

Specification Packaging Material

E-60928-00, DOOS GLICE INJECTION 0.1% 10X10ML
MALAYSIA

Author(s):

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Reviewed by:

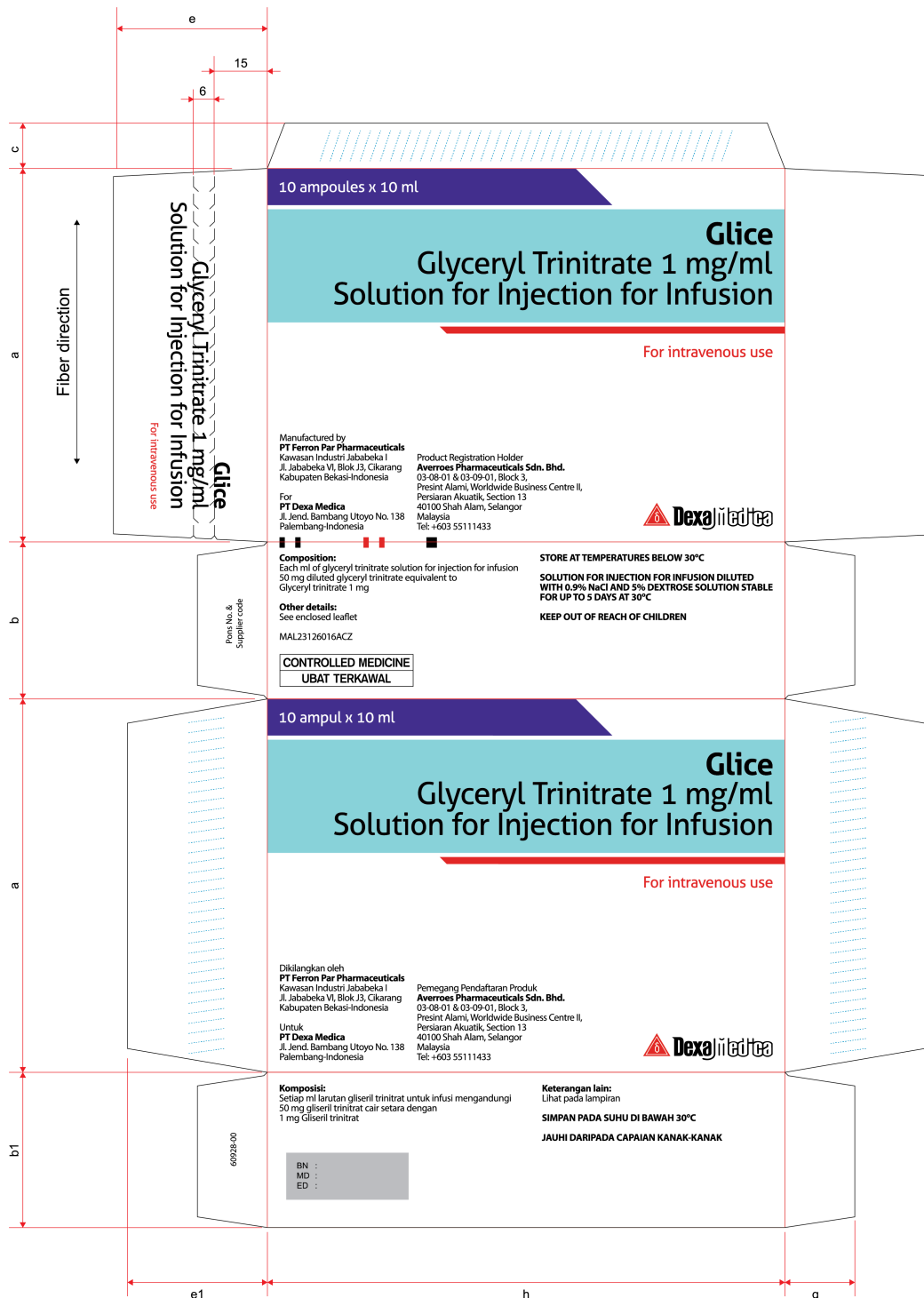
10.06.2024, Riski Amanda Tambunan, Supervisor Packaging Design,

