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	<u>951000-4000 Duma Special</u>		Approved by: CDH 2021.06.10
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Product Specification and Certificate

Product no.	951000-4000
Product name	Duma Special 1000 ml
Product description	100 mm round plastic container with a snap-on neck to be provided with Duma Handy Cap 9022. Index in the bottom. Intended for the packing of tablets and powder.
Design	<ul style="list-style-type: none"> Regulatory drawing A951000 Regulatory Standard drawing B951000
Raw material	Purell PE GF 4760, High-density polyethylene (HDPE) in compliance with Regulation (EU) 10/2011 and FDA title 21 CFR § 177.1520 , LyondellBasell Industries. This product meets the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction. Coloured with approx. 3.5% white masterbatch, containing approx. 60% titanium dioxide. Purell GF4760 Declaration
Colour	Remafin-EP-White PL00075542-ZT, linear low-density polyethylene (LLDPE) in compliance with Commission Regulation (EU) No 10/2011, FDA title 21 CFR §§ 177.1520 & 178.3297 and BfR recommendation IX, Avient (formerly Clariant). Remafin-EP-White PL00075542-ZT declaration
Production	Facility: Haarby, Denmark Process: The containers are injection blow moulded Hygiene: The production takes place in clean room Sterilisation: N/A

Measures and Properties

Dimensions:			
Container:		Neck:	
Outside height	155.0 +2.0/-2.0 mm	Inside diameter	81.6 +0.3/-0.3 mm
Outside diameter	100.0 +1.0/-1.0 mm	Upper outside diameter	90.5 +0.3/-0.3 mm
		Neck ring diameter	94.2 +0.3/-0.3 mm
Wall thickness	Min. 0.4 mm		
Other dimensions:			
Label height	Max. 124 mm	Volume	Max. 1100 ml
Label width	Max. 314 mm	Shelf life	5 years
Weight	54.5 +1.5/-1.5 gr	Bioburden	Max. 50 CFU

Test Results

<p>The container and cap comply with all demands for Moisture Vapour Transmission and Light Transmission and are in accordance with USP <671>. Documentation enclosed. MVT - 951000-4000/009022-4000/MAY2017 LT - 951000-4000/APR2017</p>
<p>The container and cap comply with all demands for Internal Reflectance and Differential Scanning Calorimetry and are in accordance with USP <661.1>. Documentation enclosed. Over time IR spectrum might show absorbance from release agent. IR - GF4760 / PL00075542-ZT DSC HDPE/AUG2016</p>

The container and cap comply with all demands for Physicochemical Tests set by the United States Pharmacopoeia USP 43 <661.2> Plastic Packaging Systems for Pharmaceutical Use and Biological Reactivity Tests, In vitro set by the USP chapter <87>. Documentation enclosed.

[Physico - GF4760/LD653](#)

[In vitro - GF4760/PL00075542/JUN2016](#)

Packing and Way of Delivery

The products are packed in 1 PE bag, which is then sealed. The PE bag is put into a cardboard carton, which is sealed with PP-tape. The cartons are packed on pallets, which are 1200 x 800 x 140 mm and weight approximately 23 kg.

Carton dimensions:

Height (mm): 645 Length (mm): 830 Width (mm): 415

Packing information:

Number of items per carton: 128 Volume per carton (m³): 0.2142
 Max. number of cartons per pallet: 9 Weight per carton (kg.): 8.5
 Max. height of the pallet (mm): 2300

Labelling

Each carton is provided with a label with the following information:

- Manufacturer name
- Material name and number
- Batch / lot number and quantity
- Customer information (if requested)
- Country of origin
- Shelf life
- Production date and machine number

Recommendation to Storage, Handling and Transportation

Stored inside in clean conditions in its original un-open packaging, protected from direct sunlight and with a temperature between 5 - 35° C and Relative Humidity between 30 - 70 %.

Quality Control

All products are quality controlled according to instructions specified in our quality control system. We therefore guarantee that all deliveries from Primary Packaging Plastics have passed our control procedures and comply with the quality demands mentioned below. If required a certificate of conformance can be issued. The classification of defects and specifications of AQL values are based on ISO 2859 and Quality Assurance of Pharmaceutical and Cosmetic Packaging Materials:
 Defect Evaluation List for Blow-moulded Plastic Containers Vol. 23 - ISBN [3-87193-405-6](#).
 Defect Evaluation List for Injection-moulded parts made of Plastic: Closures, Sealing Disks and dosage aids (droppers, etc.) Vol. 22 - ISBN [3-87193-182-9](#).
 Documentation enclosed.

[Quality Control - IBM Containers with re-processed material](#)

Declaration of Conformity

[DoC EP \(GF4760&PL00075542\)](#)
[DoC Food Law \(GF 4760 & PL00075542-ZT\)](#)
[DoC TSE/BSE](#)
[DoC Allergens, Phthalates, BPA, Latex, Melamine](#)
[DoC TBA_TCA](#)

Information on Packaging and Packaging Waste Directive 94/62/EC and/or CONEG

Both container, cap and bag are produced from material, which complies with the directions for plastics material in contact with foodstuffs. The content of heavy metals in the products, the inner bag, and the carton is less than 100 ppm.
 The packaging is recyclable for material recovery and/or well suited for energy recovery due to its high energy density. Reuse is technically possible depending on applicable regulations.

REACH

We can confirm that the raw materials used in the product are either pre-registered or exempted from pre-registration.

Complaint Handling

In case that the delivered products are outside specification, complaint must be send in writing to daily contact person in Customer Care Center.

In order to ensure a thorough investigation it is important to send the following basic information:

- Article number
- Batch number
- Cavity number (if related to specific cavities)
- Number of defective items
- Defect observed in
 - a) incoming control including sample size
 - b) production including quantity of items used
 - c) final products including quantity of items used
 - d) market complaint
- Defect found in
 - a) one carton
 - b) several cartons - please specify quantity
- Exact production date/time from carton/bag or carton/bag/pallet number products in quarantine:
 - a) Filled products - Quantity
 - b) Not filled products - Quantity
 - c) No products left
- Description of the defect

The following standard form can be used: 3.1 Customer Complaint Report.

Depending on the defect, additional information will be requested as described in the attached standard forms: 2.5 Information requested in relation to complaints.

It is very important to send samples at the time a complaint is filed, as any delay in these can have an impact on time of investigation. An investigation report is send to Customer within 21 days counting from when complaint, relevant information and samples are received.

Important !

Filled or empty products involved in a complaint to Primary Packaging Plastics, must only be destroyed by Customer after written approval from Gerresheimer. Any activity in connection with a complaint where Customer expect Gerresheimer to cover the costs must be approved by Gerresheimer in writing before initiation of the activity.

[Complaint report](#)

[Labelling](#)

[Loose silica gel-loose desiccant-defect on desiccant](#)

[Mix-up](#)

[Partly- or disconnected TE-rings](#)

[Product defect](#)

[Transport](#)

Registrations and Certifications

Primary Packaging Plastics was established in 2020. Before that time the company was working under the following names: Gerresheimer Plastic Packaging, Superfos Pharma, Superfos Pharma Pack, Dudek Plast and Duma.

Documentation, i.e. test reports, certificates etc. issued before July 2020 will be with reference to one of the names above.

Gerresheimer Vaerloese A/S has obtained the following registrations and certifications for Vaerloese and Haarby, Denmark:

ISO 9001, no. 160454-2014-AQ-DEN-DANAK

ISO 14001, no. 156579-2014-AE-DEN-DANAK

ISO 15378, no. 160455-2014-Q-DEN-DNV

ISO 45001, no. 10000341648-MSC-DANAK-DNK

The product is FDA registered in US with the following DMF number:

DMF 12077 - DMF type III Packaging material, Manufactured in Vaerloese - Denmark, Haarby - Denmark.

