, shrimp, and crab).	**16**	**13**	**9**	

Table 1: Application of this Guide to API Manufacturing

Type of Manufacturing	Application of this Guide to steps (shown in grey) used in this type of manufacturing				
Chemical Manufacturing	Production of the API Starting Material	Introduction of the API Starting Material into process	Production of Intermediate(s)	Isolation and purification	Physical processing, and packaging
API derived from animal sources	Collection of organ, fluid, or tissue	Cutting, mixing, and/or initial processing	Introduction of the API Starting Material into process	Isolation and purification	Physical processing, and packaging
API extracted from plant sources	Collection of plant	Cutting and initial extraction(s)	Introduction of the API Starting Material into process	Isolation and purification	Physical processing, and packaging
Herbal extracts used as API	Collection of plants	Cutting and initial extraction		Further extraction	Physical processing, and packaging
API consisting of comminuted or powdered herbs	Collection of plants and/or cultivation and harvesting	Cutting/ comminuting			Physical processing, and packaging
Biotechnology:fermentation / cell culture	Establishment of master cell bank and working cell bank	Maintenance of working cell bank	Cell culture and/or fermentation	Isolation and purification	Physical processing, and packaging
"Classical" Fermentation to produce an API	Establishment of cell bank	Maintenance of the cell bank	Introduction of the cells into fermentation	Isolation and purification	Physical processing, and packaging

MALAYSIAN STANDARD

MS 2424:2012

Halal pharmaceuticals - General guidelines

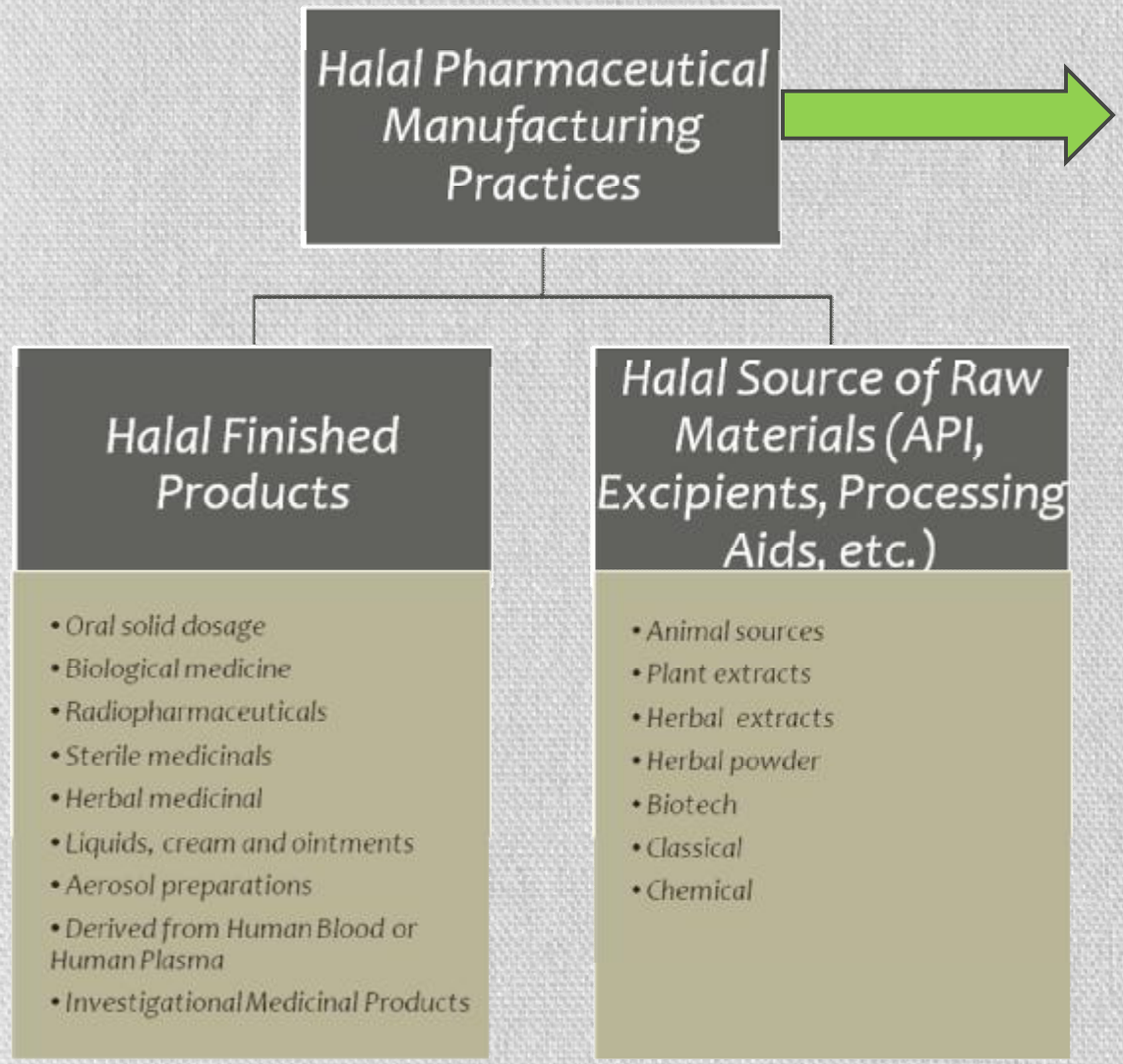
ICS: 11.120.99

Descriptors: halal, pharmaceutical products, preparation, handling, guidelines

MS 2424:2012

Background

Halal Pharmaceutical Standards Structure



Halal Pharmaceuticals – General guidelines

<u>Requirements</u>:

