Understanding specifications of insulin and erythropoietin products

Boontarika Boonyapiwat, Ph.D.
Bureau of Drug and Narcotic
Department of Medical Sciences
Ministry of Public Health, Thailand
14th June 2016
Overview

- Insulin
- Erythropoietin
- Questions
Insulin

5.8 kDa

Recombinant

Disulfide bonds
Insulin

- Fast-acting
- Short-acting
- Long-acting
- Intermediate-acting
Insulin

- **Fast**
  - 5-15 mins (Lispro)

- **Short**
  - 30 mins (Regular)

- **Immediate**
  - 1-3 hrs (Insulin zinc)

- **Long**
  - Begin 1-2 hrs and active 24 hrs (Glargine)
# Insulin

<table>
<thead>
<tr>
<th>Test items</th>
<th>Lispro (Short)</th>
<th>Insulin zinc (Intermediate)</th>
<th>Glargine (Long)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7.0-7.8</td>
<td>7.0-7.8</td>
<td>3.5-4.5</td>
</tr>
<tr>
<td>Total Zinc</td>
<td>14-35 µg/100 units</td>
<td>0.12-0.25 mg/100 units</td>
<td>27-33 µg/ml (1 ml = 100 units)</td>
</tr>
</tbody>
</table>
Erythropoietin

30 kDa

Recombinant

Glycosylated
Epoetin

Erythropoietin
Erythropoietin

Albumin

No Albumin

Erythropoietin products in Thailand
Erythropoietin

Dimers and related substances of higher molecular weight?

BP 2016
Erythropoietin injection (BP 2016)

Production
Where the product contains human serum albumin, it does not comply with the test for Dimers and related substances of higher molecular weight; however the manufacturing process is validated to show that aggregation does not occur.
Erythropoietin

Importance of sialic acids?
Thank You