The product is TPD registered in Canada with the following DMF number:

DMF 2000-108 - Packaging material – Drug Master File. Packaging material, Manufactured in Vaerloese - Denmark, Haarby - Denmark.

The product is registered in China with one of appropriate number:

B20190001892 – HDPE bottles. „I” inactive status.

B20190001894 – PP caps. „I” inactive status.

B20190001893 – LDPE caps. „I” inactive status.

B20200000747 – PP caps with Desiccant (includes Duma Desiccant Insert). „I” inactive status.

The product is registered in Russia with the following number:

C3 2011/11203 – plastic packages in size between 3ml to 3000 ml with accessories.

Revisions

Version:	Implementation:	Revision information:
1	<u>2017.09.15</u>	Created
1.1	<u>2017.09.28</u>	Purell GF4760 Declaration 2017: Updated with USP chapter <661.1> GF 4760 - PL00075542: Updated with USP chapter 661.1
1.2	<u>2017.10.03</u>	Remafin-EP-White PL00075542-ZT declaration: Updated with <u>2017/752</u>
1.3	<u>2017.10.05</u>	GF 4760 - PL00075542: Approx. instead of about
1.4	<u>2017.10.26</u>	DoC TSE/BSE: Updated (yearly update)
1.5	<u>2017.11.14</u>	Quality Control - IBM Containers with re-processed material: Updated
1.6	<u>2017.11.27</u>	DoC Food Law (GF 4760 & PL00075542-ZT): Updated Regulation <u>2017/752</u>
1.7	<u>2017.11.28</u>	DoC Allergens, Phthalates, BPA, Latex, Melamine: Yearly update
1.8	<u>2018.01.17</u>	Remafin-EP-White PL00075542-ZT declaration: Updated with ICHQ3D
1.9	<u>2018.02.12</u>	Purell GF4760 Declaration: New SVHC list 15.01.2018
1.10	<u>2018.02.27</u>	Remafin-EP-White PL00075542-ZT declaration: Updated
1.11	<u>2018.04.03</u>	Remafin-EP-White PL00075542-ZT declaration: Updated
1.12	<u>2018.05.14</u>	Purell GF4760 Declaration: Updated
1.13	<u>2018.05.28</u>	IR - GF4760 / PL00075542-ZT: Updated
1.14	<u>2018.07.30</u>	Purell GF4760 Declaration: Updated SVHC list 27.06.2018
1.15	<u>2018.08.13</u>	Remafin-EP-White PL00075542-ZT declaration: Updated due to regulation <u>2016/1416</u>
1.16	<u>2018.09.11</u>	Remafin-EP-White PL00075542-ZT declaration: Updated
1.17	<u>2018.09.18</u>	Purell GF4760 Declaration: Updated due to regulation <u>2016/1416</u> Remafin-EP-White PL00075542-ZT declaration: Updated
1.18	<u>2018.10.10</u>	DoC Food Law (GF 4760 & PL00075542-ZT): Updated
1.19	<u>2018.11.20</u>	GF 4760 - White: Unified description
1.20	<u>2019.01.21</u>	Purell GF4760 Declaration: Updated SVHC list 15.01.2019
1.21	<u>2019.01.28</u>	DoC EP (GF4760&PL00075542): Updated
1.22	<u>2019.02.11</u>	Remafin-EP-White PL00075542-ZT declaration: Updated with 37/2019
1.23	<u>2019.02.21</u>	Registrations and Certifications with FDA, TPD, Russia and China: Updated - China registration.
1.24	<u>2019.03.07</u>	DoC EP (GF4760&PL00075542): Corrected
1.25	<u>2019.03.25</u>	DoC TSE/BSE: Yearly update DoC Allergens, Phthalates, BPA, Latex, Melamine: Yearly update
1.26	<u>2019.04.30</u>	IR/DSC - General: Text updated

1.27	<u>2019.05.15</u>	IR - GF4760 / PL00075542-ZT: Updated
1.28	<u>2019.07.31</u>	Purell GF4760 Declaration: Updated SVHC list_ 16.07.2019
1.29	<u>2019.09.03</u>	Labelling: Updated
1.30	<u>2019.09.17</u>	Purell GF4760 Declaration: Updated with 2019/1338
1.31	<u>2019.10.21</u>	Remafin-EP-White PL00075542-ZT declaration: Updated with 2019/1338
1.32	<u>2020.01.28</u>	DoC Food Law (GF 4760 & PL00075542-ZT): Yearly update
1.33	<u>2020.02.11</u>	Registrations & Certifications update- China registration
1.34	<u>2020.03.17</u>	Purell GF4760 Declaration: Updated SVHC List_ 16.01.2020
1.35	<u>2020.03.24</u>	DoC TSE/BSE: Yearly updated
1.36	<u>2020.04.14</u>	DoC TSE/BSE: Updated name to Primary Packaging Plastics DoC Allergens, Phthalates, BPA, Latex, Melamine: Updated name to Primary Packaging Plastics
1.37	<u>2020.04.15</u>	Registrations and Certifications with FDA, TPD, Russia and new China: Updated name to Primary Packaging Plastics
1.38	<u>2020.04.16</u>	DoC TBA TCA: Updated
1.39	<u>2020.04.20</u>	DoC EP (GF4760&PL00075542): New division name Primary Packaging Plastic
1.40	<u>2020.04.29</u>	Complaint handling: New division name Primary Packaging Plastic
1.41	<u>2020.05.19</u>	IR - GF4760 / PL00075542-ZT: Updated
1.42	<u>2020.07.01</u>	Purell GF4760 Declaration: Updated SVHC List_ 25.06.2020
1.43	<u>2020.08.18</u>	Physico - GF4760/LD653: Physicochemical test updated Registrations and Certifications with FDA, TPD, Russia and new China: ISO 45001 obtained
1.44	<u>2020.08.19</u>	Physico/In vitro - General: USP 43 <661.2> Registrations and Certifications with FDA, TPD, Russia and new China: Updated with PP caps with desiccant
1.45	<u>2020.08.25</u>	Quality Control - General text: Updated name Primary Packaging Plastics
1.46	<u>2020.09.27</u>	Clariant PL00075542-ZT: Clariant name change to Avient
1.47	<u>2020.10.19</u>	Remafin-EP-White PL00075542-ZT declaration: Food contact and FDA declarations updated with a new Logo
1.48	<u>2021.01.15</u>	DoC Food Law (GF 4760 & PL00075542-ZT): Yearly update
1.49	<u>2021.01.26</u>	Purell GF4760 Declaration: Updated SVHC List 19.01.2021
1.50	<u>2021.03.03</u>	Quality Control - IBM Containers with re-processed material: Updated with Primary Packaging Plastics
1.51	<u>2021.04.15</u>	DoC EP (GF4760&PL00075542): Yearly update and change of company logo DoC Food Law (GF 4760 & PL00075542-ZT): Updated
1.52	<u>2021.04.22</u>	Labelling Loose silica gel-loose desiccant-defect on desiccant
1.53	<u>2021.04.23</u>	Packing and Packing waste directive: Updated. Partly- or disconnected TE-rings Product defect Transport IR - GF4760 / PL00075542-ZT: Yearly update
1.54	<u>2021.04.27</u>	Complaint report DoC TSE/BSE: Change of company logo
1.55	<u>2021.05.04</u>	Mix-up
1.56	<u>2021.05.07</u>	Labelling
1.57	<u>2021.05.10</u>	Loose silica gel-loose desiccant-defect on desiccant Mix-up Partly- or disconnected TE-rings Product defect Transport
1.58	<u>2021.05.11</u>	Complaint report
1.59	<u>2021.06.10</u>	DoC Allergens, Phthalates, BPA, Latex, Melamine: Change of company logo