1. *Quality Management*
2. *Management responsibility*
3. *Halal Assurance System*
4. *GMP for halal pharmaceutical products*
5. *Halal Quality Control*
6. *Personnel and responsibility*
7. *Training*
8. *Personal hygiene*
9. *Premise and equipment*
10. *Production and storage areas*
11. *Quality control areas*
12. *Ancillary areas*
13. *Documentation*
14. *Production*
15. *Starting materials*
16. *Packaging materials*
17. *Contract manufacture and analysis*
18. *Self-inspection*

INSULIN

Product Name	Country	Manufacture	CEP	DMF
Insulin, bovine	Netherlands	**N.V. ORGANON**	R1-CEP 2000-156-Rev 01	- - -
Insulin, bovine	Brazil	Novo Nordisk Produção Farmacêutica do Brasil Ltda	R1-CEP 2000-230-Rev 00	- - -
Insulin, bovine	Argentina	Laboratorios Beta S.A. AR C1232 A	R1-CEP 2005-214-Rev 00	- - -
INSULIN	United States	**Eli Lilly And Co**		US - -
SULPHATED INSULIN		NOVO LABORATORIES LTD		US - -
INSULIN SALT CAKE & INSULIN CRYSTALS		COMMOMWEALTH SERUM LABS		US - -
INSULIN (SALT CAKE AND CRYSTALS)		NOVO NORDISK AS		US - -
ZINC INSULIN CRYSTALS	Argentina	**Eli Lilly And Co**		US - -
INSULIN		ER SQUIBB AND SONS INC		US - -

INSULIN

INSULIN USP(MONOCOMPONENT-MC)		**NOVO NORDISK AS**	**US - -**
PORCINE INSULIN (HIGHLY PURIFIED)	Netherlands	**Diosynth bv**	US - -
PURIFIED INSULIN		NOVO NORDISK AS	US - -
BOVINE INSULIN	Netherlands	**Diosynth bv**	US - -
BOVINE INSULINE HIGHLY PURIFIED	Netherlands	**Diosynth bv**	US - -
ZINC INSULIN CRYSTALS	Brazil	BIOFAR INSUMOS QUIMICO FARMACEUTICOS SA	US - -
SYNTHETIC HUMAN PROINSULIN C-PEPTIDE		BECKMAN INSTRUMENTS INC DIV SMITHKLINE BECKMAN CORPORATION	US - -
HUMAN INSULIN-SEMISYNTHETIC BULK MATRLS & FINISHED DOS FORM		SANOFI-AVENTIS DEUTSCHLAND GMBH	US - -
HUMAN INSULIN (SEMI-SYNTHETIC) AS PROCESSED IN KALUNDBORG & BAGSVATERD		NOVO NORDISK AS	US - -
PRODUCTION OF INSULIN		NOVO NORDISK AS	US - -

INSULIN

INTRANASAL INSULIN	United States	AYERST LABORATORIES INC DIV AMERICAN HOME PRODUCTS CORP	US - -
INSULIN FROM BOVINE PANCRE	United States	SIGMA F AND D DIV LTD	US - -
BULK DRUG INSULINOTROPIN	Switzerland	**Bachem AG**	US - -
PORCINE INSULIN HIGHLY PURIFIED	United States	**N.V. ORGANON**	US - -
AER INSULIN DIABETES MANAGMENT SYSTEM	United States	ARADIGM CORP	US - -
BOVINE INSULIN HIGHLY PURIFIED	Netherlands	**Diosynth bv**	US - -
RECOMBINANT HUMAN INSULIN	United States	**N.V. ORGANON**	US - -
INSULIN HUMAN (RDNA HUMAN INSULIN) HMR 4006	Germany	MANNKIND CORP	US - -
HUMAN INSULIN-BULK (RDNA ORIGIN)	India	**Biocon Ltd.**	US - -
INSULIN-LIKE GROWTH FACTOR-I (HUMAN RECOMBINANT YEAST INSTITUTE OF MOLECULAR BIOLOGY)		INSTITUTE MOLECULAR BIOLOGY INC	US - -
HUMAN INSULIN-BULK (RDNA ORIGIN) (ANIMAL ORIGIN FREE)	India	**Biocon Ltd.**	US - -

