

**1.4.2. STATEMENT OF RIGHT TO REFERENCE**

The following Drug Master File (DMF) / Master File (MF) Letters of Authorization are provided herein as presented in Table 1.4.2-1.

**Table 1.4.2-1. DMF Letters of Authorization**

DMF/MF Holder	DMF/MF Number	DMF/MF Subject	Reference Information
Gerresheimer Buende GmbH	<a href="#">DMF 9543</a>	Type I Tubular Containers	2 mL Type I borosilicate glass vial, 13 mm finish
Gerresheimer Buende GmbH	<a href="#">DMF 15209</a>	Containers made from tubular glass as ampoules, bulk syringes, cartridges, and vials up to 100ml to be used as primary packaging containers for pharmaceutical and medicinal products	2 mL Type I borosilicate glass vial, 13 mm finish
Schott Hungary Kft.	<a href="#">DMF 011793</a>	Primary packaging material	2 mL Type I borosilicate glass vial, 13 mm finish
Schott AG	<a href="#">DMF 011820</a>	Glass vials manufactured in Mullheim, Germany	2 mL Type I borosilicate glass vial, 13 mm finish
Schott North America, Inc.	<a href="#">DMF 012683</a>	Glass products manufactured in Lebanon, Pennsylvania	2 mL Type I borosilicate glass vial, 13 mm finish
Schott Kaisha Private Limited	<a href="#">DMF 031786</a>	Glass ampoules, glass vials, glass cartridges and glass syringes	2 mL Type I borosilicate glass vial, 13 mm finish
Stevanato Group S.p.A.	<a href="#">DMF 011321</a>	0612090.5636 – VIAL VB 2mL 16.25x0.85x31	2 mL Type I borosilicate glass vial, 13 mm finish
Datwyler Pharma Packaging Belgium NV	<a href="#">DMF 10953</a>	Rubber compounds	FM457/0