| HANNS G. WERNER GMBH + Co. KG |  |   |                    |  |  |
|-------------------------------|--|---|--------------------|--|--|
| pharm-a-spheres™              | Qualitätsmanagementsystem<br>Formblätter | freigegeben und<br>gültig ab:<br>06.03.2014 | Seite: 1<br>von: 1 |  |  |
|                               |  | T   |                    |  |  |
| Version 03                    | Product specification GMP statement      | Codierung:<br>QMS-7_2-03-00-131             |                    |  |  |

# Pharm-a-spheres<sup>™</sup> pellets neutral all sizes

Item nos. 08000 - 08699

### **GMP** statement

Pharm-a-spheres<sup>™</sup> pellets neutral are a bulk pharmaceutical excipient without active ingredients (so-called non-medicine pellets). According to the German health legislation these are no subject to the official GMP supervision.

Of course, the manufacturing of the pharm-a-spheres<sup>™</sup> pellets neutral is conform to the GMP rules, especially the IPEC GMP guide for bulk pharmaceutical excipients is observed. Regular audits of some of our key customers show conformity to the current requirements.

This product information has been edited and checked carefully and corresponds to the relevant EU legislation at this moment. It is valid for one year from the date of transmission, if not withdrawn earlier because of relevant changes.

| HANNS G. WERNER GMBH + Co. KG |                                     |   |                    |  |  |  |
|-------------------------------|-------------------------------------|---|--------------------|--|--|--|
| pharm-a-spheres™              | Qualitätsmanagementsystem           | freigegeben und<br>gültig ab:<br>29.08.2014 | Seite: 1<br>von: 1 |  |  |  |
|                               | Formblätter                         | ).n   | 2.                 |  |  |  |
| Version 07                    | Product specification GMP statement | Codierung:<br>QMS-7_2-03-00-131             |                    |  |  |  |

# Pharm-a-spheres ™ globuli sacchari all sizes

Item nos. 08700 - 08799

### **GMP** statement

Pharm-a-spheres™ globuli sacchari are a bulk pharmaceutical excipient without active ingredients (so-called non-medicinal globuli). According to the German health legislation these are not subject to the official GMP supervision.

Of course, the manufacturing of the pharm-a-spheres™ globuli sacchari is conform to the GMP rules, especially the IPEC GMP guide for bulk pharmaceutical excipients. Regular audits of some of our key customers prove conformity to the current requirements.

This product information has been edited and checked carefully and corresponds to the relevant EU legislation at this moment. It is valid for one year from the date of transmission, if not withdrawn earlier because of relevant changes.

| Hanns G. Werner GmbH + Co. KG |                                      |   |                    |  |  |
|-------------------------------|--------------------------------------|---|--------------------|--|--|
| pharm-a-spheres™              | Qualitätsmanagementsystem            | freigegeben und<br>gültig ab:<br>18.11.2013 | Seite: 1<br>von: 1 |  |  |
|                               | Formblätter                          | T.  |                    |  |  |
| Version 02                    | Product specification  GMP statement | Codierung:<br>QMS-FBL-7_2-03-00-131         |                    |  |  |

# pharm-a-spheres™ xylitol globuli all sizes

Item nos. 08810 - 08819

### **GMP** statement

Pharm-a-spheres<sup>™</sup> globuli sacchari are a bulk pharmaceutical excipient without active ingredients (so-called non-medicinal globuli). According to the German health legislation these are not subject to the official GMP supervision.

Of course, the manufacturing of the pharm-a-spheres™ globuli sacchari is conform to the GMP rules, especially the IPEC GMP guide for bulk pharmaceutical excipients. Regular audits of some of our key customers prove conformity to the current requirements.

This product information has been edited and checked carefully and corresponds to the relevant EC legislation at this moment. It is valid for one year from the date of transmission, if not withdrawn earlier because of relevant changes.

| HANNS G. WERNER GMBH + Co. KG |  |   |                    |  |  |  |
|-------------------------------|--|---|--------------------|--|--|--|
| pharm-a-spheres™              | Qualitätsmanagementsystem<br>Formblätter | freigegeben und<br>gültig ab:<br>13.03.2014 | Seite: 1<br>von: 1 |  |  |  |
|                               |  | J   |                    |  |  |  |
| Version 01                    | Product specification  GMP statement     | Codierung:<br>QMS-7_2-03-00-131             |                    |  |  |  |

pharm-a-spheres™ sucrose lactose globuli

Item nos. 08830 - 08859

### **GMP** statement

Pharm-a-spheres™ globuli sacchari are a bulk pharmaceutical excipient without active ingredients (so-called non-medicinal globuli). According to the German health legislation these are not subject to the official GMP supervision.

Of course, the manufacturing of the pharm-a-spheres™ globuli sacchari is conform to the GMP rules, especially the IPEC GMP guide for bulk pharmaceutical excipients. Regular audits of some of our key customers prove conformity to the current requirements.

This product information has been edited and checked carefully and corresponds to the relevant EU legislation at this moment. It is valid for one year from the date of transmission, if not withdrawn earlier because of relevant changes.