STEARIC ACID

Product Name	Country	Manufacture	DMF
Stearic acid	Italy	Ambrogio Pagani SpA	- - -
Stearic acid	Italy	SO.G.I.S Industria Chimica SpA	- - -
Stearic acid Code number 2216	United States	**Mallinckrodt Inc**	- - -
Stearic acid Hystrene® 5016	United States	PMC BIOGENIX, INC.	- - -
Stearic acid Hystrene® 7018	United States	Chemtura Corporation	- - -
Stearic acid Hystrene® 9718	United States	Chemtura Corporation	- - -
Stearic acid Industrene® 8718	United States	Chemtura Corporation	- - -
Stearic acid Industrene® 7018	United States	Chemtura Corporation	- - -
Stearic acid Chicago Plant	United States	VANTAGE OLEOCHEMICALS, INC.	- - -

STEARIC ACID

Stearic acid Dervacid 3157 and 3158	Spain	Union Derivan S.A.	- - -
Stearic acid	Canada	Emery Oleochemicals Group	- - -
EDENOL BS (STEARIC ACID BUTYL ESTER)		HENKEL KGAA	US - -
SUCROSE STEARIC ACID ESTERS AND SUCROSE PALMITIC ACID ESTERS	Japan	MITSUBISHI CHEMICAL CORP	US - -
SUCROSE FATY ACID ESTERS-SUCROSE STEARIC ACID ESTERS AND SUCROSE PALMITIC ACID ESTERS	Japan	MITSUBISHI CHEMICAL CORP	US - -
EXCIPIENTS SUCROSE FATTY ACID ESTERS(SUCROSE STEARIC ACID ESTERS SUCROSE PALMITIC ACID ESTERS AND SUCROSE LAURIC ACID ESTERS)	Japan	MITSUBISHI CHEMICAL CORP	US - -
STEARIC ACID	Malaysia	LIPIDCHEM SENDIRIAN BERHAD	US - -

CONCLUSION

- COLLABORATIONS BETWEEN INDUSTRY, REGULATORY AND RESEARCHERS VITAL
- MNC HAVE SHOWN INTEREST
- NATIONAL, REGIONAL & GLOBAL EFFORT TO HARNESS RESOURCES IN ADDRESSING THE VARIOUS ASPECTS OF HALAL PHARMACEUTICALS.

PLAN OF ACTION

- HALAL PHARMACEUTICAL –
  GENERAL GUIDELINES (GMP principles for the manufacture of halal medicinal products).
- GUIDELINES ON GMP for active substances used as halal starting materials.
- GUIDELINES ON GMP for specific halal medicinal products
- HALAL PHARMACEUTICAL STANDARDS (MS)

PLAN OF ACTION

- Halal Pharmaceutical Commission
- Halal Pharmaceutical Standards
- Halal Pharmaceutical Formulary
- Halal Index of Pharmaceuticals
- Halal Pharmacopoeia
- Halal Pharmaceutical Monographs

COUNTRY	TITLE	1.PHARMACOPOEIA COMMISSIONS 2. PUBLISHER/DISTRIBUTOR 3. WEBSITE 4. FREQUENCY OF PUBLICATION	EDITION	YEAR	LANGUAGE
EGYPT	Egyptian Pharmacopoeia	1. Permanent Commission of the Egyptian Pharmacopoeia, Faculty of Pharmacy, Kasr El Ainy, Cairo 2. General Organization for Government Printing Office, Cairo 3. Egyptian Government http://www.egypt.gov.eg/arabic/default.asp	3rd Edition 4th Edition	1984 2005	Arabic English Arabic English
INDONESIA	Farmakope Indonesia	1. Indonesian Pharmacopoeia Commission, Direktorat Jenderal Pengawasan Obat Dan Makanan, Departemen Kesehatan R.I., Jl, Percetakan Negara 23, Jakarta 10560 2. Departemen Kesehatan Republik Indonesia ,JL. Percetakan Negara 23 Jakarta *3.* National Agency of Drug and Food Control	4th Edition	1995	Indonesian
IRAN	Iranian Pharmacopoeia	1. Iranian Pharmacopoeia Drug Administration of Iran, Division of Pharmaceuticals & Narcotic Affairs Fakhre- Razi Street Ministry of Health of Iran Building Tehran, 14, Iran			
PAKISTAN	Pakistan Pharmacopoeia	1. Pakistan Pharmacopoeia Commission, Ministry of Health, Special Education & Social Welfare, Islamabad 3. Government of Pakistan, Ministry of Health http://www.pakistan.gov.pk/ministries/index.jsp?MinID=22&cPath=251 Drugs Control Organization, Pakistan Ministry of Health http://www.dcomoh.gov.pk/			English
TURKEY	Turkish Pharmacopoeia	1. Commission of the Turkish Pharmacopoeia Ministry of Health General Directorate of Pharmaceuticals and Pharmacy Çankiri Cad. No:57 Ulus Ankara, Turkey 3. The Ministry of Health of Turkey Mithatpasa Cad. No:3 Sihhiye Ankara, Turkey http://www.saglik.gov.tr/			Turkish English

HALAL PHARMACEUTICAL STRATEGY

- HALAL QUALITY BUILT-IN, RATHER THAN TESTED FOR
- HALAL PHARMACEUTICAL STANDARDS FOR API, EXCIPIENTS, PROCESSING AIDS & PACKAGING MATERIALS
- ECOSYSTEM FOR HALAL PHARMACEUTICALS

Terima kasih
THANK YOU

UNIVERSITI SAINS MALAYSIA