

[illegible]

UMEDICA LABORATORIES PVT. LTD. SPECIFICATION FOR ARTWORK APPROVAL																			
Format No.: FM/PDD/002-01-05															Ref. SOP No.: PDD/002				
Artwork/SAP Code No. : AAAAAA										Old Version/SAP Code No. : NA					Specification Version: 01				
Product Name : Synerrv Solifenacin (Solifenacin Succinate Film Coated Tablets 5mg)										Company Name/Country : Synerrv - Malaysia									
Component Type : Blister Foil										Pack Style : 10T - Alu-PVC Blister									
Description : New development Blister Foil Artwork as per export-country, Malaysia country requirement.																			
Specifications : 050 4255(R1)										Site : Umedica									
Full Size / Size : NA										Type / Blister / Strip Size / Adhesive / Tube Type : 77x30 MM									
Size - Catch Cover / Foil / BOPP : 162 MM ± 1 MM										Sachet Size/Pocket Size/Fold Size/Release Paper : NA									
Space between Labels : NA										Transparent Paper Thickness : NA									
GSM of Paper / GSM of Aluminum Foil : Between 63.5 & 71.6 g/m²										Type of Paper / GSM : NA									
Thickness of Foil : 0.025 MM										Type of Foil / Fold / Coating GSM : Aluminum / Between 6.0 & 8.0 g/m²									
Cylinder : 1 Nos.										Lamination / Varnish / Material Grade : DMF Grade									
Repeat/Tolerance : 29.98 ± 0.01 MM										Partition / Plate Size / Total GSM / : NA									
10 Repeats 299.7-299.9 (Eyemark)										Sealing / Embossing / Core Diameter : 76 MM ± 2 MM									
GSM/BF of Printed Shipper : NA										Paper Grade / Flute Type / PLY of Shipper : NA									
(Top/Middle/Bottom and Flute layer : NA																			
Printing Colour :										P-485 C [Red Shade]					or as per Sample				
Approved by Export/Marketing :										[Approval attached with ADF]									
CHECKLIST FOR CHECKING ARTWORK & SPECIFICATION																		Artwork Approved by Sign with Date	
Brand Name and Generic Name(As per IP/BP/USP/ In-house Pharmacopelia)	Dosage Form and strength	Prefix Rx/ XRx	Mfg. Lic. No. / Code	Regulatory Agency Approval	Packing (Qty.) / Presentation	Dosage details if required	Size / Design	Composition /Label Claim	Schedule 'H', 'H1', 'G' or 'X' etc warning for local product / Red line for oral products	Item Code	QR Code/ Barcode (1D / 2D) as per requirement	Material and printing colours specification	Storage Condition as per pharmacopelia/Buyer requirement/Registration	Registration No. / Other requirement	Mfg. Name and Address, (Tel. No. and e-mail in the insert)	Marketed by / Distributors Name	Route of Admin. [in case of Inj./ Multidose Vial matter		
																			PDD Department
																			PPIC/Packing Department
																			QC Department
																			RA Department
																			QA Department
Note to Printer: ● Return the original approved artwork along with the sample. ● The overprinting area should be unvarnished. ● Machine proof must be verified against the approved hard copy in Light, Standard and Dark shade should be certified and signed by an authorized person. ● Any deviation must be brought to the notice of the Packaging Development Department immediately in the writing. ● For any clarification, please contact Packaging Development Department.																			