Approved by:

12.06.2024, RA Officer 03, Regulatory Affairs Officer,

Effective date: 12.06.2024

SpecPacGen006534/7
CONFIDENTIAL



a	b	b1	c	e	e1	g	h
107	45	44.5	13	43	40	20	148

Unit in millimeter

400% MAL23126016ACZ

BN :
MD :
ED :

Grey area is a block area for inserting batch number (BN); manufacturing date (MD); expiry date (ED) during manufacturing process, it will not appear in commercial packaging.

Color :
Black
P Violet C
P 318 C
P 485 C

Font type : Aller
Font size (Product name) : 25 pt
(Generic name) : 25 pt
(Redactional) : 8 pt
(Strength) : -

No.	Parameters	Specification
1.	Material	Dupleks / <i>Duplex</i> (Lihat CoA / <i>See CoA</i>)
2.	Gramatur / <i>Grammature</i> (gsm)	279 – 341 gsm
3.	Dimensi panjang / <i>Length dimension</i> (mm)	147.5 – 148.5 mm
4.	Dimensi lebar / <i>Width dimension</i> (mm)	106.5 – 107.5 mm
5.	Dimensi tinggi / <i>Height dimension</i> (mm)	44.5 – 45.5 mm
6.	Arah serat / <i>Fiber direction</i>	Vertikal / <i>Vertical</i>
7.	Varnish	Waterbase
8.	Warna / <i>Colour</i>	Lihat proof print / <i>See proof print</i>
9.	Redaksional / <i>Redactional</i>	Lihat proof print / <i>See proof print</i>
10.	Karakter spesifik / <i>Spesific character</i>	Detil dan dimensi mengikuti drawing mesin cartoning / <i>Detail dimension and lay out must be precision with drawing of cartooning machine.</i>

HISTORY

Revision No.	Revision Date	Details	Reason
00	-	Dokumen baru	ProdCom001147/1
01	22 Juli 2022	- Perubahan nama brand menjadi Glice Glyceryl Trinitrate 1mg/ml for Injection or Infusion - Perubahan komposisi - Revisi "Route of Administration: For intravenous use" - Penambahan "The solution mixtures stored at 30±2°C are stable for up to 5 days"	CMCOthRec089480/1 CMCOthRec089481/1
02	10 Okt 2022	- Perubahan dimensi menjadi 148x107x45 mm mengikuti acuan drawing cartoning - Perubahan penulisan komposisi - Perubahan letak Route of Administration "For intravenous use" menjadi di main panel - Perubahan storage condition after reconstitution menjadi "Diluted solution stable at 30°C for 5 days. Microbiologically, use immediately"	CC006418/1 CMCOthRec092608/1 CMCOthRec092649/1
03	27 Mar 2023	- Update penulisan klaim rekonstitusi - Perubahan dari "Diproduksi oleh" menjadi "Dikilangkan oleh" - Perubahan dari "Lihat brosur terlampir" menjadi "Lihat pada lampiran"	CMCOthRec100936/1 CMCOthRec100937/1
04	04 Juli 2023	- Perubahan bentuk sediaan menjadi "Solution for Injection for Infusion" - Perubahan komposisi - Perubahan in use storage condition "after reconstitution" menjadi "after dilution" - Perubahan alamat manufactur	CMCOthRec105614/1
05	25 Sep 2023	- Perubahan in use storage condition	CMCOthRec109710/1
06	04 Jun 2024	- Perubahan desain DIB branded (Penambahan warna TC) - Penambahan nomor registrasi Malaysia "MAL23126016ACZ"	CMCOthRec122548/1 CMCOthRec122695/1 CMCOthRec122954/1 CMCOthRec122956/1