

TECHNICAL DATA SHEETEffective date: 01.2020
Rev.0**Ambra glass jar with lid, 30 ml****CONFORMITY DECLARATION**

We do hereby certify that the quality of the above mentioned items delivered to you is conform to our Sales Specifications in force at the present date.

Is a customer's responsibility to check the chemical compatibility as well as the seal with the specific products.

Furthermore we do declare that the packaging for the cosmetic and pharmaceutical field supplied by us is fully conform to what foreseen by the current law.

Plastic

- D.M: of 21/03/73 published on the G.U. 104 del 20/04/1973 with D.M. 220 of 26/04/1993 and subsequent updates (for material intended to come in contact with food and drugs);
- 94/62/CEE Directive, granted by D.L. N° 22 of 05/02/97 Art. 43 C 4 on the content of heavy metals.;
- 2023/2006/CE Directive, 1935/2004/CE Regulation and 10/2011 UE Regulation (Materials and objects intended to get in contact with food);
- 1907/2006 CE Regulation (Reach-SVHC);
- 282/2008/UE Regulation (Material recycling);
- 2007/19/CE Directive (Fhthalates);
- Bisphenol-A and Nitrite Substances: we state that this materials are not used during the production or intentionally incorporated;
- Recycling: the material is recyclable. The mainly operation is the mechanical material's recall. Most of the packaging components are divisible to allow the separate collection.

Pharmaceutical glass and Rubber

- Same references as for "Plastic", excluding 282/2008/UE Regulation;
- European Pharmacopea currently in force;
- American Farmacopea USP currently in force.

Cosmetic glass

- Same references as for "Plastic", excluding 282/2008/UE Regulation;
- Containers for its chemical composition and characteristics are conform to what foreseen for objects in glass of Category A (Encl. 2° Sect. 5 D.M. dd 21 March 1973) and from Art. 2 paragraph 1, a) b) c) from D.L. N° 108/92 and are suitable for food packaging.

CONFORMITY DECLARATION ON GLASS

According to the Decree 1935/2004 of 27/10/2004 we therewith declare that all glass containers:

- are classified as class "A" and therefore suitable to contain any foodstuffs including sterilisation, according to the Ministerial Decree of 21/03/1973 and any subsequent modifications;
- respect technical specifications as per technical drawing and the quality requirements as agreed in the Supply specifications. In absence of personalised supply specifications, the containers are in accordance with its Standard supply specification.
- have a lead content below the scheduled limits, in accordance with the EC's directives n°1/156 concerning refuse, n°1/689 concerning dangerous refuse and n°4/62 concerning packaging and packaging refuse, directives concerning the maximum concentration of heavy metals measured on the annual average container production.

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Typical glass compositions of our soda-lime-silica glasses are as follows:-

Constituent	AMBER	WHITE FLINT
	%	%
SiO ₂	73.0	73.0
Al ₂ O ₃	1.6	1.6
Fe ₂ O ₃	0.3	0.04
CaO	11.5	11.5
MgO	0.1	0.1
Na ₂ O	12.9	13.1
K ₂ O	0.9	0.6
SO ₃	0.1	0.3

All glass testing is performed by Glass Technology Services, Sheffield.

The soda-lime-silica glass manufactured in both amber and white flint by Beatson Clark plc meets the requirements of the British Pharmacopoeia and the European Pharmacopoeia 2002 for hydrolytic resistance type III and the U S Pharmacopoeia (25) Type III for hydrolytic resistance.

Amber glass also meets the requirements for light transmission in the U S and European Pharmacopoeiae and the British Standard BS1679 - Containers for Pharmaceutical Dispensing.

All glass testing is performed by Glass Technology Services, Sheffield.

Both white flint and amber glass also meet the Materials and Articles in Contact with Food (England) Regulations 2005 and the Regulation (EC) No. 1935/2004.

Beatson Clark has U S Food and Drug Administration Drug Master Files (DMF) covering both amber and white flint glass containers, with the following designations:-

Amber	DMF No 10500
White Flint	DMF No 10501

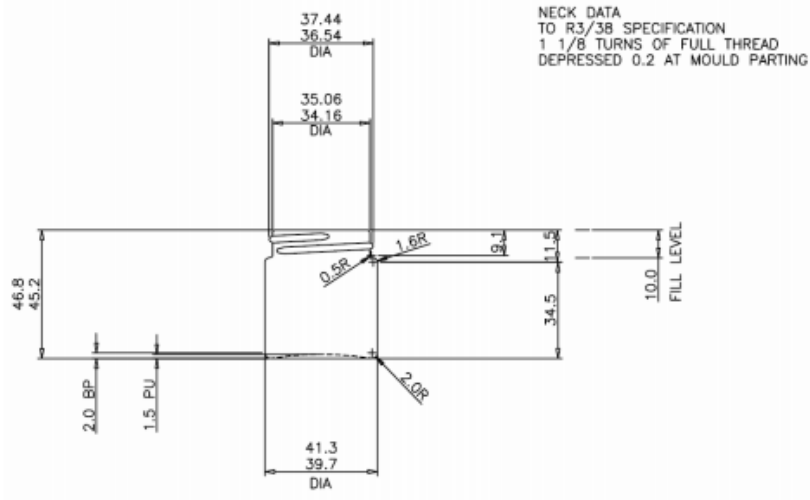
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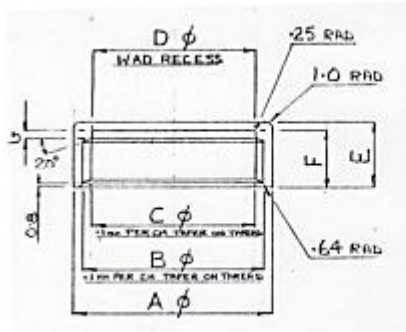
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TECHNICAL DRAWINGS

Ambra glass jar, 30 ml



38 / R3 mm black, smooth, pressed lid, with waxed KKPVDC insert, weight approx. 6.85 g



Technical Details	
material	UREA-Urochem 371 formaldehyd
colour	Black
size	CT- 38 mm
weight	7 g
Liner	KKPVDC

Material	Glass
Nominal / full Volume	30 / 36 ± 1 ml
Weight	46 g

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications.